LABORATORY SCIENCE

# Evaluation of preloaded intraocular lens injection systems: Ex vivo study

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**Purpose:** To compare preloaded intraocular lens (IOL) injection systems.

**Setting:** Sussex Eye Hospital, Brighton, United Kingdom.

**Design:** Experimental study.

**Methods:** In 30 porcine eyes, 5 preloaded +22.0 diopters IOLs were implanted from each of the following preloaded IOL systems: Ultrasert (U), iTec (iT), Eyecee (E), iSert (iS), Rayone (R), and CT Lucia (CT). External and internal wound size was measured. Nozzle damage was assessed using digital photography. The ease of opening the pack, ophthalmic viscosurgical device (OVD) injection, advancing into the nozzle, nozzle insertion, and IOL delivery was scored on a 4-point Likert scale, and the time was recorded.

**Results:** The iT, E, and iS injectors with acute angled bevels and shorter nozzle tips showed more damage after implantation. The fastest with regard to opening the pack and nozzle insertion was U, OVD injection and advancing into the nozzle was E, and IOL delivery was R. The maximum postimplantation wound stretch was 20% with the CT (mean 2.64 mm $\pm$ 0.1 [SD]), and the least was 11.8% with the iT (mean 2.46 $\pm$ 0.1 mm). Both the U and R scored 4 (very easy) for all parameters measured; the E, iS, iT, and CT scored 4 or less in some parameters with decreasing scores, respectively.

**Conclusions:** The models, design, and injection systems varied with each brand; however, the longer and more parallel the nozzle and less acute the angle of the bevel tip, the lesser the stress with less nozzle damage after surgery. All preloaded systems varied in the ease-of-use and time for surgical steps, and all lead to postoperative wound stretch.

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Online Video

As cataract surgery evolves and advances are made, improved techniques and technology can yield better visual quality and speedier visual recovery for patients. A critical step in cataract surgery is the delivery of the intraocular lens (IOL) into the eye, and recent advances in how IOLs are deployed means surgeons now have the option to use both manual IOL injectors and preloaded IOL injectors.

It has been shown that to induce minimal astigmatism in the patient, cataract incisions of 2.2 mm or smaller are desirable.[1] Previously, this presented a problem because microincisions made IOL insertion tricky to achieve with manually loaded systems. Moreover, with the difference in designs of the manual injection systems from various companies, the additional steps to load and prime the IOL meant longer training for the operating room staff and longer time for the overall surgery. Furthermore, the risk for error in these steps was a factor, leading to losses caused by damage to the IOLs before delivery into the eye. The introduction of microincision-compatible preloaded injectors to the market has advanced IOL delivery in numerous ways, improving safety, accuracy, and efficiency.

Although problems during cataract surgery are infrequent, they occur, and the procedure has the poorest record of surgical errors in ophthalmology (including incorrect IOL insertion).[2] Surgical instrument contamination from inadequate cleaning or foreign-body introduction during surgery and postoperative endophthalmitis from a bacterial infection after IOL implantation have been recorded.[3] Preloaded IOL injectors heighten microbiologic safety through the elimination of a mechanical loading step and the removal of an opportunity for potential contamination. Because the IOL is already loaded, the introduction of an ophthalmic viscosurgical device (OVD) is all that is needed before the IOL is ready for insertion. Furthermore, surgical outcomes are enhanced because a preloaded IOL is deployed directly from the manufacturer to the eye, minimizing the risk for IOL damage through handling.

