

## New square-edged IOL minimises glare

**Cheryl Guttman  
in Munich**

THE new foldable, multi-piece LI61SE (SoFlex SE, Bausch and Lomb) IOL is a surgeon-friendly implant that produces high levels of patient satisfaction, according to the early results of a study conducted by Mark Tomalla MD.

Speaking at the XXI Congress of the European Society of Cataract and Refractive Surgeons, Dr. Tomalla presented results from a series of 80 eyes of 80 patients implanted with the SoFlex SE. Data collected at one month after surgery demonstrated that the new foldable IOL offered safe, easy handling and good quality of vision outcomes. Refractive predictability was reasonable, although deviation from target refraction was somewhat higher than expected, Dr. Tomalla said.

"Visual acuity was an important endpoint, of course, but I was also interested to see how the new square-edged design of the SoFlex SE would influence PCO development and patient satisfaction, particularly as regards glare. While it is too early to determine the association of this implant with PCO and our refractive outcomes suggest it may be necessary to adjust the A constant, this new implant has performed very well intraoperatively, vision results are good, and it seems to be achieving the goal of minimising postoperative glare," said Dr. Tomalla.

**“Insertion of the SoFlex SE was easy. Folding, delivery, and positioning of the IOL inside the eye were generally excellent”**

The patients studied were randomly selected for participation in the prospective trial and were required only to have age-related cataract with no other ocular pathology that could affect the efficacy and safety outcomes of the SoFlex SE. All patients underwent phacoemulsification through a 3.0 mm incision with implantation of the SoFlex SE IOL through an unenlarged wound. Insertion can be performed using either a forceps or the MPort SI single-use inserter, although Dr. Tomalla noted he prefers forceps insertion

and found the lens handled well at all stages of surgery.

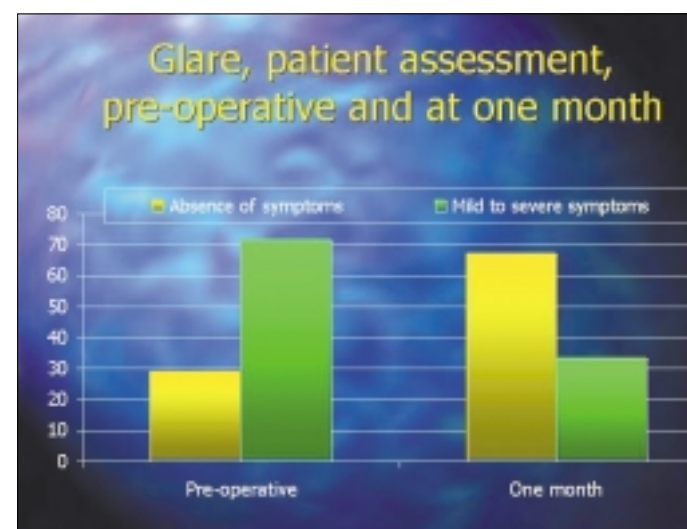
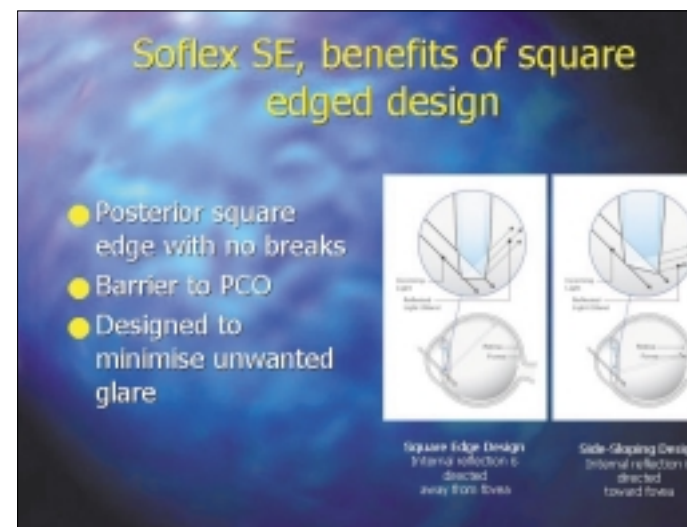
He rated handling as "excellent" in 69% of eyes and "good" in 30%.

