US FDA trial confirms myopic ICL’s safety and efficacy

Cheryl Guttman in Paris

The recently published three-year results from the US FDA clinical trial of the Implantable Contact Lens (ICL, Staar Surgical) provide strong support for the efficacy and safety of that posterior-chamber phakic refractive implant for treating between -3.0 D and -20.0 D of myopia.

Nevertheless, other data presented at the XXII Congress of the European Society of Cataract and Refractive Surgeons (ESCRS) reinforce lingering concerns about the risk for cataract formation.

The US FDA study enrolled 526 eyes of 294 patients aged 21 to 45 years old (mean 36.5 years) who were implanted with Version 4 (V4) of the ICL. A total of 369 eyes were seen at the three-year visit, and as reported in the September 2004 issue of the journal Ophthalmology, patients achieved rapid refractive correction and good visual acuity that remained stable over three years.

Prooperatively, nearly 80% of eyes had an MRSE above -7.0 D, and mean MRSE for the group was -10.1 D. At one week, mean MRSE was about -0.5 D and it remained at that level during continued follow-up.

Predictability was also excellent. At three years, two-thirds of eyes had an MRSE within 0.5 D of intended, and in 88% of eyes, achieved MRSE was within 1.0 D of the target.

At one week after surgery, more than 80% of eyes achieved UCVA of 20/40 or better, and that proportion remained constant throughout follow-up. At three years, 41% of eyes had UCVA of 20/20 or better.

Considering only eyes that had BCVA of 20/20 or better preoperatively who were targeted for emmetropia, 59% achieved UCVA of 20/20 or better and 95% reached the UCVA level of 20/40 or better. In addition, post-op UCVA was equal to or better than preoperative BCVA in 60% of eyes.

Safety has been excellent. Only five (1.0%) eyes had persistent loss of two or more lines of BSCVA, while 40 (10.8%) eyes gained two or more lines. Visually significant anterior subcapsular opacity developed in only two eyes. Five eyes developed clinically significant nuclear cataracts after two to three years, and cataract extraction was performed in only three eyes.

“The safety profile of the ICL, at least during the first three years, meets or exceeds all FDA guidance criteria for refractive implants.”

John A Vukich MD

“Not only do these data satisfy the scrutiny of the peer-reviewed literature, but they are derived from a large, rigorously monitored, FDA clinical trial and are the basis for ICL approvability in the US. As such, they clearly represent the most thorough look at the efficacy and safety of the ICL to date, and the results address many of the questions about this phakic IOL,” said John A. Vukich, MD, assistant clinical professor of ophthalmology, University of Wisconsin, Madison, and investigator in the US FDA ICL study.

“Reassuringly, the safety profile of the ICL, at least during the first three years, meets or exceeds all FDA guidance criteria for refractive implants. Importantly, however, it would also satisfy the standards that reasonable clinicians would set in offering this technology to patients,” he told EuroTimes.

He added, “We are now collecting five-year data and anecdotally the outcomes appear to be mirroring closely what we’ve seen and four years, there was a 0.1% gain in endothelial cell density.

The excellent efficacy and safety results also translated into high levels of patient satisfaction. Among study participants seen at three years, 92% indicated they were very or extremely satisfied, 7% were moderately satisfied, and only 1% stated they were unsatisfied with their outcomes. In addition, 97% of patients said they would undergo the procedure again.

“Safety is a requisite issue for establishing the clinical role of a new modality. From a practical standpoint, however, patient satisfaction is also a critical determinant since no intervention will find widespread use unless patients are pleased with it. The 99% satisfaction rate of patients implanted with the ICL demonstrates clearly that recipients of this phakic IOL are quite happy,” Dr. Vukich said.

An evaluation of the eyes developing crystalline lens changes showed that one of the five eyes with a nuclear cataract had undergone silicone oil tamponade for a macula-off retinal detachment while the other four eyes represented bilateral changes in two patients who had high myopia (-14 to -17 D).

Other complications consisted of macular hemorrhage at one week in one eye, subretinal hemorrhage at three months in one eye, and retinal detachment in two eyes.

At the ESCR Congress, ophthalmologists from the Medical University of Vienna, Austria, presented their analyses from a four-year follow-up study of 76 eyes of 46 patients implanted with the V4 myopic ICL. Some 14.5% of eyes in that study developed lens opacifications.

The patients were about equally divided by gender, and similar
cataract extraction. Based on our study results, we would prefer refractive lens exchange rather than this implant to patients older than age 45," said Birgit Lackner MD.

Patients in this study were followed prospectively at one, three, six, 12, 24, 36, and 48 months after surgery and underwent optical measurement of vaulting using the Jaeger II pachymeter and slit-lamp examination for evaluation of crystalline lens opacities. Among the 11 eyes that developed lens opacification, the changes were noted within six months after surgery in six eyes and in three more eyes by one year. Forty-two eyes were seen at two years, of which one had a new lens opacification. There were no new opacities in 19 eyes seen at three years, while de novo opacification was seen in one of eight eyes evaluated at four years.

Four of the six cases of early opacifications (within six months after surgery) occurred after lens traumatisation during a prolonged and difficult surgical procedure associated with narrow pupils and extensive manipulations in the anterior chamber in patients over 47 years of age. In all five cases of late opacifications, the patients were over 50 years of age. All opacifications were of the anterior or subcapsular type. Three eyes (3.9%) which lost between 1 and 2 lines of BCVA underwent cataract surgery.

In five eyes, BCVA remained stable during continued follow-up, while progressive opacification in the remaining six eyes was associated with BCVA losses between 0.5 and 3.5 lines relative to preoperative levels. Three of those eyes underwent cataract surgery.

Recognising the association between older age and cataract development, the Austrian researchers also raised the question of whether ICL implantation would make recipients of this posterior chamber lens more susceptible to cataracts as they get older.

"It remains to be seen through further follow-up whether with the presence of the ICL and the potential for occasional, intermittent touch to the crystalline lens, the aging lens in these eyes becomes at increased risk for cataract formation compared with the general population," Dr. Lackner said.