Block Time

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It's All in the Bag: Prosthetic Capsular Bag Could Transform IOL Implantation

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As vitreoretinal (VR) surgeons, we are often referred patients with dislocated intraocular lenses (IOLs), subluxed crystalline lenses, and complications of cataract surgery with aphakia and no capsular support. We have challenged ourselves by doing IOL gymnastics.

In February at the Vail Vitrectomy meeting, Frank Brodie, MD, MBA, presented his work on developing a prosthetic capsular bag (PCB). An innovation comes along once in a blue moon that can be an inflection point in IOL implantation. We believe the PCB is one of those inventions.

Block Time had the pleasure of interviewing Drs. Brodie, Matthew Simunovic, and J. Michael Jumper about this groundbreaking device.

What inspired you to design a PCB?

Frank Brodie: I saw what a challenge these IOL cases were and how surgeons were using their non-preferred lenses in awkward ways to solve the problem of getting an IOL into the posterior

Panelists

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segment. I designed the PCB to recapitulate anatomy; my aim is to allow surgeons greater freedom to use the lens they want with less gymnastics.

How did you come up with the design?

Frank Brodie: Designing the capsule was an iterative process; I was fortunate to work on this during my year as a Stanford Innovation Fellow, when I could dive deeply into the design process. I thought of the design as having 2 key elements: the capsule in which the IOL is situated, and the anchoring haptics.

Knowing that we needed to accommodate almost any IOL helped drive many capsule design considerations. For the anchoring haptics, we explored a huge range of possible designs looking for inspiration, from other medical—often non-ophthalmic—products to industrial designs and building components.

I had seen many secondary lenses rotate postoperatively, so I knew that having 3 points of fixation would be key for stability. Working alongside David Buickians, a researcher at Stanford, we modeled and 3D printed different capsule and footplate designs, tried them in the wet lab in the evening, then took those learnings and modified our designs the following day.

The combination of rapid 3D printing and being able to road test models in the ex vivo pig eye is a huge benefit in ophthalmologic device development—designs would look great on paper but often failed immediately once tested. After about 9 months of testing, we had a functional prototype.

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At that point I was convinced this technology could work and I turned to my former mentor from residency—Ayman Naseri, MD—who had left the University of California, San Francisco to work with Eugene de Juan Jr, MD, FASRS, at the ophthalmic device incubator, ForSight Labs.

With Ayman, Gene, and Matt Clarke, MS, a spectacular engineer at ForSight, we started Long Bridge Medical, Inc (LBM) to develop and bring the PCB to patients. LBM continued the iterative design process to optimize each element of the device for surgical ease and postoperative safety.

After both in vivo and ex vivo model development, LBM executed the first-in-human (FIH) trial,

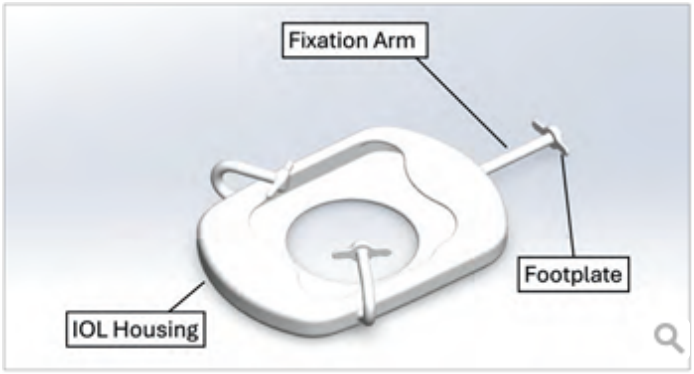

Figure 1. LensOne schematic showing the 3 components of the prosthetic capsular bag, 1) IOL housing, 2) fixation arms, and 3) transscleral, subconjunctival footplates for fixation.

