Restoring Natural Accommodation With an IOL

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BY LOUIS D. "SKIP" NICHAMIN, MD

PowerVision Inc. is currently developing a unique accommodating IOL, the FluidVision lens (Figures 1 and 2). Forces from the ciliary muscle transport fluid within the lens and thereby change its shape. This conformational alteration, similar to that which occurs in the natural crystalline lens, creates an accommodative range averaging more than 5.00 D—equivalent to that of a 35-year-old. The lens is implanted using time-tested techniques of conventional intracapsular insertion. The technology relies only on existing muscle forces to create accommodation of the same potential magnitude and in the same direction as the body's youthful, natural accommodative mechanism.

HOW IT IS MADE AND HOW IT WORKS

The FluidVision lens is composed of an optic body and two haptics. These elements contain a very small amount of optically clear fluid. When the ciliary muscle moves to its accommodated position, fluid is "pumped" from the haptics into the optic's body, increasing the radius of curvature and allowing the patient to see at near. When the ciliary muscle moves to its disaccommodated position, fluid is pumped from the optic's body into the haptics, decreasing the radius of the curvature and allowing the patient to see at distance. The lens can therefore operate at near, distance,

Figure 1. The FluidVision IOL.

or anywhere in between. The optic's body and haptics are made of a proprietary flexible hydrophobic acrylic polymer, and the fluid is proprietary silicone oil, similar to that which is used in today's retinal tamponade procedures. The acrylic and silicone oil have a matched index of refraction. The amount of fluid is minimal, in

Figure 2. The FluidVision injection system.

the range of a drop (ie, approximately 30 µL).

The IOL's design leverages very small forces and movement by the ciliary muscle acting upon the capsule to create relatively large accommodative change in the lens, with excellent optical quality through its full range of accommodation. The lens' design is the product of intensive mechanical and optical modeling and analysis as well as much experimentation. Bench testing has been conducted using extensive optical, biological, and mechanical characterization techniques as well as a sophisticated cadaveric eye model. The lens meets all current International Organization for Standardization requirements.

The FluidVision lens was designed to be used in a manner consistent with standard cataract surgery. The original criteria required implantation through a 4-mm or smaller clear corneal incision and insertion into the capsular bag through a standard 5.5-mm capsulorhexis.

CLINICAL DATA

PowerVision has conducted two human clinical studies and a variety of animal (rabbit) studies. The former initially involved five blind eyes[1] and subsequently 13 sighted eyes.[2] These studies confirmed that the lens was well tolerated, it remained stable and well centered after placement in the bag, and there was sufficient muscular force to activate the device. The IOL created a magnitude of accommodation averaging more than 5.00 D. Patients had good visual acuity, and accommodation and visual performance were stable out to 1 year (the follow-up period for the study).

Several studies have also been conducted using a rabbit model. These investigations confirmed reliable performance by the injector, biocompatibility, very little posterior or anterior chamber opacification, and minimal to no capsular reaction to the implant.

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To date, all human implantations have been performed with a nonfoldable version of the device. The company will soon initiate the first clinical trial of its newest-generation foldable device utilizing a novel injector system. The incision for these first implants will be 4 mm or less. The company believes it can readily reduce this to a 3-mm or smaller incision in future iterations.

CONCLUSION

Based on extensive laboratory investigation, the initial clinical experience, and newer designs about to enter clinical study, the FluidVision lens appears to have the potential to be a revolutionary solution to presbyopia. The lens delivers at least 3.00 D of accommodation to all patients, and it does not require any change to the conventional intracapsular implantation technique. Because the device is powered by the body's own muscles, accommodation occurs in a physiologic manner, with movement in the same direction and magnitude as the natural eye, thereby providing a dynamic range of vision from near to far. Although further clinical studies are needed, the IOL has already demonstrated its unique potential, and I look forward to emerging data from its upcoming international clinical trial. ■

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1. Roux P. Early clinical experience with PowerVision's FluidVision accommodating IOL. Paper presented at: ASCRS Symposium on Cataract, IOL and Refractive Surgery; April 6, 2008; Chicago, IL.
2. Roux P. Early implantation results of shape-changing accommodating IOL in sighted eyes. Paper presented at: ASCRS Symposium on Cataract, IOL and Refractive Surgery; April 9-14, 2010; Boston, MA.