

# The Maker of the First IOL Introduces a New Product to Surgeons

Innovative material, design, and easy surgical handling highlight Rayner's return to the American market.

BY MARK PACKER, MD

It is perhaps ironic that it has taken 60 years for the manufacturer of the original lens implant (Rayner Intraocular Lenses Ltd., Hove, East Sussex, United Kingdom) to offer an IOL to the largest market in the world. On November 29, 1949, as most cataract surgeons know, Sir Harold Ridley placed the world's first IOL in a patient's eye at St. Thomas' Hospital in London.<sup>1,2</sup>

Rayner's manufacture of IOLs has continued uninterrupted since then. In 1981, the company's implants were the first to be approved as safe and effective by the FDA. In the summer of 2003, Rayner received IDE approval from the FDA to begin a multicenter investigation of the company's C-flex lens, with its patented antivaulting haptic and enhanced square-edge technology. James A. Davison, MD, at Wolfe Clinic in Marshalltown, Iowa, was the first US surgeon to implant the C-flex in a US patient on October 24, 2003. Implantation of the new lens soon followed at my ophthalmic investigational site, Drs. Fine, Hoffman and Packer in Eugene, Oregon. My colleagues and I participated in the entire course of the clinical investigation. This article describes the configuration of the new lens and what we found during our clinical research.

## OUR EXPERIENCE AND THE FDA CLINICAL TRIAL

After carrying out his first procedure with the new IOL, Dr. Fine reported, "This is great technology. The injector tip went in easily through a 2.8-mm incision. ... The lens cen-

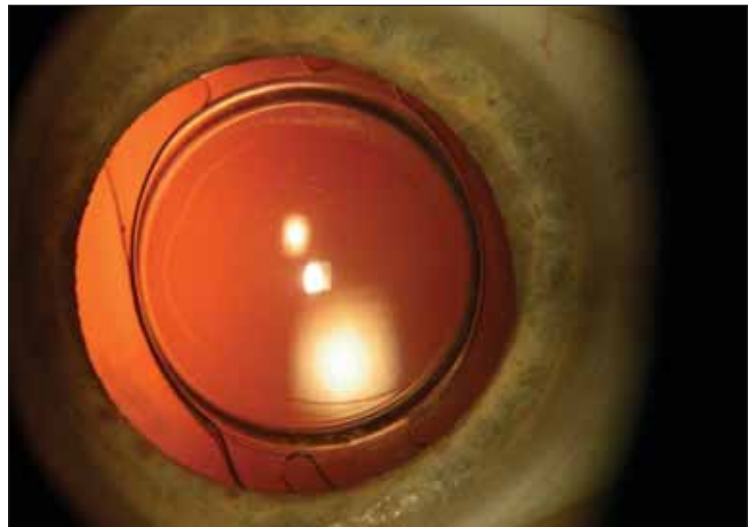


Figure 1. A slit-lamp image of the Rayner C-flex IOL demonstrates capsular clarity.

tered by itself and it looked splendid." I noted that "delivery is the best controlled and simplest that I've seen. The lens centers superbly and it looks stunning in the eye."<sup>3</sup>

The FDA study of the C-flex IOL included a total of 483 patients enrolled through the end of 2004. Approval was granted on June 14, 2007. I had the pleasure of implanting these lenses and observing patients during the trial; I am excited to be able to offer this technology to my patients now that the lens is commercially available.

## THE LENS' MATERIAL, IMPLANTATION, AND EASY HANDLING

The C-flex IOL is manufactured from Rayacryl (Rayner Intraocular Lenses Ltd.). This unique hydrophilic acrylic

TABLE. YAG RATES FOR THE C-FLEX IOL WITH DOUBLE 360° SQUARE EDGE

IOL model	Sites	IOLs	YAGs performed ≤ 12 months postoperatively	YAG	YAGs performed ≤ 24 months postoperatively	YAG
C-flex	7	301	9	2.99%	16	5.31%

polymer yields a soft, single-piece lens that is easy to handle. Rayacryl has been in use for more than 12 years with more than 3 million lenses implanted worldwide. In 2005, researchers noted, "The Rayacryl material, now implanted in more than 1 million eyes for more than 5 years, does not show a single case of primary calcification on the IOL surface or within the IOL's substance."<sup>4</sup> In my experience, a major benefit of the C-flex is the extreme ease with which it is implanted through a 2.8-mm incision. The design allows me to place the leading haptic in the bag without difficulty and with minimal manipulation; the trailing haptic often automatically locates itself in the proximal bag. The patented looped design featuring antivaulting haptic technology virtually ensures perfect centration and stability of the IOL. Rayacryl provides a pristine, clear, equally biconvex optic with a low 1.46 refractive index (Figure 1). Postoperatively, I have observed a high degree of biocompatibility and very quiet eyes.

"I believe that these IOLs represent exciting opportunities for surgeons dedicated to offering high-quality vision and spectacle independence."

Another important feature of the C-flex's design is its double square edge, which is based on observations on the effect of the sharp edge in preventing capsular opacification in rabbit eyes by David J. Apple, MD,<sup>4</sup> and clinical observation by Michael Amon, MD.<sup>5</sup> The design incorporates a 360° continuous square edge around the entire lens, including the optic and the haptics. This double wall is very effective in preventing posterior capsular opacification.<sup>5</sup>

## STUDY RESULTS

In the FDA trial, the C-flex IOL met or exceeded historical controls for posterior chamber IOLs in all areas, and specifically for BCVA at the 12-month postoperative examination. Best-corrected case and overall visual acuity greater than 20/40 were 98.2% and 99.5%, respectively, compared with the FDA historical control figures of 92.5% and 96.7%, respectively. The YAG rates at 1 and 2 years were quite low (Table). For

C-flex IOLs, ray-tracing studies show no general increase in glare as a result of the enhanced square-edge technology. In fact, only 0.6% of subjects in the FDA study complained of halos, and 0.2% described visual disturbances.<sup>3</sup>

## NEW PLATFORMS ON THE HORIZON

Given its exceptional rotational and axial stability, the C-flex IOL represents a natural platform for the development of high-quality toric and multifocal optics. These designs are already available outside the United States. The T-flex toric IOL (Rayner Intraocular Lenses Ltd.) provides correction of preexisting corneal astigmatism of up to 11.00 D. The M-flex multifocal IOLs (Rayner Intraocular Lenses Ltd.) are the latest generation of presbyopia-correcting IOLs. These lenses are based on Rayner's unique multizoned refractive aspheric optic technology that features either four or five annular zones (depending on the IOL's base power) and provides either +3.00 or +4.00 D of additional refractive power (equivalent to +2.25 or +3.00 D at the spectacle plane). I believe that these IOLs represent exciting opportunities for surgeons dedicated to offering high-quality vision and spectacle independence. ■

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