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Start-Up Spotlight: LensGen, Eye On The Presbyopia Prize

by Bob Kronemyer

Restoring the eyes' ability to accommodate and seamlessly focus on near and far objects continues to be the holy grail in ophthalmology. Accommodating intraocular lenses offer one approach to tackle presbyopia and allow patients the possibility of eschewing reading glasses. LensGen is one company going down that road and it successfully raised \$21m in series A financing – with major optical lens maker Hoya among its backers – in April to advance its fluid-based accommodating IOL, Juvene.

Most patients who undergo cataract surgery with the implantation of an intraocular lens achieve better distance vision, but are not corrected for near vision or presbyopia.

Hoping to shift this paradigm is [LensGen Inc.](#), which has a permanent accommodating intraocular lens (IOL) in development designed to treat presbyopia. However, unlike many other standard monofocal IOLs that are single-piece lenses, *Juvene* is a modular, two-piece IOL design that combines both a standard monofocal lens optic (the base lens) with a fluid lens optic. The fluid lens optic changes shape on demand by the brain via the eye muscles when focusing on an object anywhere from near to distance automatically.

The base lens is inserted into the capsular bag first and is similar to a traditional IOL with haptics that surround the optic to securely position and hold the lens in place. The fluid lens optic is then inserted through the same small incision and tucked inside the base lens and held in place by three tabs.

“Juvene is implanted with a surgical procedure that is identical to standard cataract surgery,” says company founder and CEO Ramgopal Rao. “In a sense, Juvene restores the youthful vision people lose starting in their 40s.”

LensGen is initially targeting the cataract market, representing about 27 million cataract surgeries worldwide annually, for a yearly market opportunity approaching \$4bn for Juvene. The company expects CE mark for the lens in 2019, followed by premarket approval 2021.

Rao was sparked to start the company after his own disappointing cataract surgery in 2011, which was unable to address his presbyopia and resulted in him needing to wear reading glasses. The serial entrepreneur was determined to create an IOL with clear optics and a sufficient amount of accommodation. This led him and his team to create a lens that could mimic the eye's natural lens by changing shape for various visual distances.



Source: Source: LensGen, Inc

“We had to find the muscular forces in the eye that could be manipulated to change the shape of the fluid lens,” Rao explains. “Fortunately, we had cutting-edge materials and came up with a design to amplify those tiny muscular forces.”

Moreover, to be able to insert the new IOL through an incision less than 3 mm in diameter, the lens became modular, with each piece made of foldable silicone. “Silicones are generally more malleable compared to other optical materials,” says Rao, whose ophthalmic background includes co-founder of Tomey Technologies Inc. (corneal topography imaging) in 1990; a co-founder of AcuFocus Inc. (a corneal implant device for presbyopia) in 2002; and CEO of 2C Tech Corp. (nanotechnology for treating age-related macular edema and retinitis pigmentosa) from 2010 – 2016, for which he became chairman of the board last November.

Advanced engineering and analysis tools were used to design and fabricate Juvene, including optical ray tracing, finite element analysis and state-of-the-art reaction cast molding. “A smaller incision is also highly desirable for cataract surgery because it reduces trauma, requires no sutures and can be performed under topical anesthetic,” Rao says.

LensGen has one issued and 10 pending patents, and does not share any royalties/revenues with another entity.

An ophthalmic surgeon who mostly specializes in anterior segment surgery (front of the eye) uses a stereo microscope to first remove the cataract through the top of the capsular bag by creating a small incision near the cornea, followed by a technique called phacoemulsification, which fragments the cataract lens with ultrasound energy, then aspirates the fragments. Cataract

extraction takes a maximum of 5 minutes and is performed under topical anesthesia.

The base lens of Juvene is then folded and placed in an injector, which inserts the lens into the back of the empty capsular bag, where the lens unfolds. “The lens nearly automatically positions itself, but the surgeon may need to manipulate the lens slightly,” Rao conveys.

A different injector is used to position the fluid lens, where it sits snugly on a shelf inside the base lens, like a jigsaw puzzle.

No further adjustments are needed for the IOL to be permanently fixated, and the two lenses are surrounded by the eye’s natural saline fluid (aqueous).

In addition, the top of the capsular bag is left open because the bag is avascular (lacking blood vessels), so there is no healing process, per se. The initial small incision is also self-sealing and there is no patient downtime.

The entire surgical procedure, including lens extraction, takes about 15 minutes.

Michael Landreville, chief operating officer for LensGen, says the surgeon learning curve to implant Juvene is minimal. “The only difference is that with a standard cataract procedure, only one lens is inserted, whereas we insert two lenses,” he says.

