**Phakic IOLs**

**Concern about the long-term safety of angle-supported phakic IOLs** has been brought into sharp focus by the decision earlier this year of the French health and safety authority to withdraw a number of angle-supported phakic IOL models from the market.

The measures announced by the French Health Products Safety Agency (AFSSAPS) resulted initially in the withdrawal of Vivarte and NewLife phakic IOLs (both IOLTech/Carl Zeiss Meditec) followed by the ICARE phakic IOL (Corneal) temporary suspension some months later.

The reason cited by the French health and safety authority was the alarming rate of endothelial cell loss experienced by a significant number of patients two to three years after implantation.

A retrospective study conducted at centres throughout France showed that 27 out of 2,324 patients who had received the NewLife and Vivarte presbyopic implants had to have their implants removed due to excessive endothelial cell loss. The GBR-Vivarte myopic IOL was also withdrawn from the market due to an accelerated endothelial loss at the two-to-three-year point.

Similarly, a retrospective study carried out by Corneal in conjunction with AFSSAPS found high rates of endothelial cell loss occurring in the two-to-three-year time period for the ICARE lens.

"The current situation is that the ICARE phakic IOL has been temporarily withdrawn from the market until the results of more detailed retrospective studies with two-year endothelial cell counts can be compiled and properly analysed," said Philippe Sourdille MD, scientific director with Cornéal.

**Cause of cell loss unknown**

Dr Sourdille told EuroTimes that it was important not to rush to judgement until all the relevant data has been gathered and more is known about the possible causes of the sudden endothelial cell loss.

"There is a lot at stake here. We need first and foremost to consider the safety of patients and to present the known facts in a clear manner. The situation depends partly on the French regulatory authorities. It is therefore a matter of public health where a decision taken in haste might possibly deprive some patients of their one and only opportunity to improve their vision," he said.

Dr Sourdille said that he believes that the lens material – which in the case of ICARE is hydrophilic acrylic – is not to blame for the sudden loss of endothelial cell density.

"The material is not responsible but the sizing and the design are absolutely critical. The most important issues concerning these IOLs today relates to sizing, angle-to-angle measurement, and closely adapting the diameter of the IOL to individual patients. We also need rigorous and regular follow-up of the endothelial cell counts of these patients," he said.

Dr Sourdille noted that interim explantation data for the ICARE lens, which he presented at the recent ESCRS Congress in Stockholm, supports his claim that sizing is probably the single most important issue relating to endothelial cell loss in angle-supported phakic IOLs.

The retrospective analysis of two groups of eyes implanted with the ICARE lens showed that the cell loss after surgery was 10 times higher in the group of patients who were measured pre-operatively with the subjective white-to-white system compared to those evaluated with modern imaging technologies. Of 78 eyes measured with white-to-white, there were 17 examinations, compared to none in the 41 eyes that had been measured angle-to-angle using ultrasound biomicroscopy.

"For Dr Sourdille, the conclusion to be drawn from these data is patently clear.

"All phakic IOLs, whether anterior or posterior chamber, angle or iris-supported, will benefit from a complete analysis of the dynamic anatomy of the anterior segment of the eye. This includes the sizing of structures, volumes and morphology, and physiological changes throughout life will have to be documented and repeated during the follow-up," he said.

Dr Sourdille added that phakic IOLs would still have a viable future if strict indications, adapted designs and materials, and comprehensive pre- and postoperative evaluations were applied to all potential candidates.

"If these parameters are present, a phakic IOL will remain the only alternative in some cases, and the only reversible solution," he said.

**Safety first: the best approach**

For Georges Baikoff MD, widely considered as one of the pioneers who helped to spark a revival of interest in modern phakic IOLs, the watchword today is caution.

"The endothelial cell loss observed with this latest generation of implants demonstrates clearly that any modification of a surgical ‘device’, whether in terms of geometry, material or another aspect, opens the door to possible iatrogenic complications and should be closely monitored," he said.

Dr Baikoff told EuroTimes that the appearance of accelerated endothelial cell loss in the NewLife implants had been particularly surprising to him.

"When we look at the curve of endothelial cell loss from my own series of NewLife patients, it is clear that for the first three years of follow-up the decline in cells is completely normal. However, there is a sharp decline during the course of the fourth year postoperatively.

A retrospective study carried out by Carl Zeiss Meditec/IOLTech reached the same conclusion," he said.

Dr Baikoff said that in his own series of patients it had not been possible to establish a link between the anterior chamber depth and endothelial cell loss. He noted that the NewLife implant has a design profile that is very close to the ZB5M and NuVita IOIs, both of which were derived from the Kelman implant, and which carry only a slight risk of endothelial loss.

He said this contrasts with the design of the ICARE lens, which has a more pronounced anterior vaulting and a peripheral optic edge that seems closer to the endothelium than in either the NewLife or Vivarte IOLs.

