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LABORATORY SCIENCE

Comparison of a new IOL injector system against 3 standard IOL injector systems with different incision sizes: Miyake-Apple view experimental laboratory study

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Purpose: To compare 1 new intraocular lens (IOL) injector system against 3 standard injector systems in porcine eyes.

Setting: David J Apple Center for Vision Research, Department of Ophthalmology, University Hospital Heidelberg, Heidelberg, Germany.

Design: In vitro laboratory study.

Methods: In 70 porcine eyes, +20.0 diopter IOLs were implanted with the following systems: multiSert, UltraSert, iTec, and RayOne, that is, S1.8 (incision size: 1.8 mm), S2.0 (2.0 mm), S2.2P (2.2 mm, push mode), S2.2S (2.2 mm, screw mode), U2.2 (2.2 mm), iT2.2 (2.2 mm), and R2.0 (2.0 mm). Corneal incision sizes were measured before and after implantation with an incision gauge set. Ease of use was evaluated using a Likert scale. IOL delivery time and performance were determined based on Miyake-Apple view videos.

Results: Of the 70 eyes studied, the incision enlargements were 0.36 ± 0.08 mm (S1.8), 0.15 ± 0.07 mm (S2.0), 0.17 ± 0.12 mm (S2.2P), 0.28 ± 0.10 mm (S2.2S), 0.32 ± 0.09 mm (U2.2), 0.30 ± 0.08 mm (iT2.2), and 0.35 ± 0.11 mm (R2.0). Total scores of ease of use were 23.00 (S1.8), 25.00 (S2.0), 29.00 (S2.2P), 26.00 (S2.2S), 26.00 (U2.2), 25.00 (iT2.2), and 24.00 (R2.0). As for the mean delivery time, iT2.2 took the longest time (13.20 ± 3.29 seconds), whereas S2.2S took the shortest time (4.50 ± 0.71 seconds). Optic–haptic adhesion was observed in S1.8 (4, 40%), S2.2P (2, 20%), U2.2 (5, 50%), and iT2.2 (5, 50%).

Conclusions: Injector S, with the appropriate incision size and implantation method, could achieve better results regarding incision enlargement, ease of use, delivery time, and performance than other injector systems. There was an indirect relationship between incision size and inadvertent events.

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With the development of modern cataract surgery, better visual outcomes and speedier recovery are highly expected by both surgeons and patients. Continuous efforts have been made to meet such ends with technology and instruments being advanced.

A key step in cataract surgery is intraocular lens (IOL) delivery into the eye. IOL loading and handling during implantation could be complicated and require delicate skills. Improper handling can lead to IOL damage or abnormal IOL movement during injection.[1] Manually loading the IOL into the injector cartridge not only extends the surgical time but also increases the risk for many complications. These complications could be incorrect IOL insertion, toxic anterior segment syndrome (TASS), endophthalmitis, and so on.[2–4] The advent of preloaded IOL delivery system has brought the delivery procedure a large step forward. The benefits of such systems may include elimination of manual setting variability, avoidance of potential IOL loading errors and damages, shortened surgical time, fewer surgical instruments, reduced surgical cost and complexity, and lower risk for instrument contamination with microorganisms or other foreign bodies.[5]

In the previous studies, the performance of different IOL injector systems was evaluated regarding wound stretching, ease of use, or delivery characteristics.[5–8] However, to our knowledge, there have been no data on the comprehensive

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evaluations of IOL injector systems. Since multiSert injector system is newly launched, evaluation about this product is sparse. Furthermore, evaluation of the delivery performance of IOL injector systems based on Miyake-Apple view videos is scarce. Hence, we designed this study to comprehensively evaluate IOL injector systems available from different manufacturers regarding parameters of nozzle tips, wound stretching after IOL delivery, ease of use during preparation and implantation, delivery time and delivery performance using an in vitro porcine eye model. Miyake-Apple view videos were also taken for capsular bag analysis of IOL performance, with the advantage of showing details of IOL delivery performance that could not be obtained from the surgeon's view.

METHODS

Tested Porcine Eyes

Seventy freshly excised porcine eye globes were retrieved from a local slaughter house (FVZ Mannheim GmbH) and used within 6 hours after being delivered to the authors' laboratory. The porcine eyes used in the experiments showed varied degrees of corneal opacity but no vitreous leakage and gross ocular damage. The 70 porcine eyes were randomly assigned to 7 test groups (10 eyes per group). The room temperature was kept between 22 and 24°C at all timepoints.

Tested IOL Injector Systems

Seven injector groups from 4 models were evaluated in the experiments (Supplemental Table 1, http://links.lww.com/JRS/A416 and Supplemental Figure 1, http://links.lww.com/JRS/A412). Injector systems S1.8, S2.0, S2.2P, and S2.2S belong to the same type (multiSert) with different incision sizes and different implantation methods. Insert shield, controlling the penetration depth and protecting the wound integrity, is positioned on the outside of the cartridge in injector S. Insert shield is switchable between on and off (Supplemental Figure 2, *a*: on, *b*: off, http://links.lww.com/JRS/A413).

