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Sulcus-fixated intraocular implant for refractive enhancement in pseudophakic patients: two case reports

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Introduction

Cataract surgery is the most commonly performed operation in the National Health Service (NHS). Modern phacoemulsification cataract surgery is safe and most patients achieve a postoperative subjective refraction within 1D of the predicted value (Gale et al. 2009). However, post-cataract surgery refractive surprises can still occur despite various advances in intraocular lens (IOL) power calculation. Replacing the IOL may appear to be the logical option but there is an increased risk of intraoperative capsular rupture or zonular dehiscence. Surgical complications are even more common if the IOL exchange is performed late after the onset of capsular fibrosis.

The idea of a piggyback IOL implant (or polypseudophakia) was first described nearly 20 years ago (Gayton and Sanders 1993). The authors creatively decided to use two IOLs in order to achieve adequate power to correct a very hypermetropic eye. Since then, this technique has been adopted and refined to add or subtract power to an underpowered or overpowered pseudophakic eye, or even correct astigmatism by insertion of a toric IOL implant (Holladay et al. 1996; Shugar et al. 1996). Traditionally, a secondary IOL is implanted in the same capsular bag. However, a serious side-effect, known as interlenticular opacification (ILO), can occur. This phenomenon is characterised by Elschnig pearls or membrane formation between the interface of the IOL optics, causing reduced vision and hypermetropic shift (Gayton et al. 2000; Shugar and Keeler 2000; Shugar and Schwartz 1999). The true incidence is unknown since in most cases this occurs at least a year after the operation (Eleftheriadis et al. 2001). Explantation of both IOLs through a large corneal or scleral incision is usually required.

One of the suggestions to prevent ILO is to increase the distance between the two IOL's optics by implanting the secondary IOL into the ciliary sulcus (Gayton et al. 2000). Conventional one-piece IOLs designed for capsular bag implantation are not suitable due to the (smaller) size of the implant or the angulation of the haptics. In additional, the sulcus-fixed IOL may rotate, decentre or the haptics may chafe the iris, causing an increased incidence of uveitis, glaucoma or hyphaema, or all three signs of the UGH syndrome (Masket 1986).

Monofocal IOLs for capsular bag implantation tend to have convex anterior and posterior surfaces. Even with a secondary three-piece IOL implanted in the sulcus, the risk of optic touch with the primary capsular bag IOL remains high, especially with higher-power IOLs. The point of contact between these surfaces may cause deformation and hyperopic shift and possibly undesirable photoptic phenomena.

The Sulcoflex pseudophakic supplementary IOL (Rayner Intraocular Lenses, East Sussex, UK) is designed to be implanted in the sulcus (Figure 1).

Figure 1. Front view of multifocal Sulcoflex (far left image) and toric Sulcoflex (centre image) intraocular lenses (IOLs). Side view of the IOL (far right image). (Courtesy of Rayner.)

This is a single-piece IOL made from Rayacryl, a hydrophilic acrylic material which has high uveal biocompatibility (Abela-Formanek et al. 2002). The 6.5mm optic diameter with a posterior concave surface prevents central zone contact with the primary IOL in the capsular bag. The 13.5mm diameter haptics with undulated edge are designed to prevent IOL rotation, which is particularly important in the rotational stability of the toric Sulcoflex. The haptics are posteriorly angulated 10° to reduce the risk of iris chafing and optic capture by the iris (Figure 2).

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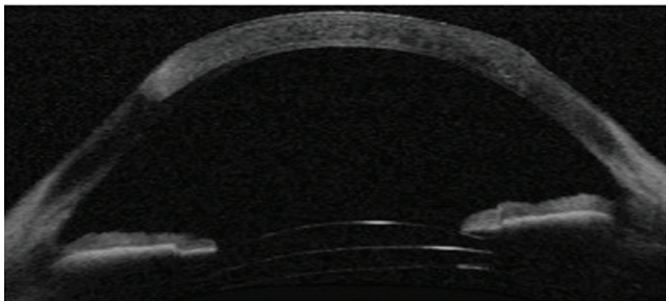

Figure 2. Scheimpflug image confirms good separation of the Sulcoflex from the primary intraocular lens.

The round-edge haptic design may also reduce irritation of the ciliary sulcus. Since capsular opacification is not considered likely with a sulcus-fixated IOL, the optic edges are rounded to reduce glare and dysphotopsia.

Another advantage of Sulcoflex is the lower risk of complication from explanting a sulcus-fixated IOL than that from explanting a capsular-implanted IOL. This is especially useful in eyes with changing refraction such as in children, keratoconics, temporary silicone oil and corneal grafts.

The Sulcoflex range includes multifocal IOL. Sulcoflex DUET is a planned, sequential implantation of a multifocal Sulcoflex lens and a primary monofocal IOL in the capsular bag in a single session. Patients who would like to try multifocality but may be intolerant of the visual side-effects, such as glare and dysphotopsia, could have the sulcus IOL removed even after a few months.