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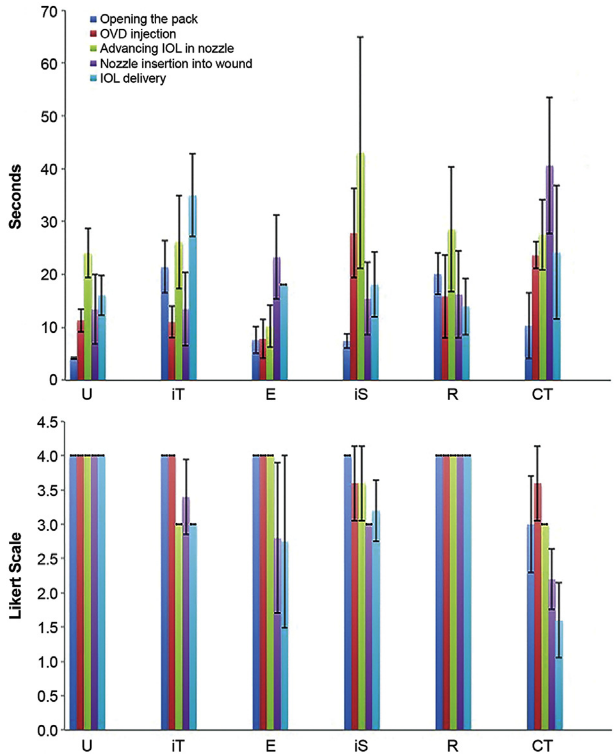


**Figure 1.** *Top*: Time taken for each step. *Bottom*: Likert-scale scores (IOL = intraocular lens; OVD = ophthalmic viscosurgical device).

A recent pilot study across 3 sites in the United States, France, and Canada[4] evaluated the operational impact of using preloaded IOL delivery systems compared with manual delivery during 154 routine cataract surgeries. The researchers found that for routine cataract surgeries, converting from a manually loaded IOL delivery process to a preloaded IOL delivery system reduced total case time and surgeon IOL time, indicating the potential to increase case throughput. As the demand for cataract surgery grows with the aging population and increased prevalence, improved safety and efficiency in the operating room become more important. Newer preloaded IOL systems might help satisfy these ever-increasing stringent requirements. Therefore, we designed this ex vivo study of porcine eyes to evaluate the ease of the steps used in preloaded IOL injection systems and assess the wound stretch and nozzle damage after IOL delivery.

## MATERIALS AND METHODS

This ex vivo study of 30 porcine eyes was performed at Brighton and Sussex University Hospitals NHS Trust, Brighton, England, between January and March 2016. The local research department approved the study. For the consistency of the study, fresh porcine eyes retrieved from a local butcher were used within 48 hours of supply.

Five ex vivo porcine eyes were implanted with preloaded IOLs of +22.0 diopters each for each of the following company products: Ultrasert (U) (Alcon Laboratories, Inc.), iTec (iT) (Abbott Medical Optics, Inc.), Eyecee (E) (Bausch & Lomb, Inc.), iSert (iS) (Hoya Surgical Optics, Inc.), Rayone (R) (Rayner Intraocular Lenses Ltd.), and CT Lucia (CT) (Carl Zeiss Meditec AG). The same surgeon (M.A.N.) performed all surgeries. The surgical steps are described in Video 1 (available at http://jcrsjournal.org). A 2.2 mm single-plane limbal incision was created. The anterior chamber of the eye was filled with sodium hyaluronate–sorbitol OVD (Ophteis FR Pro). The wound size was measured with a dedicated wound gauge (Duckworth & Kent Ltd.).

The time taken for each step was recorded in seconds using a dedicated stopwatch by a single observer (M.K.-K.). The IOL pack was opened and primed by the same surgeon. Using the Likert scale, the ease of package opening, OVD priming, IOL advancement into the nozzle, nozzle insertion into the wound, and IOL delivery was also evaluated. There was a deliberate attempt to keep the speed of IOL delivery constant for all surgeries. For each step, a Likert-scale rating was assigned as follows: 1 = very difficult, 2 = difficult, 3 = easy, and 4 = very easy. The time taken and the Likert-scale scoring for each step were recorded by an independent observer (M.K.-K.).

The IOL was delivered into the anterior chamber. Except for the U IOL, which has a shoulder near the tip of its nozzle to aid wound-assist delivery only, the nozzles of all IOLs were inserted through both the external wound and internal wound for delivery into the anterior chamber. The wound size was once again calculated using a dedicated wound gauge. The sclera at the equator of the globe was perforated using a 15-degree blade 2 to 3 cm on the equator under the main incision (Video 1, available at http://jcrsjournal.org). The internal wound was measured by passing the wound gauges through the external wound in increasing sizes (Video 1, available at http://jcrsjournal.org).