Delivery was considered "excellent" in nearly all eyes, 91%, and "very good" in 4%, while intraocular control was judged consistently "good". Ratings for insertion, handling, and placement were also good to excellent in more than 92% of eyes.

"Insertion of the SoFlex SE was easy. Folding, delivery, and positioning of the IOL inside the eye were generally excellent, but that was really not surprising given the similarities between this lens and the original SoFlex," Dr. Tomalla said.

The lens was delivered without damage in all cases but one. No complications have been encountered during postoperative follow-up of up to five months. The SoFlex SE IOL has maintained good centration, and at one month post-op, median UCVA was 0.89 and median BCVA was 1.0. Fifty percent of eyes have 20/20 or better UCVA and 69% achieved 20/25 or better. However, only one-fourth of eyes achieved intended refraction while about half of the eyes were at least 0.5 D off the target and a significant number required correction for good distance vision.

Preoperative patient questionnaires indicated that only one-fourth of patients rated their quality of vision as excellent or good in either sunlight or dim light and only 32%



reported no night vision difficulties. At one month post-op, the rates of patients with excellent to good vision in sunlight and dim light and with no night vision difficulties rose to between 65% and 70%.

Regarding glare, fewer than 30% of patients were without symptoms of glare preoperatively, while after surgery, nearly 70% had no glare symptoms. The results were similarly favourable for the SoFlex SE in terms of blur-

ry vision and ghosting. PCO development with the SoFlex SE. Dr. Tomalla noted that in another study he presented at the same meeting, the LI6IU was associated with the lowest PCO rate when compared with the Acrysof (Alcon) and SI40 (AMO) implants. Among 120 eyes implanted with the SoFlex 2, 30% showed evidence of PCO during follow-up extending to two years. Recipients of the LI6IU also rated the IOL very high with respect to glare.

optic, and blue extruded, modified C-loop PMMA haptics angulated at five degrees. However, the optic was redesigned for optimal intraocular performance with respect to minimising the development of posterior capsule opacification (PCO) without increasing dysphotopsias.

To form a barrier against lens epithelial cell migration, the new lens features a sharp, posterior square edge that makes full 360 degree capsular bag contact without any gaps at the haptic junctions. However, the edge is also angled with a slide-sloping profile to direct internal edge reflections toward the fovea of the eye.

The designers say that the equi-biconvex optics of the SoFlex SE and the relatively low refractive index of its silicone material (1.43) complement that design in minimising the potential for postoperative glare.

**Mark Tomalla MD**  
Evangelisches and Johanniter Klinikum,  
Duisburg, Germany  
mark.tomalla@ejk.de

**“I expect that as postoperative assessment continues, we will find an increase in the percentage of patients who are totally free of dysphotopsic symptoms”**

ry vision and ghosting.

"Of those who still experienced glare, most noted the severity was decreased. However, we must remember that while patients are very glad to have restored vision after cataract surgery, in the early post-op period they can have difficulty adjusting to unaccustomed levels of light. I expect that as postoperative assessment continues, we will find an increase in the percentage of patients who are totally free of dysphotopsic symptoms," Dr. Tomalla said.

Available follow-up in this series of patients is currently too short to assess the rate of

"The study of the SoFlex SE was started less than six months ago, and so the post-implantation period is not sufficiently long to enable us to draw any conclusions about the effect of the square edge on PCO rates. We hope to see that the theory regarding the benefit of circumferential contact of the square posterior edge with the capsular bag for minimising PCO rates is confirmed as our follow up continues," Dr. Tomalla said.

The SoFlex SE is a modified version of the SoFlex (LI6IU) IOL, which like its predecessor, has an overall length of 13.0 mm, an equi-biconvex, second generation silicone, 6.0 mm