Image courtesy Long Bridge Medical; reprinted with permission.

which I presented at Vail Vitrectomy. LBM also has developed surgical instrumentation concurrently with the implant to facilitate implantation of the LensOne device (Figure 1).

Where do you envision this PCB will be used?

Matthew Simunovic: The PCB is likely to be a game-changer in managing aphakia. In the FIH trial, we encountered patients with aphakia or subluxated crystalline or intraocular lenses—the prime candidates for this surgery.

The PCB could also be used in cases involving loss of capsular support during primary cataract extraction; the cataract surgeon could refer directly to a retina specialist—or, if a retina surgeon is performing the cataract procedure, the cases could be "converted" intraoperatively with minimal fuss.

How do the benefits of this device compare to those of current scleral-fixated IOL techniques?

Matthew Simunovic: The first advantage of the LensOne is that the procedure is quick—in the first case, it took me 2 minutes and 14 seconds to implant the device. As the PCB can be inserted with an IOL pre-loaded, it's faster than even the most seamless sutured and sutureless scleral-fixated approaches.

The LensOne device itself is highly compliant; it is not prone to damage during externalization, as many 3-piece IOLs or Carlevale lenses can be. And evidence from the FIH trial confirms that the PCB does not have the same issues with line tilt/yaw or curvature and decentration as other approaches, such as scleral sutured or sutureless techniques (Figure 2). This subsequently avoids problems with induced ametropia or curvature of field.

The PCB platform also allows for placement of a wide array of lens types (Figure 3). Although we haven't yet trialed toric or multifocal IOLs with the device, it would theoretically lend itself to housing them in the absence of a native capsule.

How is the device implanted?

Matthew Simunovic: The LensOne device is very well thought through, as reflected in its ease of

implantation. After marking, 3 cannulas (we used 25 gauge and 27 gauge in the FIH trial) are placed 120 degrees apart at 3.5 to 4.0 mm posterior to the limbus, in addition to placing a standard infusion.

Following vitrectomy, the device is inserted superiorly (180 degrees from the inferior port) and intraocular forceps are used to grasp the leading arm of the LensOne in a handshake maneuver. The cannula is removed before externalization of the leading arm, so the latter is not damaged during externalization.

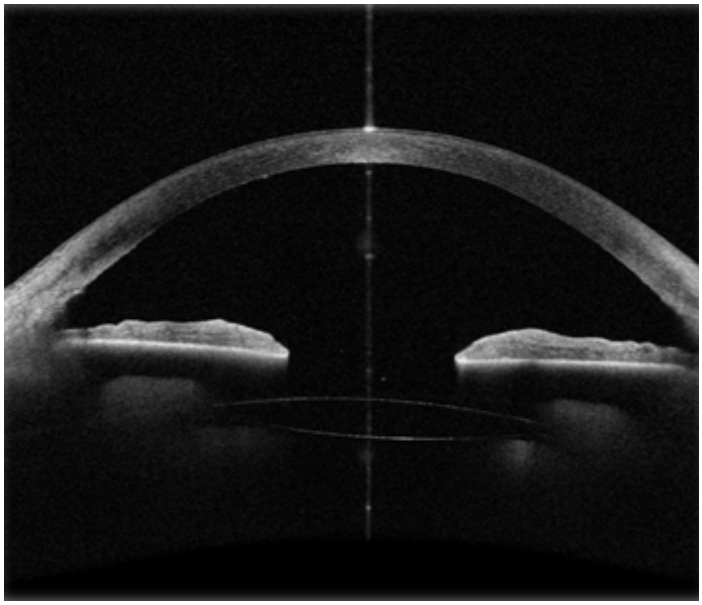

Figure 2. Anterior segment OCT shows IOL in the prosthetic capsular bag behind the iris.

Image courtesy Long Bridge Medical; reprinted with permission.

Two approaches can be used for externalization. You can externalize the footplate completely and later manipulate the Tenon's capsule and conjunctiva over it, or the Tenon's capsule and conjunctiva can be tented during externalization so the footplate exits the sclera only.

