SofPort™ -

Easy-Load Lens Delivery System

Thomas Heyman, R&D Program Director; Keith H. Edwards, BSc FCOptom DIP CLP FAAO, Bausch & Lomb

Overview

This paper summarizes the characteristics and advantages of Bausch & Lomb's new Easy-Load Lens Delivery System. This system facilitates lens loading and uses any B&L viscoelastic to deliver the three-piece SofPort™ Advanced Optics Aspheric Lens (LI61AO), which adds no spherical aberration to the eye, through a sub-3.0 mm incision.

The lens is loaded directly from the packaging retainer into the body of the injector, thereby preventing contamination or damage to the lens. The resulting clinical benefits include improved ease of use, improved delivery predictability and reliability, improved efficiency in surgery, reduced damage caused by loading difficulties, and reduced stress in the operating room.

The Easy-Load Lens Delivery System consists of four parts - a syringe-shaped body and tip with a plunger, drawer and haptic puller, along with a specially designed lens case that helps position the lens in the body correctly each time. The injector is a sterile, disposable plastic device, designed for single use only. Combined with the lens case, it provides fixture loading with no direct lens contact, and a small tubular pathway in which the lens can be placed into the eye with one continuous forward motion.

Surgeons who use the Easy-Load Lens Delivery System will get one of the most advanced lenses on the market with an almost foolproof method of loading, and one-handed, planar delivery.

Background

Advances in intraocular lens (IOL) design, insertion techniques and instrumentation have allowed for safer, more efficient cataract surgery. Lenses are now more frequently made from the more flexible silicone, acrylic or hydrogel materials than the original polymethylmethacrylate (PMMA), allowing them to be inserted through smaller incisions.[1] In addition, inserters are being designed to fold lenses more efficiently, and inserters continue to become more refined for use in smaller incisions.

In recent years, foldable IOLs have become the first choice for lens replacement, largely because they result in less induced astigmatism, less invasiveness and faster visual recovery. Foldable acrylic and silicone IOLs with 6 mm optic currently are the most frequently implanted lenses.[2]

Developments in inserters also have contributed to improved success in cataract surgery. Since the first folder was introduced in 1984, IOL implantation with inserter systems has been divided into three main steps: take the IOL out of the package, position the IOL into the folding device with the use of forceps and implant the IOL into the capsular bag.[3]

In general, there is more of a trend away from folding and insertion forceps toward cartridge injector systems. There are many advantages of implanting foldable IOLs with injector systems, including greater sterility, ease of folding and insertion and implantation through smaller incisions.[4] However, within most injector systems, the IOL still has to be manipulated directly by forceps or other instruments. Forceps folding has been reported to cause problems such as surface alterations; [5-7] scratches, glistenings or marks;[8,9] stress fractures;[10] or structural damage.[11] (In some cases, the damage did not significantly affect visual function[8,9] or resolved itself postoperatively.[6]) A recent study by Mencucci et al demonstrated that the surface irregularities caused by forceps folding also make the IOLs susceptible to bacterial adhesion.[12]

The Easy-Load Lens Delivery System avoids those problems by combining an advanced technology IOL with a loading mechanism designed to ensure quick and proper lens placement during every surgery, through a sub-3.0 mm incision.

While most systems require manipulation of the IOL, the B&L system takes the lens directly from the retainer to the injector with no direct handling. The foldable lens is loaded into the body of the device and folded into B&L's patented "M" shape through a side drawer. The lens naturally relaxes out after insertion.

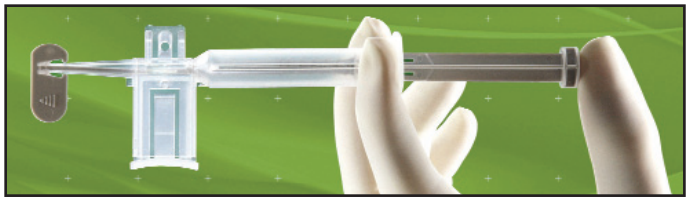
Product Features

Ease of Use

The Easy-Load Lens Delivery System consists of a syringe-shaped injector and a specially designed lens case. Loading the lens takes only a few steps. After opening the package and placing both parts on a sterile field, the surgeon or technician applies Bausch & Lomb viscoelastic to the floor of the loading area and near the drawer fingers. After separating the lens retainer from the lens cover, the retainer is plugged into the loading area. The drawer is then actuated and pushed slowly forward until the lens retainer stops the drawer movement. Only then is the lens ready to be removed from the lens retainer.