The Juvene fluid lens is slightly different than the base lens because it is designed to fit inside the base lens, therefore the fluid lens is

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Industry Segment: Ophthalmology

Business: Modular, fluid-optic accommodating IOL fully compatible with small-incision cataract surgery

Founded: February 2012

Founder: Ramgopal Rao, CEO

Employees: 6

Financing to Date: \$28m

Funding: The Hoya Group; Relativity Health Care Partners; Angel Investors; Grant from the Johnson and Johnson Corporate Office of Science and Technology

Board of Directors: Ramgopal Rao; Michael Colaco (Gems Holding LLC); Akiteru Furukawa (The Hoya Group)

slightly smaller and flatter. “It looks almost like a disc,” Landreville notes. The amount of silicone fluid contained in the lens is a fraction of a drop of water. “One surface of the fluid lens moves slightly,” he says. “However, the movement is almost imperceptible.”

The base lens of the IOL will likely come in three sizes, with one size around 9.2 mm in diameter and the other two, 0.5 mm smaller and 0.5 mm larger. The fluid lens, though, will be available in one size only, around 6.6 mm in diameter.

The company has an ongoing clinical pilot study of Juvene that started two years ago, with 20 eyes of 20 patients (ranging in age from 55 to 75) treated to date. All patients were candidates for standard cataract surgery. “Juvene has been found to be safe,” Landreville reports. “Most patients are also achieving objective and subjective accommodation.”

Landreville worked at 3M Vision Care from 1984-1993, departing as international business manager of the surgical division for the Asia region, after 3M divested its ophthalmic franchise to Alcon. In addition, he served in various operating roles, including category leader for the refractive franchise, at Bausch + Lomb from 1996-2003; and director of medical marketing for the cardiac rhythm management division at St. Jude Medical from 2008-2012 (now part of Abbott Laboratories Inc.).

LensGen’s closest competitor in this new classification of shape-changing, fluid-optic accommodating IOLs is *FluidVision* from PowerVision Inc. “FluidVision pumps fluid (silicone oil) from their haptics that look like tiny pontoons into the lens optic to create the shape change when the eye muscles and capsule contract,” Landreville explains. “The fluid then returns to the pontoon like haptics when the eye muscles relax. In contrast, Juvene’s mechanism is direct and relies on the direct forces of the capsule contraction on our haptic to generate the shape change on our fluid lens.”

Likewise, FluidVision is single-piece design, not a two-piece like Juvene. “Because of its bulk, the [FluidVision] lens requires a larger incision,” Landreville says. Maintaining the smallest possible incision in cataract surgery is important, including no induced astigmatism, faster healing and visual recovery, and usually better outcomes.”

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Multifocal IOLs from major ophthalmic companies like Alcon (a division of Novartis AG), Johnson & Johnson Vision and [Carl Zeiss Meditec AG](#) are also competitors.

“These lenses are more similar to bifocal glasses,” Landreville observes. “Some people have difficulty adjusting to multifocals. They can create optical issues like glare, halo and night-vision problems because you are splitting light, which reduces contrast. Juvene, on the other hand, does not compromise quality of vision because it works in a continuous manner, like the natural lens. Instead of splitting light, Juvene changes curvature to produce the power change. This way, the optics are preserved.”

Another disadvantage of multifocal IOLs is that it is challenging to predict which patients will encounter problems and which patients will adapt well to the lenses, according to Landreville. “Screening patients is not a perfect science; therefore, some surgeons have opted to avoid using multifocal IOLs all together,” he says.

Juvene is expected to start selling in Europe and Asia in either 2019 or 2020, at a price of roughly \$1,000, through a hybrid direct/distributor sales force. The IOL will be partially reimbursable.

US sales are planned for 2021 through a direct sales force, with the lens also partially covered by insurance.

The \$28m secured by LensGen to date represents three phases of financing: about a \$250,000 grant from the Johnson and Johnson Corporate Office of Science and Technology, which was received in 2012; approximately \$6.5m in several early seed rounds, mostly from angel investors, which concluded the end of 2016; and a \$21m Series A round, led by The Hoya Group, which closed in May.

A \$5m extension of the same Series A will be decided by early next year, either funded by Hoya or a third party. Furthermore, a Series B in the amount of nearly \$50m is scheduled for 2019, relying on large venture capital firms, strategic partners like Johnson & Johnson, and existing investors.

“However, we would prefer not to commercialize our IOL,” Rao says. “We would rather be bought out by a major IOL manufacturer in 2019.”