IOL SHOWS PROMISE
New lens simulates crystalline lens

by Dermot McGrath in Crete

Initial results with a novel accommodative IOL (WIOL-CF, A.M.I. Care) indicate that the lens delivers very good uncorrected vision at all distances and sustained a consistent level of pseudo-accommodation over time, according to Ioannis Pallikaris MD, PhD and Dimitra Portaliou MD.

"The WIOL-CF can be considered a promising alternative solution for patients that lead an active life and require good vision for near, intermediate and far. In our patient series, all patients obtained some level of accommodation that remained stable throughout the follow-up period. No complications occurred intraoperatively or postoperatively, although naturally we need a larger series of patients and longer follow-up to confirm these encouraging results," Dr Portaliou told delegates attending the Aegean Cornea X meeting.

Dr Portaliou, Institute of Vision and Optics, University of Crete School of Medicine, Heraklion, Crete, said that analysis of the results indicate that there may be a rehabilitation component to the procedure, although this needed to be verified by larger studies with longer follow-up. The results also seemed to correlate with other individual factors such as higher order aberrations, manifest refractive error, eye dominance and pre-existing residual accommodative capacity.

Invented by the late Prof Otto Wichterle, a Czech chemist who is also credited as the inventor of the soft contact lens, the WIOL-CF is based on the biomimetic principle, said Dr Portaliou.

"This essentially means that both the hydrogel material used and the lens geometry (Figure 1) simulate some of the key properties of the crystalline lens itself. From this perspective, the WIOL-CF can be actually considered more as a natural product and not a typical engineered one," she said.

The lens characteristics were selected to ensure adequate contact with the biggest part of the posterior capsule but without alteration of the capsule shape, said Dr Portaliou. The material used for the construction of the WIOL-CF has a high water content, a negative surface charge and a low refractive index. These parameters ensure maximum biocompatibility, resistance to calcification and elimination of cell attachment or spreading deemed to be the main causes of lens and posterior capsule opacification.

"The large continuous aspheric optics of the WIOL-CF assures lens centricity and reduces reflections and haloes that can cause night vision problems. The lens design is intended to provide up to 2.0 D of pseudo-accommodation capability, facilitating near vision," she said.

The WIOL-CF can be inserted through a 2.8mm incision. Once the lens is inserted it unfolds inside the capsule and gradually hydrates using the fluid present in the eye. Complete hydration is achieved within the first 48 hours and full equilibrium with the ocular fluids is achieved in this time frame, said Dr Portaliou.

Dr Portaliou noted that the large optics of the WIOL-CF ensure good optical performance even in large-diameter pupils in scotopic conditions. The large optical zone also means that the IOL can be used for younger patients, and that it will perform better in mesopic conditions, and will not impede vitreoretinal surgery.

The pseudo-accommodative effect of the WIOL-CF appears to result from several different mechanisms, said Dr Portaliou. The first is the anterior-posterior movement of the implant due to tightening and relaxation of the ciliary muscle, with the movement of the lens causing an increase or decrease in the distance between the lens plane and the retina. Another possibility is that the far focus is due to a combination of lens polycylarity, anterior-posterior movement and shape relaxation. iTrace technology helps us visualise the lens movement during accommodative effort (Figure 2) says Dr Portaliou.

Dr Portaliou said that so far 30 eyes of 15 routine cataract patients with a mean age of 67 have been implanted with the WIOL-CF. All implantations were performed at the University of Crete by Prof Pallikaris who is the main investigator of this clinical study being held at the Institute of Vision and Optics.

Exclusion criteria for the WIOL-CF includes astigmatism higher than 1.25 D, pre-existing ocular history, corneal endothelial disease, abnormal cornea, macular degeneration, retinal degeneration, glaucoma and previous refractive surgery, said Dr Portaliou.

The lens should not be implanted in patients with retinal pathologies, amblyopia, clinically severe corneal dystrophy, very shallow anterior chamber depth, recurrent inflammation of the anterior or posterior chamber, aniridia, optic nerve atrophy or trauma.

Turning to the results, Dr Portaliou said that the mean uncorrected distance visual acuity improved from 0.45 D to 0.66 D postoperatively. The mean corrected distance visual acuity improved from 0.57 D preoperatively to 0.75 D at the last follow-up. No eyes lost any lines of corrected distance visual acuity and 71 per cent of eyes gained lines of corrected distance visual acuity. Approximately 65 per cent of patients achieved J1 near vision without any spectacle aid.

Putting the results into context, Dr Portaliou said that the WIOL-CF seems to represent a promising solution for patients who lead an active life and require good near, intermediate and far vision. However, the nature of the lens means that postoperative patient training is critical in order to achieve the maximum degree of pseudo-accommodation and provide high-quality near vision without the use of glasses.