Surgeons review phakic IOLs

Dermot McGrath

AN international panel of surgeons shared their experiences and expertise of a wide range of phakic IOLs during a special symposium devoted to the topic during the 9th Winter Refractive Surgery meeting of the ESCRS.

Following are discussions of many of the phakic IOLs that are available internationally, some surgical pearls for implanting them as well as comments on their clinical results and known complications to date.

Verisyse-Artisan

The Verisyse-Artisan (AMO/Ophthece) IOL remains the gold standard for phakic implants given its excellent safety record and first-rate visual outcomes over more than a decade of clinical use, said Camille Budo MD.

“If the indications and contraindications are respected and the surgical technique is of a high calibre, the Artisan lens gives excellent results”

Camille Budo MD

The Artisan IOL is a one-piece lens for the correction of myopia in phakic eyes. It is an elliptical lens, 8.5 mm in overall length.

Dr Budo presented data from a series of 71 eyes with preoperative myopia of between –8.0 D and –17.0 D that were implanted with the Artisan lens between 1991 and 1995. Of the eyes that were re-examined in 2004, Dr Budo noted that the greatest percentage of eyes remained emmetropic up to 14 years after implantation.

“It is interesting to see that the refractive results one day postoperatively and at the time of the removal of the sutures are practically the same as 14 years later. With this type of refractive procedure we have very stable results and very rapid visual rehabilitation,” he said.

Dr Budo said that the results were similarly encouraging when considering endothelial cell loss and showed without question that the Artisan lens was not itself responsible for endothelial cell loss. “It’s clear that, apart from the trauma of the surgery itself, this lens is not responsible for endothelial cell loss, if the proper surgical protocol and indications are respected,”

Dr Budo stressed that it was absolutely vital to respect the indications and contraindications for each patient.

“Every patient is not a good candidate for refractive surgery and the Artisan lens. For example if you implant an Artisan lens in patients with an anterior chamber depth less than 2.8 mm or in patients without a flat iris, you will create a contact between the IOL and the crystalline lens. It is we surgeons who are responsible for that and not the Artisan lens because we have not respected the indication for the lens,” he said.

Implantable Contact Lens

Long-term follow-up of eyes implanted with the Implantable Contact Lens (Staar Surgical) indicate that it is a safe, effective and predictable phakic IOL for correcting moderate to high myopia, according to Francesco Carones MD.

Dr Carones presented three-year data from a prospective multicentre FDA clinical trial to evaluate the safety and effectiveness of the posterior chamber phakic IOL, now called the Visian ICL. In the FDA trial, 526 eyes of 294 patients with preoperative myopia ranging from –3.0 D to –20.0 D were implanted with the ICL.

The ICL is currently available in three models: ICM for myopia, ICH for hyperopia and TICM, a Toric ICL for astigmatic myopia. Dr Carones emphasised that the ICL used in the trial data he was presenting was the V4 version, which is optimally vaulted to produce consistent clearance from the crystalline lens; an improvement over earlier versions of the lens.

Of 369 eyes available for examination three years postoperative, 41% had 20/20 or better distance visual acuity, 60% had 20/25 or better and 81% had 20/40 or better. For those patients whose preoperative BCVA was 20/20 and who were targeted for emmetropia, almost 95% had 20/20 or better postoperative uncorrected visual acuity.

Reports of symptoms such as glare, haloes, double vision, night vision problems and difficulty driving at night either decreased or remained unchanged, according to Dr Carones. The cumulative three year corneal endothelial cell loss was less than 10%.
Artiflex foldable IOL

Medium-term results for the flexible iris-fixated phakic IOL (Artiflex, Ophtec) indicate that it provides myopic patients with the safety and efficacy of the parent Artisan implant combined with the advantages of small incision surgery, according to Francois Malecaze MD.

The flexible version of the iris-fixated implant is available in powers to correct between -2.0 D and -12.0 D of myopia. It features flexible PMMA claws and a 6.0 mm convex-concave optic made of a silicone material with a high refractive index. The Artiflex has an overall length of 8.5 mm and is extremely thin, allowing it to be inserted through a self-sealing, 3.2 mm incision.

Antonio Marinho MD described the surgical procedure for Artiflex implantation. A paracentesis is created at 10 o’clock and 2 o’clock, just as in surgery for the rigid Artisan. A spatula is used, allowing a slow, controlled entrance of the lens through a 3.2-mm incision. The lens then unfolds itself without contact with the corneal endothelium. Once it is inside, the spatula is disengaged and removed.

Dr Malecaze reported that data from a two-centre prospective randomised study indicated that the small-incision, anterior chamber phakic IOL is associated with excellent accuracy, early and stable good visual acuity, and no significant complications.

“We had great refractive results with all patients within 1.0 D of target refraction and rapid visual rehabilitation with the Artiflex. Safety was also excellent with no patient losing any lines of Snellen visual acuity. It was also particularly encouraging to note that the endothelial cell count actually showed an increase one year after implantation,” he said.
said that accurate patient selection and close, constant six-month follow-up are essential to achieve optimal results with the lens.

Candidates for the GBR should have astigmatism of 2.5 D or less, said Dr Camesasca. They must have an endothelial cell count of more than 2,500/mm² and a minimum anterior chamber depth of 3.2 mm. The GBR can be used for patients with myopia of –9 D to –20 D, he said.

He emphasised the critical importance of correct IOL sizing to ensure safe and easy implantation and reduce the risk of postoperative complications. He noted that a final intra-operative check with a surgical sizer is mandatory for this type of implant.