The lens retainer is pivoted slightly away from the drawer stop and lifted vertically away from the body, then discarded. Immediately before lens insertion, the drawer is closed to compress the lens for delivery. As the plunger is pushed forward, the haptic puller begins to move away from the body tip; about half way down the body tip the haptic puller is removed straightening the leading haptic. The haptic puller is then discarded.

After filling the distal end of the injector with viscoelastic material or balanced salt solution to reduce the possibility of introducing air pockets into the eye, the surgeon can position the injector tip through the eye incision. Pressing forward on the plunger will express the lens from the tip into the proper position in the capsular bag.



Releasing pressure on the plunger will retract the plunger to capture the proximal haptic. Moving the plunger forward a second time will allow the proximal haptic to be placed into the capsular bag.

Improved Delivery, Predictability and Reliability

Although small-incision surgery has become the method of choice for cataract surgery, the rapidly increasing use of foldable IOLs has caused an increase in the number of complications requiring explantation. During a surgeon's or technician's learning curve in working with IOLs, the risk of damaging the lens during the various loading, folding and unfolding maneuvers increases.

In a 2003 survey by Mamalis et al, the most common reasons for explanting foldable IOLs were dislocation/decentration, incorrect lens power, IOL calcification and glare/optical aberrations.[13] A later study by Schmidbauer et al confirmed that dislocation/decentration was the most frequent reason for explanting foldable IOLs, followed by optic or haptic damage. Foldable IOLs were explanted during the initial cataract implantation procedure at a higher percentage than rigid IOL designs, in part because the implantation of most foldable IOLs generally required more steps during loading, folding, unfolding and delivering into the capsular bag.[14]

The Easy-Load Lens Delivery System greatly reduces these potential reasons for explantation. First, the system offers fixture loading; i.e., the lens is situated in the proper loading position by the lens case itself. Also, since there is no direct contact with the lens, the risk of damaging the lens during loading is minimized, yielding a reliable result every time.

Thanks to the unique "M" fold, the lens is delivered into the capsular bag in a flat plane, sparing surgeons the need to manipulate the lens placement by twisting their wrists. The lens then steadily unfolds, perfectly controlled and centered.

Reduced Surgery Time

In some cataract surgery practices, a nurse or technician picks up the 6 mm lens and, without the benefit of an operating microscope, must load it correctly within the injector, while the surgeon is waiting to be able to insert the lens into a patient's eye. The loading time can take several minutes.

With the Easy-Load Lens Delivery System, the lens is pre-loaded in the retainer and easily transferred to the injector drawer. Surgeons who have used Easy-Load estimate this saves them minutes per surgery.[15] Busy practices conducting 20 cases a day could save as much as 20 minutes a day - enough to add an extra case to the surgical schedule.

Reduced Damage Caused by Loading Difficulties

As noted previously, the use of forceps to load or fold IOLs prior to implantation can yield surface alterations;[5-7] scratches, glistenings or marks;[8,9] stress fractures;[10] or structural damage,[11] leading to potential bacterial growth.[12] With the Easy-Load Lens Delivery System, the lens comes already properly loaded and sterile in the retainer. This greatly limits the possibility of damage to the lens and limits the possibility of contamination.

Reduced Stress in the Operating Room

In some busy practices, surgeons may use two operating rooms per day, alternating back and forth between cases. A problem loading the lens in just one case could throw off the entire OR schedule. The Easy-Load Lens Delivery System ensures quick, proper loading of the lens every time, reducing stress for both the surgeon and the OR staff.