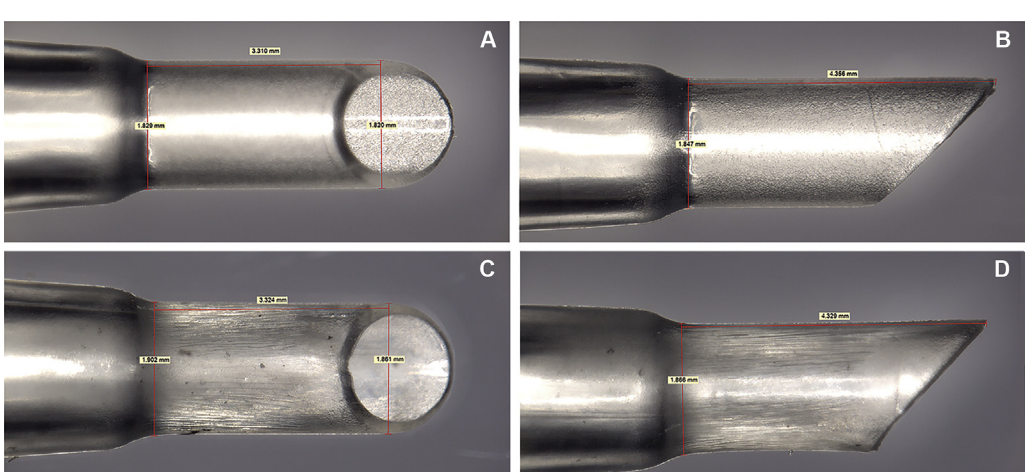


**Figure 2.** *A*: Axial view of the iT before IOL implantation. *B*: Profile view of the iT before IOL implantation. *C*: Axial view of the iT after IOL implantation. *D*: Profile view of the iT after IOL implantation.

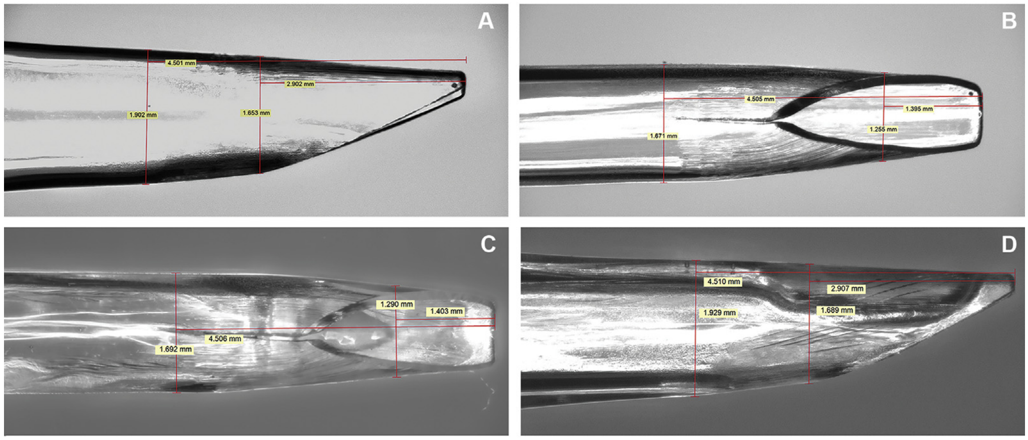


**Figure 3.** *A*: Axial view of the E before IOL implantation. *B*: The profile view of the E before IOL implantation. *C*: The axial view of the E after IOL implantation. *D*: The profile view of the E after IOL implantation profile view.

To assess potential nozzle tip damage, the tip of 1 IOL (1 of 5) from each company was photographed before and after the experiment using a Leica DVM2500 digital microscope with images processed and analyzed by Leica Application Suite software.

All data were entered into an Excel spreadsheet (Microsoft Corp.), from which the mean and standard deviation were calculated for each measurement. Graphs were prepared using an Excel spreadsheet. A *P* value less than 0.05 was considered significant.

