Joshua Ben-nun, MD, founded NuLens, Ltd. (Herzliya Pituah, Israel), in 2002 with the invention of a flexible lens that could change its curvature in response to the movements of the eye’s accommodative system. The NuLens Dynacurve IOL—named for the lens’ dynamic curvature-changing feature—was designed to adjust its true power during accommodation through the alteration of the lens’ curvature. This is unlike other accommodating IOLs that use the axial movement of one or two fixed-power optical surfaces.

HOW IT WORKS

The NuLens Dynacurve IOL uses the capsular bag as a component of a moving diaphragm, consisting of the collapsed capsular bag, zonules, and the ciliary processes. The dynamic diaphragm transfers force from the contracting and relaxing of the ciliary muscles to the device attached to it. A piston, activated by the capsular diaphragm, pressurizes a small, rigid chamber containing a silicone gel. The chamber is fixated to the eye wall at the ciliary sulcus so that movements along the optical axis are avoided. The silicone gel is pressurized by forward movements of the capsular diaphragm and depressurized by backward movements of the diaphragm. In the lens prototype (2003-2006), the pressurized gel was displaced through a round hole in the anterior (or posterior) chamber wall to form a lens-shaped bulge that continuously changed its curvature in correlation with the ciliary muscle’s movements. In the more current design, the “hole” has been replaced by a flexible membrane that can be modified to provide a spherical or aspherical dynamic surface.

TRUE ACCOMMODATION

As described by Dr. Ben-nun and Jorge L. Alió, MD, PhD, 3.00 D of accommodation should allow comfortable reading at a focal length of 33 cm in a phakic or pseudophakic individual. In a human eye, however, one-third to one-half of the accommodative amplitude must be left in reserve to enable comfortable reading. Thus, reading comfortably at 33 cm requires 4.50 to 6.00 D of accommodative amplitude. It was found that, in the human eye, the natural accommodative amplitude between 20 to 30 years of age is approximately 6.00 to 8.00 D.

“NuLens found that in order to restore accommodation, 6.00 to 8.00 D of free accommodative range is required, because from a physiologic and biologic perspective, the eye muscle cannot work at 100% capacity 100% of the time,” said Ori Gal, chief executive officer.
of NuLens. “Therefore, 2.00 to 3.00 D will be available only if the lens relies on 50% of its entire capabilities. Such a dynamic range can only be achieved digitally, electronically, or with a lens that can mimic the natural lens. The Dynacurve achieves approximately 10.00 D of accommodation for every 1.50 µm of movement.”

**SCIENTIFIC BACKING**

Inherent to NuLens’ approach was a lack of scientific evidence to support its technology. Whereas most IOLs currently on the market are rigid and flat, the NuLens Dynacurve IOL is soft and curved. Furthermore, it is implanted in front of the collapsed capsular bag (anterior and posterior lens capsules) instead of inside the bag.

“We had to research a new field of basic science to justify the operation of our lens,” Mr. Gal said. “We had to convince people how things could be and how things should be different.”

First, bench testing evaluated the predictable forces, availability, and design of the IOL. Next, the company conducted primate studies at the University of Wisconsin in Madison and in Alicante, Spain, to determine if it was possible to capture and harness forces available in the entire accommodative system to activate the lens when the direction of action was changed from known lenses. In Spain, primates implanted with the initial prototypes of the NuLens Dynacurve demonstrated more than 40.00 D of change in dioptric power in response to pharmacological stimulation. In Wisconsin, a more advanced lens design limited to 12.00 D was implanted in primates. At 21 months postoperatively, the lens continued to provide 6.00 to 8.00 D of accommodation through electrical stimulation of the Edinger-Westphal nucleus, as measured by a Hartinger refractometer.

In 2006, NuLens conducted a clinical pilot investigation of the Dynacurve IOL at the Vissum Eye Institute in Alicante, Spain, that included 10 patients with advanced age-related macular degeneration and low vision. The company tested the new sulcus-fixation method as well as the IOL’s performance for short- and long-term ocular reaction.

After 12 months, no safety issues were identified. Four eyes underwent uneventful Nd:YAG capsulotomy for posterior capsular opacification. All patients were able to focus for distance viewing, obtaining the best visual acuity for each eye limited only by retinal pathology.

Significant improvement was noted in near vision performance, including a low vision reading chart, identifying time on a watch, and cell phone dialing at an average uncorrected distance of 10 cm (= 10.00 D = 2.5X magnification).1 Repeated ultrasound biomicroscopy examinations during the 12-month follow-up demonstrated a backward shift of the lens’ piston following pilocarpine-induced cyclospasm.

The amount of observed change correlated with the preclinical optical bench performance of the IOL. On average, the observed change was 8.00 D. Posterior capsular opacification resulted in a reduction of IOL performance as noted by piston movements, but significant recovery of piston movements (although not full) was noted after the Nd:YAG capsulotomy.

**REDESIGN**

The prototype of the Dynacurve used in the pilot study required a 10- to 11-mm incision for implantation. To decrease the incision size and improve the surgical procedure, NuLens redesigned the Dynacurve IOL to what it looks like today—a base plate and a haptic unit that requires a 5-mm incision. With recent modifications to the rigid components of the lens, it is reasonable to expect a sub–3.5-mm incision version of the device in the near future, Mr. Gal said.

The NuLens Dynacurve IOL has been tested in primates and human cadaver eyes and is currently being tested in human clinical trials in Mexico and Peru. “We have implanted more than 50 patients in these trials, and we are seeing 6.00 to 8.00 D of accommodative range achieved in all of them,” Mr. Gal said.

NuLens plans to evaluate the potential of piggybacking the current Dynacurve design in patients with previous lens implantation (pseudophakes) to restore accommodation in these individuals.

**REGULATORY APPROVAL**

“Some of the top surgeons are helping us bring the Dynacurve to market, including Dr. Alió; I. Howard Fine, MD; Richard L. Lindstrom, MD; Douglas Koch, MD; Emanuel Rosen, BSc, MD, FRCS Ed, FRCOphth; David J. Apple, MD; R. Doyle Stulting, MD; Stephen G. Slade, MD; and David F. Chang, MD,” Mr. Gal said. “We meet at least once a year with these key opinion leaders to learn how to make this lens right.”

According to Mr. Gal, NuLens hopes to obtain CE Marking in Europe by early 2012, with US FDA trials beginning around this time. NuLens hopes that the IOL will be available for sale in the United States by 2014, but this depends on the results of the FDA clinical trials, Mr. Gal said.

“The NuLens has the potential to re-create the ophthalmic industry and give patients a real wide range of accommodation so that they will have spectacle-free vision at all distances for the rest of their lives,” Mr. Gal said. “In the future, not only will we be able to help cataract and presbyopic patients, but we can help the entire field of impaired vision.”