SofPort™ Advanced Optics Aspheric Lens Design

Within the past several years, research focused on prevention of posterior capsule opacification (PCO) has indicated that it is not the IOL material that makes a difference as much as design. Several authors note that the major factor in preventing PCO development is a sharp-edge design; the optic material is a minor factor.[16-18]

In 2003, Bausch & Lomb introduced the SoFlex SE, a silicone IOL featuring the superior optics and favorable materials characteristic of B&L's existing silicone IOL, the LI61U, but with square anterior and posterior edges. A study of this lens by Nixon showed better centration, reduced capsular contraction and inhibition of lens epithelial cells (LECs) from colonizing the posterior optic in the square-edged IOL.[19]

More recently, Bausch & Lomb has developed a new aberration-free IOL technology called Advanced Optics™ (AO). During in-house testing, AO lenses, with prolate anterior and posterior lens surfaces and no inherent spherical aberration, performed better optically than a well-centered standard IOL. Because AO lenses are designed to avoid introducing spherical or higher-order aberrations to the visual system, they also prevent the degradation of the retinal image from decentration and tilt, conditions that can compromise acuity if the IOL has positive or negative spherical aberration.[20]

The Easy-Load Lens Delivery System is designed for use with this advanced IOL, giving doctors and their patients access to wavefront-optimized IOL technology without intraoperative or postoperative visual surprises.

The Surgeon's Viewpoint

Surgeons who have implanted SofPort AO IOLs with the Easy-Load Lens Delivery System have strong praise for this new lens inserter. One cataract surgeon calls the new system "essentially foolproof,"[21] and another sees it as "the best lens delivery system on the market, from any company."[22]

"You're not touching the lens, so there's no chance of crimping the haptics or tearing the optics," said P. Dee G. Stephenson, MD, FACS, of Stephenson Eye Associates in Venice, Fla. "In addition, none of the [lens case] parts will come off unless you're loading the lens correctly."

Stephenson, who loads all of her own lenses prior to surgery and has taught courses on proper folding techniques, says she can do so quickly, "but I could see where other practices could save a good couple of minutes per case, especially if the scrub hands it to the doctor."

Douglas K. Grayson, MD, assistant clinical professor at New York Eye & Ear Infirmary, said that, in his experience, surgical technicians quickly recognize that Easy-Load helps them do their jobs better. "Especially at a facility with a less experienced staff, you're going to see the difference. It's going to save time overall," he said.

"If a tech is older than 43 years old and they need reading glasses, they have difficulty seeing to position a lens accurately," Dr. Grayson added. "With Easy-Load, the tech doesn't have to visualize the lens to load it correctly. Techs are happy loading this lens."

Consequently, tech and surgeon can count on Easy-Load to protect against lens damage that can occur with other inserters. "If a lens isn't loaded correctly, it will come out either decapitated with no trailing haptic, or with a damaged haptic - and then you would have to explant," Dr. Grayson said. "We've had no mis-loads at all with Easy-Load."

Intraoperatively, the SofPort system with Easy-Load is "elegant" where other inserters are awkward, and it surmounts the 2.7-mm barrier with ease, Dr. Grayson said. "It has a very smooth, planar delivery," he said. "And it's a big advantage to be able to consistently deliver the IOL through a sub-2.7 mm incision."

His summary: "It's definitely the best lens delivery system on the market, from any company."

What the Techs Say

For an ophthalmic surgical tech with presbyopia, the Easy-Load™ Lens Delivery System is just what the eye doctor might order.

That's because Easy-Load eliminates the need for using forceps to manipulate and position the hard-to-see intraocular lens in the inserter, say surgical technicians who have used the Easy-Load to prepare the SofPort TMAO intraocular lens for insertion.

"It comes preloaded and you don't have to fuss around with the haptics. You only need your fingertips and not any other instruments to load it," said Fernando Caro, a surgical tech at the River Drive Laser Surgery Center in Elmwood Park, N.J. "You just do a few steps, and the lens is in place, ready for delivery."

Nigeria Thompson, a fellow tech at River Drive, noted that all of the IOL systems she used before Easy-Load required handling the tiny IOL during loading. At age 26, she doesn't have any trouble visualizing the IOL, but she recalls a middle-aged colleague who was unable to easily see the lens and left the cataract area in frustration.

Conclusion

Bausch & Lomb's Easy-Load Lens Delivery System packages one of the most advanced IOLs with a simple loading mechanism that allows operating room staff to transfer the lens directly from the packaging retainer to the injector. The IOL remains sterile and undamaged during loading. The operating room staff is spared from the stress of having to accomplish a delicate maneuver under pressure, and the time it takes to load the injector is minimized. Cataract surgeons who use the system can count on safe, predictable IOL insertions time after time.

Financial Disclosure:

Drs. Stephenson and Grayson are consultants for Bausch & Lomb, but they hold no financial or proprietary interest

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