## RESULTS

### Time Taken for Each Step

When assessing the parameters in preparation for and during IOL insertion, the U preloaded IOL emerged as the least time consuming with regard to opening the pack and nozzle insertion into the wound. The E was the fastest to use for injecting (or priming) the OVD material and advancing the nozzle. The R was the least time-consuming system for delivering the IOL (Figure 1, *top*).

### Likert Scale

Both the U and R scored 4 (very easy) on the Likert scale for all parameters measured (opening the pack, OVD priming, advancing IOL in the nozzle, nozzle insertion into the wound, and IOL delivery). The E, iS, iT, and CT scored 4 or less in some parameters with decreasing overall scores, respectively (Figure 1, *bottom*).

### Tip Damage

When comparing the before-insertion and after-insertion photographs, the iT (Figure 2), E (Figure 3), and iS IOLs (Figure 4) showed more damage after injection. The U (Figure 5), R (Figure 6), and CT (Figure 7) showed less post-insertion damage.

### Wound Stretch

The maximum post-IOL implantation external wound size and percentage stretch was noted with the CT at 20.0% (mean 2.64 mm $\pm$ 0.1 [SD]) and the least was with iT at 11.8% (mean 2.46 $\pm$ 0.1 mm) (Figure 1). The maximum post-IOL implantation internal wound size and percentage stretch occurred with the E and less was with the iT and R (Figure 8).

Two of 5 IOLs from the CT and iT and 1 of the 5 from the E were partially stuck in the wound after IOL delivery.

## DISCUSSION

Preloaded IOL systems differ depending on their design, usefulness, and necessary surgical steps. Table 1A and Table 1B show an overview of the brands tested that showed the best ease of use and processing efficiency, respectively. To reduce the biases and variables in this study, the same surgeon, who was familiar with all preloaded IOL systems, performed all the steps, including the pack opening, priming, and so forth.

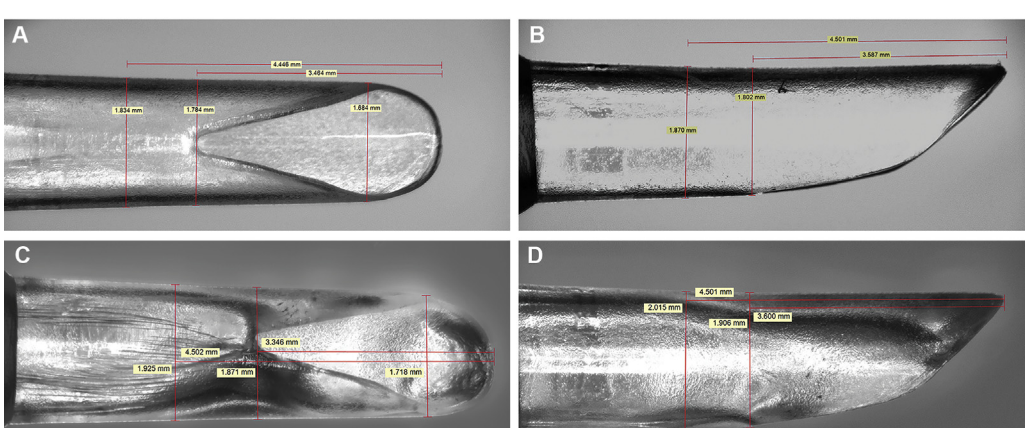


**Figure 4.** *A*: Axial view of the iS before IOL implantation. *B*: Profile view of the iS before IOL implantation. *C*: The axial view of the iS after IOL implantation. *D*: The profile view of the iS after IOL implantation.