To date, there have only been two published case series on the Sulcoflex IOL implant (Kahraman and Amon 2010; Khan and Muhtaseb 2011). Khan and Muhtaseb reported four cases. Three eyes implanted with multifocal Sulcoflex had good visual outcome with no ocular side-effects after 6–12 months of follow-up. The fourth case had 4.00D of preoperative cylinder and received a toric Sulcoflex IOL implant. The result was an undercorrection of 1.00DC, although the authors were uncertain about the cause of the undercorrection.

Kahraman and Amon reported good visual outcomes in 12 eyes of 10 patients. There was no report of uveitis, iris chafing, hyphaema or ILO at 17 months postoperatively. Decentration of the IOL by 0.5mm occurred in one eye. However this remained stable throughout the follow-up period and did not adversely affect the patient's vision. Both groups of authors concluded that the Sulcoflex was safe.

We present here two cases under our care highlighting the use of the Sulcoflex IOL.

Case 1

A pseudophakic lorry-driver had a right deep anterior lamellar keratoplasty for corneal scarring due to previous *Pseudomonas* keratitis. The patient had an uneventful recovery from the operation. After graft suture removal, the unaided acuity was 6/60. The left acuity was 6/5. The subjective refraction was RE +4.50/–4.50 X 177, achieving 6/12 and pinholing to 6/9. A rigid gas-permeable toric contact lens was fitted; however the acuity was often worse than 6/12. The patient complained of ocular foreign-body sensation and was increasingly intolerant of the contact lens. Peripheral neovascularisation was noted to encroach on the superior part of the corneal graft.

The Driver and Vehicle Licensing Authority (DVLA) in the UK stipulates that the requirement for large-goods-vehicle drivers is best-corrected visual acuity of at least 6/7.5 in the better eye, at least 6/12 in the worst eye and uncorrected acuity of at least 3/60 in both eyes. The patient struggled to meet the required standard.

The patient underwent a secondary Sulcoflex toric IOL implant to correct the residual refractive error fully in the right eye. One month after the operation, his unaided vision was 6/12, which improved to 6/9 with pinhole. The subjective refraction was RE +1.75/–2.25 X 180. He was able to continue his occupation as a lorry driver. One year later, the corneal graft had remained clear, the eye quiet, intraocular pressure normal and there was no iris transillumination defect.

Case 2

An 82-year-old woman had an uneventful right extracapsular cataract extraction with capsular bag IOL implant 20 years ago. She had a residual refractive error of RE –2.75/–4.50 X 90. The left eye underwent phacoemulsification 13 years later and the residual refractive error was –3.00/–0.50 X 50. She had a few drusen in both maculas. The patient was unhappy with the need for both distance and near spectacle corrections to achieve good vision. She wished to be spectacle-independent for distance in both eyes. She declined monovision and was prepared to wear reading glasses.

A toric Sulcoflex IOL was implanted in the right eye. The left eye was operated 2 months later. After 6 weeks, the unaided acuities were RE 6/9 and LE 6/6. Autorefraction revealed prescriptions of RE +1.00/–1.50 X 54 and LE plano –1.00DC X 69. The eyes recovered uneventfully and the patient was very pleased with the outcome.

Conclusion

With continual improvement in cataract surgery and increasing patient expectation, significant postoperative residual refractive error is less acceptable, especially hypermetropia. Patients should be referred to ophthalmologists for further management if there are refractive surprises or dissatisfaction with their postoperative refractive error. The limited published data in the literature and our experience suggest the sulcus-fixated intraocular implant is a useful management option to correct pseudophakic ametropia. The Sulcoflex IOL allows patients

and surgeons to have another option when corneal laser refractive surgery or other methods of corrective surgery may not be viable. This type of IOL is likely to be adopted by non-refractive surgeons to correct pseudophakic refractive errors.

Summary

The Sulcoflex intraocular lens (IOL) is designed to be implanted in the sulcus. Its use is exemplified by two cases. The IOL haptics are round-edged and designed to reduce irritation of the ciliary sulcus. The round optic edges reduce glare and dysphotopsia. The IOL can be used to enhance pseudophakic ametropia. Explanting a sulcus IOL has lower risk compared to one implanted in the capsular bag. This is useful in eyes with changing refraction (eg children, keratoconics). The Sulcoflex range includes multifocal and toric IOLs. The Sulcoflex IOL is an option when corneal refractive surgery or other methods of corrective surgery may not be viable.

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CPD Exercise

After reading this article can you identify areas in which your knowledge of intraocular implants for refractive enhancement in pseudophakic patients has been enhanced?

How do you feel you can use this knowledge to offer better patient advice?

Are there any areas you still feel you need to study and how might you do this?

Which areas outlined in this article would you benefit from reading in more depth, and why?

Reflection

1. What impact has your learning had, or might it have, on:
   - your patients or other service users (eg those who refer patients to you, members of staff whom you supervise)?

   - yourself (improved knowledge, performance, confidence)?

   - your colleagues?

2. How might you assess/measure this impact?

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