"The most common complication of phakic IOL implantation with the GBR/Vivarte is mild pupil ovalisation, which has no negative effect on the visual outcome or any problem for the patient’s eyes," Fabrizio Camesasca MD said.

The lens is inserted through a 3.75 mm incision into the anterior chamber. A calibrated metal knife is used to ensure the exact size of the incision and a folder and forceps are used to assist in the implantation.

Dr Camesasca said he does not perform a surgical iridectomy, but uses high-molecular-weight viscoelastic such as Healon GV to maintain the space in the anterior chamber during implantation. The viscoelastic must be carefully removed by mechanical irrigation and aspiration at the end of the surgery, he said.

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Ahmed Galal
Instituto Oftalmologico de Alicante
Alicante, Spain
lagal@ortello.com

Kelman Duet
One to two-year clinical data suggests that the Kelman Duet phakic implant is an excellent alternative for the correction of medium, high and extreme myopia, according to Ahmed Galal MD.

The Kelman Duet Implant is a two-piece, anterior-chamber phakic IOL developed by the late Charles Kelman, MD, a clinical professor at New York Medical College and Tekia Inc. (Irvine, Ca).

The IOL incorporates two separate supporting parts. The haptic and the optic are separately implanted and then fixed together inside the eye. The lens allows optic or haptic exchange depending on the anatomical, refractive, and visual outcome of the patient.

Dr Galal presented data from 159 patients implanted with the Kelman Duet lens in an ongoing European multi-centre trial with one to two years follow-up. Reviewing the inclusion criteria, Dr Galal said that suitable candidates for this IOL should be between 20 and 40 years of age with a stable myopic refractive error (-10.0 D to –20.0 D), astigmatism between -0.5 D and -2.00 D, a minimum anterior chamber depth of 2.8mm and an endothelial cell count greater than 2000 cells/mm².

Results were excellent for postoperative best-corrected visual acuity and uncorrected visual acuity, noted Dr Galal, with patients continuing to recover vision up to 18 months after surgery. Endothelial cell count showed a loss of around 6% at the first year and was more or less stable after two years.

The biocompatibility of the lens was also acceptable, said Dr Galal. "We have a very good distance from the corneal endothelium and the lens is posteriorly situated at the deepest part of the anterior chamber. We have nice clearance from the anterior capsule and the angulation of the lens keeps it away at the periphery of the optic from the endothelial cells at the periphery of the cornea," he said.

Complications included six cases out of 140 with eccentric pupil, which Dr Galal said was expected in high myopes. Seven out of 140 eyes experienced slight pupil ovalisation, but no further treatment was necessary. Three eyes experienced severe inflammatory reaction in the anterior chamber after surgery but these cases were resolved soon after treatment with topical steroids.

Summing up, Dr Galal said the Kelman Duet lens is an excellent option in terms of safety, efficacy and predictability.

"This IOL is an alternative for the correction of high myopia with the advantage of having a separately exchangeable optic and haptic. So a badly sized haptic can be changed if necessary and also if you need to add more dioptres for the patient, you have the option to do that in the future," he said.
Phakic Refractive Lens

The Phakic Refractive Lens or PRL (Ioltech) offers a predictable and stable method for correcting high myopia and hyperopia, according to one-year study results presented by Bo Philipson MD.

The PRL is a posterior chamber lens made of a silicone material with a refractive index of 1.46. The lens has been designed not to touch the anterior capsule of the crystalline lens to avoid formation of a cataract or capsular opacification and is indicated for patients with refractive errors of –3.0 D to –30 D and +2.5 D to +11 D.

The multi-centre study included 195 myopic patients with a mean spherical equivalent of –13.0 D. Visual acuity results were excellent and showed good stability over the 12-month follow-up period. Almost 78% of patients gained more than one line of Snellen BCVA after surgery while around 64% gained two lines.

Predictability was also first-rate noted Dr Philipson, with 81% of patients with 0.75 D of target refraction and 90% within 1.0 D of intended refraction. Endothelial cell count loss was about 8% after 12 months and was probably largely due to the trauma of the surgery itself, said Dr Philipson.

Serious complications associated with PRL implantation were rare. There were six cases of PRL decentration, and two instances of trabeculectomy, probably due to pigment dispersion resulting in elevated IOP.

“The worst complication was that one PRL luxated in the vitreous cavity and we had four cases of traumatic cataract which occurred soon after surgery,” Bo Philipson MD

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ACRIOL is a safe, stable and efficacious lens that offers patients an excellent quality of vision, according to results presented by its developer, Albino Rapizzi MD.

The ACRIOL comprises a large PMMA optic and an original three-point haptic design which ensures perfect stability in the anterior chamber. Dr Rapizzi said that the lens offers perfect centration and long-term stability and minimal trauma to ocular tissues.

Indications for the ACRIOL include patients with a stable axial myopia who are not good candidates for conventional laser treatment, aged between 21-55 years, with an endothelial cell count of at least 2,200 cells/mm², and an anterior chamber depth greater than 2.9 mm.

Presenting results from his own series of 52 eyes of 29 patients with an average follow-up of 18 months, Dr Rapizzi reported that the postoperative BCVA improved by two lines on average. The mean postoperative SE was –1.0 D and most patients said they found the procedure very comfortable and expressed satisfaction with their postoperative visual outcome.

“Complications associated with this lens were rare and no severe complications were observed.” Albino Rapizzi MD

Complications associated with this lens were rare and no severe complications were observed, said Dr Rapizzi and included one postoperative temporary rise in IOP, three IOL rotations, three mild cases of pupil ovalisation, one case of postoperative anterior uveitis, three cases of night glare and haloes and one case of elevated astigmatism.