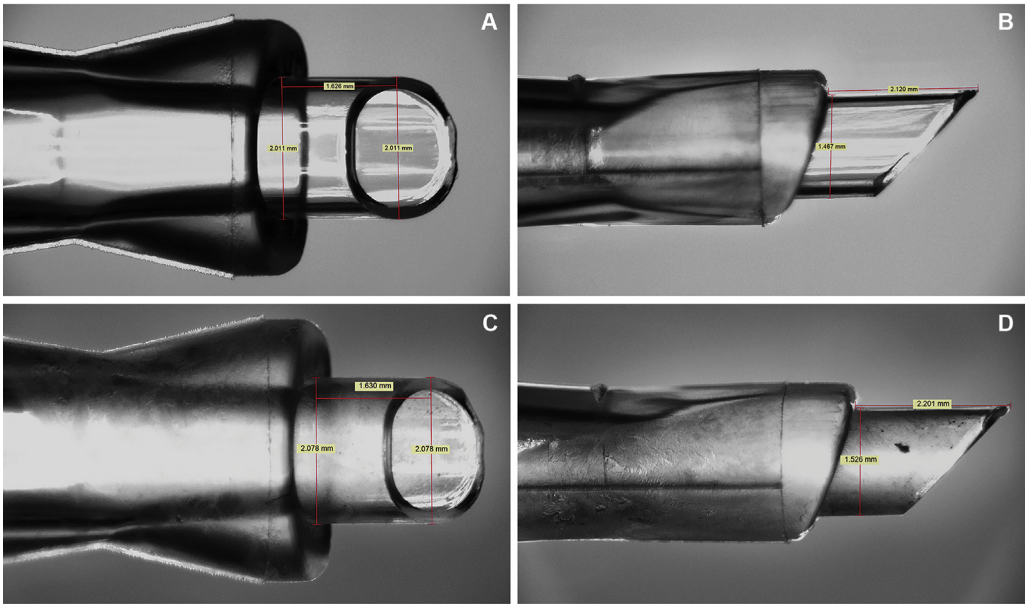


Figure 5. *A*: Axial view of the U before implantation. *B*: Profile vie of the U before implantation. *C*: Axial view of the U after IOL implantation. *D*: Profile view of the U after IOL implantation.

In an ideal scenario, the surgical assistant/scrub nurse is responsible for opening the pack and priming it before handing the IOL to the surgeon. The Ultrasert and Rayone scored the maximum on the Likert scale for the ease of use overall for all steps—both the surgeon's steps and the assistant's steps (Table 1A). The Ultrasert and Eyecee scored highest for the speed of use overall with all steps—both the surgeon's and the assistant's (Table 1B). For the surgeon's steps alone, the Ultrasert, Eyecee, and Rayone all received maximum scores with regard to the speed of use (Table 1B).

The IOLs of the iSert, Eyecee, and iTec had more damage after they were inserted insertion. None of these 3 IOLs generated the largest wound stretch, however. This could be because the Eyecee and iSert have a notch at the tip, which acts as a stretch absorber during the IOL insertion stage. On the other hand, the iTec has a tapered nozzle with a shorter segment, which is most parallel. Such designs might transmit more force to the elasticity of the nozzle itself rather than the wound. Moreover, the angle of the bevel in the cartridges that showed more damage was more acute than the angle of the models that produced less damage after IOL insertion. The models, design, and injection systems vary with each brand; however, in general, the longer and more parallel the section of the nozzle, the slighter the stress, which results in less nozzle damage after surgery.

The shape of the cartridge or nozzle has previously been found to be a significant factor in causing depositions on the surface of IOLs after implantation.[5] These linear deposits were particularly associated with hexagonal-shaped cartridges rather than round.[5] Although the IOL systems tested in this experiment all had round cartridges, nozzle damage in the form of compressions and indentations or striations were still encountered, in particular in the iTec, Eyecee, and iSert models. Whether this nozzle damage caused depositions on IOLs was not analyzed in this comparison; however, it might be a consideration when selecting preloaded IOL systems.