The 2 trailing haptics are designed to be easily visualized and are externalized using a similar technique (Figures 4 and 5). If the IOL has not been preloaded, it can then be inserted into the PCB similarly to inserting a lens into a native capsular bag, though the haptics must be tucked under the PCB awning with intraocular forceps.

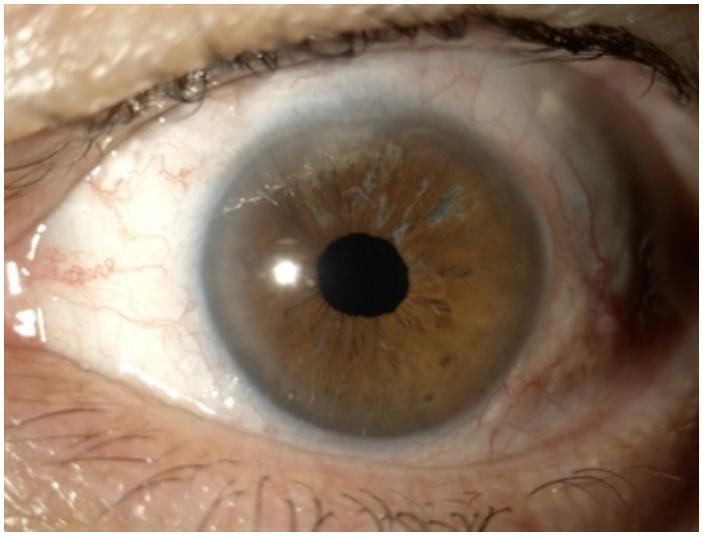

Figure 3. Slit lamp photo of undilated pupil with prosthetic capsular bag. Footplates can just be seen superotemporally and

What types of IOLs can be placed in the device?

Matthew Simunovic: The LensOne is not particularly proscriptive in the IOL design it can house. As discussed, we used only one-piece monofocal spherical lenses in the FIH trial, though it should be possible to implant other types of one-piece lenses, including torics and multifocals, as well as 3-piece lenses.

The posterior aperture is equivalent to an

superonasally.

Image courtesy Long Bridge Medical; reprinted with permission.

approximately 5 mm diameter pupil, so it's likely to be highly compatible with a range of optical designs—but again, this wasn't evaluated. I think this approach to intraocular fixation opens a wide range of possibilities and it will be exciting to see what the company does with this technology.

If the IOL needed to be exchanged later, how difficult would it be?

Matthew Simunovic: Removing the IOL would be straightforward, though the surgeon would have to be mindful of, and ensure, correct location of the fixating arms and footplates. Lens insertion is the same as inserting the lens sequentially in an initial surgery: good pupillary dilation is key to ensuring the IOL is secured in the PCB.

Eyes with small pupils would require pupil management with iris hooks or a Malyugin ring. Placement is easier using a bimanual approach, which is familiar to VR surgeons.

What are some of the known or expected risks with this procedure and device? Do you have any concerns about long-term issues?

J. Michael Jumper: Thus far, the outcomes have been very encouraging with successful placement in all cases. Refractive outcomes, PCB/IOL centration, and tilt measurements have been excellent.