"It seems therefore quite possible that secondary endothelial contact is the origin of the incidents observed with the ICARE implant," he said.

In terms of the NewLife lens, Dr Baikoff said that it was more difficult to explain the endothelial cell decline as due to possible contact between the optic and the endothelium.

"Maybe there are points of contact at the level of the haptics, or perhaps we might point the finger at the IOL material or the manufacturing process, since what both these lenses have in common is that they are made of hydrophilic material," he said.

Referring to the earlier generation angle-supported NuVita implant (Bausch & Lomb), Dr Baikoff said that his own studies have shown a low explantation rate of five per cent for this PMMA lens at the longest time interval of more than 10 years after its first implantation.

"If the imaging technology that we use today to measure the internal dimensions of the anterior chamber such as the Visante OCT had been available when we first started implanting these NuVita lenses, it is probably that the implant would have met all the current FDA requirements for phakic implants because the endothelial cell loss observed with these IOIs was minimal. Apart from some issues with pupil ovalisation due to oversizing, there has not been an epidemic of cataract, glaucoma or corneal dystrophies associated with this lens," he said.

While the market withdrawal of the angle-supported lenses undoubtedly represents a serious setback for proponents of phakic IOLs, Dr Baikoff believes that better use of the latest imaging technology combined with closer monitoring of patients represents the best opportunity for progress.

"At the moment it is not possible to say categorically whether there is a viable future for angle-supported phakic IOLs, because as we have seen with the IOIs that have been withdrawn from the French market the complications may only occur at a much later stage. It is therefore best to adopt a ‘safety first’ approach and to..."
insist once again on the importance of comprehensive measurements of the internal structure of the anterior chamber for all material implanted in the anterior segment,” he said.

On a more general note, Dr Baikoff suggested that inspiration could be taken from the retrospective study carried out for the Artisan lens which formed the basis for defining clear exclusion criteria for iris-claw implants: an anterior chamber internal diameter less than 11.5mm, anterior chamber depth less than 3.2mm and a ‘crystalline lens rise’ greater than 300 microns.

“Any one of these exclusion criteria is sufficient to exclude the implantation of iris-claw implants in a patient. Similar studies should be carried out with respect to phakic implants in the posterior chamber,” noted Dr Baikoff.

While other European countries are likely to eventually follow the French lead in removing angle-supported phakic IOLs from their respective markets, it is expected that the process may take some time.

More retrospective studies needed
So should surgeons continue to implant these lenses if they are available? Not for the moment, advises Joseph Colin MD, who discussed angle-supported phakic IOL complications at the recent ESCRs Congress in Stockholm.

“My advice is that current models of angle-supported phakic IOLs should not be used until the results of retrospective studies provide more reliable information on the safety of these implants,” he said.

Dr Colin, head of the ophthalmology department of Bordeaux University Hospital, described the evolution of phakic IOLs over the years as a “story of short-term success and long-term failure.”

He noted that as a result of the decision of the French health authority, endothelial cell counts of all angle-supported phakic IOLs must be conducted at least every six months.

“We have a lot of patients with such implants at the moment and we have to follow them more carefully than before. If a decrease of more than 30 per cent of corneal endothelial cells or a rate of less than 1,500 cells/mm2 is observed, then explantation is recommended,” he said.

Dr Colin said that one of the benefits of phakic IOLs is that the process is reversible.

“I suggest that surgeons do not wait until the cell count is too low. Most of the current models are foldable and so it is possible to cut the soft optic with scissors and then to remove the two pieces through a small incision. Viscoelastic also helps to protect the ocular tissues during the explantation. In most such cases, we perform a refractive lensectomy because if we implant another phakic IOL in these eyes with a low cell count, there may be serious implications for the future transparency of the cornea,” he said.

On a more positive note, Dr Colin said that the initial data from the European multicentre study of the AcrySol Phakic IOL (Alcon) suggested that it was too early to write the obituary for angle-supported phakic lenses.

“The results have been very promising, although it is still early days. The IOL is perfectly centred in most cases. The haptics are designed in such a way that sizing is not so critical an issue with this lens, because according to the size of the sulcus the flexible haptics will adapt accordingly. The lens shows nice clearance between the cornea and the IOL and between the IOL and the crystalline lens. The visual results are superb, with good predictability, and so far the endothelial cell counts in the centre and the periphery of the cornea shows very acceptable numbers. But, as we have seen with other phakic IOLs, only time will tell just how safe the lens really is,” he said.

Dr Colin suggested that a few simple rules would help surgeons to decide whether such lenses are suited to a particular patient.

“We should avoid eyes with an anterior chamber depth of less than 3.0mm and corneal diameter should be at least 11mm. I would advise against using very high power IOLs, because the higher the power the thicker the edges of the IOL. We must also be careful about the pupil size in order to avoid glare effects. Finally, it is very important to try to prevent complications by a more accurate evaluation of the diameter of the ciliary sulcus using modern technology imaging,” he said.

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