A possible cause of the cartridge damage during IOL insertion has been identified as friction arising during the transit through the injector nozzle.[6] The factors influencing this could be the plunger, IOL, OVDs, and their surface interactions. The cartridge material properties that affect cartridge cracking are the tensile strength, extensibility, and surface

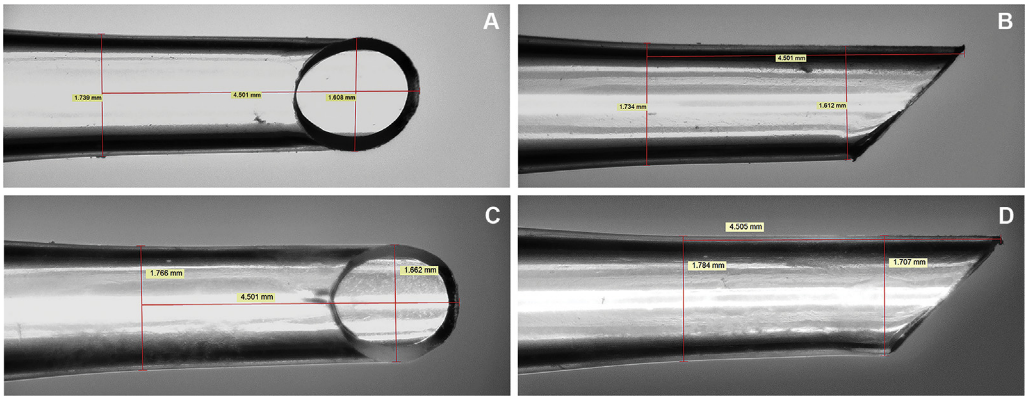


Figure 6. *A*: Axial view of the R before IOL implantation. *B*: Profile view of the R before IOL implantation. *C*: Axial view of the R after IOL implantation. *D*: Profile view of the R after IOL implantation.

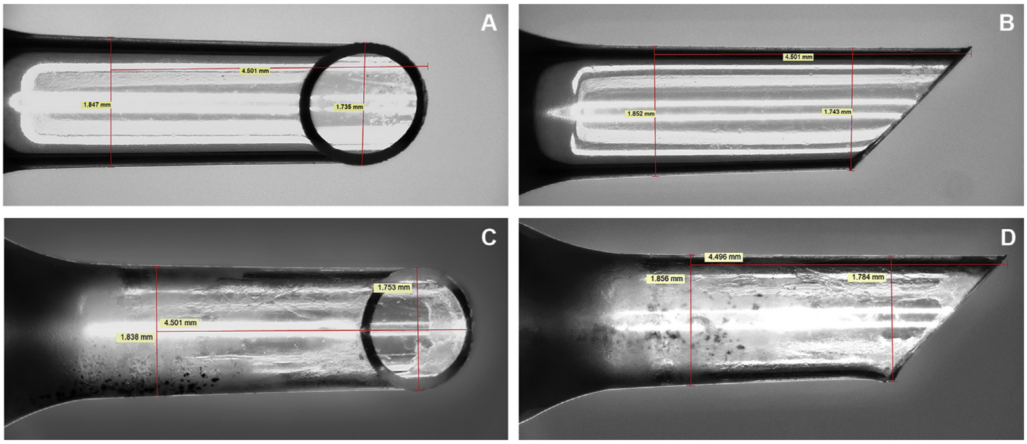


**Figure 7.** *A*: Axial view of the CT before IOL implantation. *B*: Profile view of the CT before IOL implantation. *C*: Axial view of the CT after IOL implantation. *D*: Profile view of the CT after IOL implantation.

lubricity of the nozzle tube.[6] The tensile strength determines the radial forces that can be withstood by the tube. The extensibility of the tube determines brittleness and the extent to which it can expand before fracturing. The tensile strength and extensibility can be optimized by the cartridge shape and polymer morphology without changing the tube's inner or outer diameter.[6] In a previous case report, Habib et al.[7] noted cracked cartridges during folding IOL implantation and attributed this to stress forces that altered the physical properties of the biomaterial. Other authors have found that such friction forces can be altered by cartridge shape and polymer morphology.[6,8] Faschinger[9] suggested that it was the hydrophilic nature of the IOLs and the resulting absorption of any aqueous solution that might generate friction of the IOL against the injector's barrel.