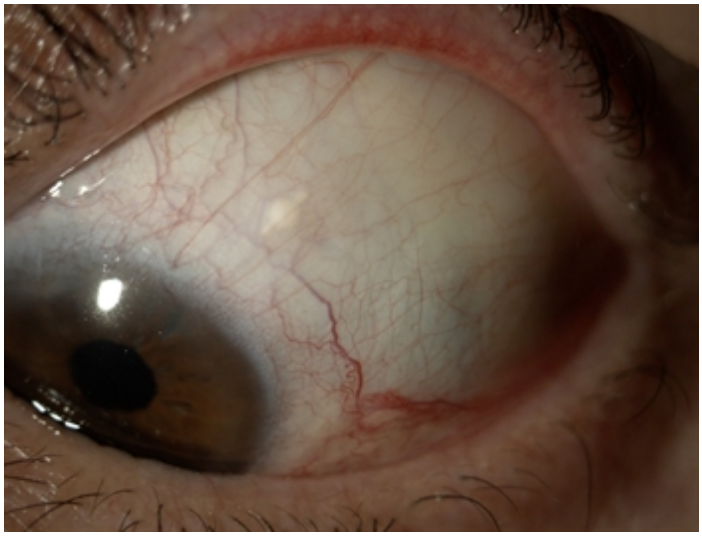

Figure 4. Slit lamp photo of superotemporal footplate.

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There was one case of a young woman with Marfan syndrome in which one of the 3 fixation arms became displaced, requiring re-fixation. Since then, the fixation arm design has been modified to make this less likely to happen again.

Have you had any feedback on negative dysphotopsias or other visual phenomena occurring in patients who have received this device?

Matthew Simunovic: We've not had any reports of negative dysphotopsias, though the FIH trial is obviously limited in its sample size. It is possible that negative dysphotopsias may be minimized by the PCB, as its "entrance pupil" largely obscures the optic edge. In theory, the aperture size

could limit absolute visual threshold and the visual field, but these effects are anticipated to be negligible for most eyes.

Some patients may notice the platform when their pupils are dilated, as it is white in the FIH trial. I understand that the company has a clear device and can produce devices in other colors—eg, blue, green, hazel, brown.

What is the status of human trials, and when might we expect the PCB to become commercially available?

J. Michael Jumper: Human trials have been performed in Australia and Mexico. The Investigational Device Exemption (IDE) has been submitted with the goal of initiating a US trial in 2026.

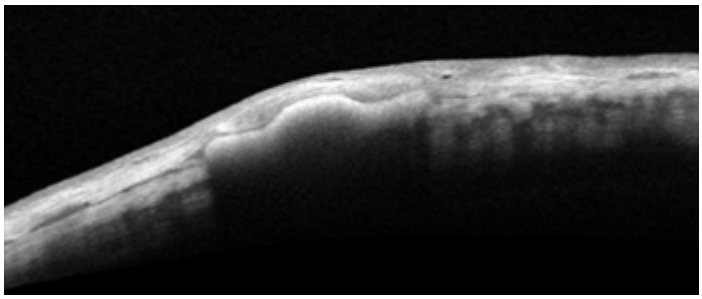

Figure 5. Anterior segment OCT showing single footplate at 1 year underneath conjuctiva and Tenon's capsule.

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We thank the panelists for their insights and information about this novel device. Hopefully, the clinical trials soon will lead to approval for commercial use.

FINANCIAL DISCLOSURES

Dr. Brodie – GENENTECH, INC: Consultant; LONG BRIDGE MEDICAL: Stock Private; RX SIGHT: Stock Public.

Dr. Hsu – ASTELLAS PHARMA US, INC: Principal or Named Investigator; GENENTECH/ROCHE: Principal or Named Investigator; REGENERON PHARMACEUTICALS, INC: Principal or Named Investigator; STEALTH BIOTHERAPEUTICS, INC: Principal or Named Investigator.

Dr. Jumper – DUTCH OPHTHALMIC RESEARCH CENTER: Speakers Bureau; EYEBIO: Advisory Board; GENENTECH/ROCHE: Principal Investigator; REGENXBIO, INC: Principal or Named Investigator.

Dr. Mehta – ASTELLAS PHARMA US, INC: Speakers Bureau; MERCK & CO, INC: Consultant.

Dr. Simunovic – ALCON LABORATORIES, INC: Advisory Board, Speakers Bureau; APELLIS PHARMACEUTICALS, INC: Advisory Board; NIKON: Speakers Bureau; NOVARTIS PHARMACEUTICALS CORPORATION: Speakers Bureau.

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