Creating an incision necessary for the removal of cataracts and IOL implantation has long been associated with varying degrees of surgically induced astigmatism.[10,11] Stretching this incision or wound enlargement is affected by the type of injector cartridge or insertion method used, and studies have shown that the wound stress was greatest when the IOL passed through the incision.[12] All preloaded IOL brands tested generated postoperative wound stretching after IOL insertion; however, some created more stretching than others. The largest was seen with the CT Lucia IOLs and the least with the iTec IOLs. The other important aspect is that the corneal wound is like a slit and the IOL cartridges are like a cylinder (oval or circular in section). Thus, by the law of physics, insertion of a cylinder through a slit would always lead to some stretch

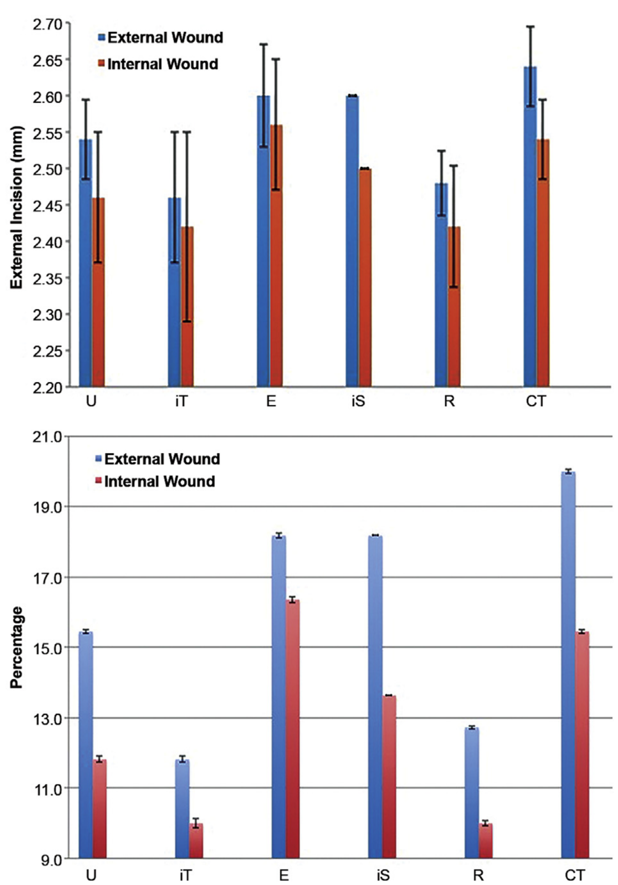


**Figure 8.** *Top*: Postoperative wound stretch. *Bottom*: Percentage wound stretch.

| **Table 1A. Overview of highest scoring IOL brands for ease of use on the Likert scale.** | | | | | | |
|---|---|---|---|---|---|---|
| **Very Easy (Likert Scale: 4)** | **U** | **iT** | **E** | **iS** | **R** | **CT** |
| Opening the pack* | ✓ | | | | ✓ | |
| OVD priming* | | | | ✓ | | ✓ |
| Advancing the IOL into the nozzle | ✓ | | ✓ | | ✓ | |
| Nozzle insertion in the wound | ✓ | | | | ✓ | |
| IOL delivery | ✓ | | | | ✓ | |

IOL = intraocular lens; OVD = ophthalmic viscosurgical device
*Steps normally performed by scrub nurses

| **Table 1B. Overview of the preloaded IOL brands with most rapid processes.** | | | | | | |
|---|---|---|---|---|---|---|
| **Fastest** | **U** | **iT** | **E** | **iS** | **R** | **CT** |
| Opening the pack* | ✓ | | | | | |
| OVD priming* | | | ✓ | | | |
| Advancing the IOL into the nozzle | | | ✓ | | | |
| Nozzle insertion in the wound | ✓ | | | | | |
| IOL delivery | | | | | ✓ | |

IOL = intraocular lens; OVD = ophthalmic viscosurgical device
*Steps normally performed by scrub nurses

or damage to the slit architecture unless the cylinder diameters are significantly smaller then the slit width. Creating smaller diameter injector nozzles would hamper the ease of IOL insertion. Reducing the thickness of the nozzle material or designing a slit in the nozzle to buffer the stretch force (as seen in a few of the study IOLs) would be a good compromise.

Notwithstanding the obvious limitations of an ex vivo porcine eye study, this assessment provides a practical comparison of the existing, very different preloaded IOL delivery systems on the market. The results are intended to supply a useful thumbnail guide to preloaded IOLs by which ophthalmic surgeons can make a decision based on their process efficiency, ease of use, and potential for wound stretching or nozzle damage for cataract surgery.

### WHAT WAS KNOWN

- With the difference in designs of the manual injection systems from various companies, the additional steps to load and prime the IOL mean longer training for the operating room staff and longer time for the overall surgery.
- The risk of errors in these steps is a factor in manual IOL injectors, leading to losses from damage to the IOLs before delivery into the eye.
- Newer preloaded IOL injectors reduce total case time and surgeon IOL time, indicating the potential to increase case throughput.

### WHAT THIS PAPER ADDS

- The models, design, and injection systems varied with each brand; however, the longer and more parallel section of the nozzle, the less the stress with less nozzle damage after surgery.
- The cartridges with more nozzle damage had a more acute angled bevel at the tip.
- All preloaded systems varied in the ease of use and time for surgical steps, and all led to postoperative wound stretch, with some showing more than others.

## REFERENCES


1. Kim Y-K, Kim YW, Woo SJ, Park KH. Comparison of surgically-induced astigmatism after combined phacoemulsification and 23-gauge vitrectomy: 2.2-mm vs. 2.75-mm cataract surgery. Korean J Ophthalmol 2014; 28:130–137. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3958628/pdf/kjo-28-130.pdf. Accessed February 15, 2017
2. Simon JW, Ngo Y, Khan S, Strogatz D. Surgical confusions in ophthalmology. Arch Ophthalmol 2007; 125:1515–1522. Available at: http://jamanetwork.com/journals/jamaophthalmology/fullarticle/419999. Accessed February 15, 2017
3. Pathengay A, Flynn HW Jr, Isom RF, Miller D. Endophthalmitis outbreaks following cataract surgery: causative organisms, etiologies, and visual acuity outcomes. J Cataract Refract Surg 2012; 38:1278–1282
4. Jones JJ, Chu J, Graham J, Zaluski S, Rocha G. The impact of a preloaded intraocular lens delivery system on operating room efficiency in routine cataract surgery. Clin Ophthalmol 2016; 10:1123–1129. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4918740/pdf/opth-10-1123.pdf. Accessed February 15, 2017
5. Kleinmann G, Marcovich AL, Apple DJ, Mamalis N. Linear deposits on the surfaces of intraocular lenses implanted through a hexagonal cartridge which mimic scratches/cracks on the lenses. Br J Ophthalmol 2005; 89:1474–1477. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1772926/pdf/bjo08901474.pdf. Accessed February 15, 2017
6. Rath R, Singh AD, Singh A. Cartridge cracks during foldable intraocular lens insertion [letter]. J Cataract Refract Surg 1999; 25:306
7. Habib NE, Singh J, Adams AD, Bartholomew RS. Cracked cartridges during foldable intraocular lens implantation. J Cataract Refract Surg 1996; 22:630–632
8. Dick HB, Schwenn O, Fabian E, Neuhann T, Eisenmann D. Cartridge cracks with different viscoelastic agents [letter]. J Cataract Refract Surg 1999; 25:463–465; reply by R Rath, AD Singh, A Singh, 465–466
9. Faschinger CW. Surface abnormalities on hydrophilic acrylic intraocular lenses implanted by an injector. J Cataract Refract Surg 2001; 27:845–849
10. Desai P, Reidy A, Minassian DC, Vafidis G, Bolger J. Gains from cataract surgery: visual function and quality of life. Br J Ophthalmol 1996; 80:868–873. Available at: http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=505640&blobtype=pdf. Accessed February 15, 2017
11. Shepherd JR. Induced astigmatism in small incision cataract surgery. J Cataract Refract Surg 1989; 15:85–88
12. Ouchi M. Effect of intraocular lens insertion speed on surgical wound structure. J Cataract Refract Surg 2012; 38:1771–1776


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