Insert shield was used for the S1.8 group and S2.0 group but not in S2.2P and S2.2S groups for better comparing the impact of insert shield. S injector allows both screw insertion and push insertion. Push method was used in the S1.8, S2.0, and S2.2P groups but not in the S2.2S group. Injector system U also bears the specially designed depth guard, similar to the insert shield in injector S. Injector systems R and U are both push-type, preloaded injectors, whereas injector iT is a screw-type, preloaded injector. Representative microscopic images of 4 injector nozzle tips are shown in Figure 1. All 4 groups of nozzle tips were cut vertically where the bevel starts to get the cross-section surface. Pictures of the cross-section surfaces were taken under the microscope (Olympus BX50, Olympus K.K.). Parameters of the cross-section surface were measured by using a ruler under the same magnification under the microscope as a standard to calibrate measurement and then using ImageJ software (v. 1.52a, NIH) to measure the parameters on the pictures. Inner and outer cross-section areas were also calculated using ImageJ software.

Surgical Procedures

Miyake-Apple Posterior View Video Analysis The preparation for Miyake-Apple view globes was conducted in a way similar to that described by Apple et al.[9] All surgical procedures were performed by 2 ophthalmic surgeons (L.Z. and F.A.). Liquid around the porcine eyes was wiped off with a paper towel. Excessive extraocular tissues (ie, conjunctiva, muscles, and orbital) were removed from the globes using tissue forceps and corneoscleral scissors. The cleaned porcine eyes were then glued to a specially designed plastic eye mold, with the central part being hollow to fit in with the anterior part of a porcine eye. After the glue dried and the anterior part was firmly attached to the eye mold, the posterior part of the eyeball was cut coronally around the eye mold plane with corneoscleral scissors. The excessive vitreous and other remnants were gently cut off from the porcine eyes with corneoscleral scissors, followed by filling in an appropriate amount of ophthalmic viscosurgical device (sodium hyaluronate 1% [Healon]) to better support the structures inside the eyes and eliminate the bubbles. A glass slide was put on top of the eye mold with the help of glue. Several minutes later, the glue dried, and the bisected globes in the eye mold were firmly affixed to the glass slides.

Surgical Preparation and IOL Implantation The bisected globes attached to the eye holders and glass slides were laid on the specially designed Miyake-Apple table. Since the porcine eyes were acquired several hours postmortem, corneas were usually removed with corneoscleral scissors for better visualization. A rim of corneas was preserved for incision making. Thus, implantation of IOL was performed under an open-sky condition. Attempt was made to remove the iris by forceps or corneoscleral scissors as much as possible, under the premise not to damage the capsular bag. Continues curvilinear capsulorhexis approximately 5.0 to 5.5 mm in diameter was conducted using capsulorhexis forceps. Hydrodissection was performed, followed by removal of the nucleus and cortex by phacoemulsification and irrigation/aspiration. The anterior chamber and capsular bag were filled with 0.5 mL Healon. The 1.80 mm, 2.00 mm, or 2.20 mm clear-cut corneal incisions were made using a 1.80 mm knife (Bausch & Lomb, Inc.), 2.00 mm knife (Alcon Laboratories, Inc.), or 2.20 mm knife (Alcon Laboratories, Inc.), respectively, as per the study design. The IOL injectors were primed with the recommended ophthalmic viscosurgical devices (OVDs) Supplemental Table 1, http://links.lww.com/JRS/A416) and, then, used to deliver IOLs into the eyes. Every attempt was made to make sure that the time taken for the IOLs in the nozzle tip for each injector system was appropriate and almost identical before implantation.

Camera and Light Setting

The apparatus used for recording video was a camera (Blackmagic Pocket Cinema Camera, Blackmagic Design Pty. Ltd.) attached to a microscope (Leica M220; Leica Microsystems GmbH). The microscope was pointed right through the hollow part of Miyake-Apple table onto the glass slides attached to the bisected globes. Light was provided by a light setup that contained 2 adjustable light cables, pointing to the back of the bisected globes.

Data Collection

The IOL packs were opened, primed, and injected by a surgeon (F.A.). Incision sizes before and after IOL implantation were measured with DK incision gauge set (Duckworth & Kent Ltd.). Enlargement of the corneal incision size was the value of the incision size after implantation minus the incision size before implantation (Supplemental Figure 3, http://links.lww.com/JRS/A414). Degree of enlargement in percentage was the value of enlargement of the corneal incision size divided by the incision size before implantation and, then, multiplied by 100. A 5-point Likert scale was used for ease of use evaluation, with 1 = very difficult, 2 = difficult, 3 = acceptable, 4 = easy, and 5 = very easy. For evaluation of the resistance force during IOL delivery, a 5-point Likert scale ranging from 1 = the strongest force to 5 = the smallest force was used. Higher total scores indicate better performance. All 5-point Likert scales were filled by the same surgeon (F.A.) right after injector priming and IOL implantation.

The occurrence of abnormal leading haptic configuration, trapped trailing haptic, optic–haptic adhesion, IOL attachment to the plunger, successful IOL delivery, and gross damage to IOLs was observed from the Miyake-Apple view videos by a single observer (L.Z.). Delivery time refers to the period when the leading

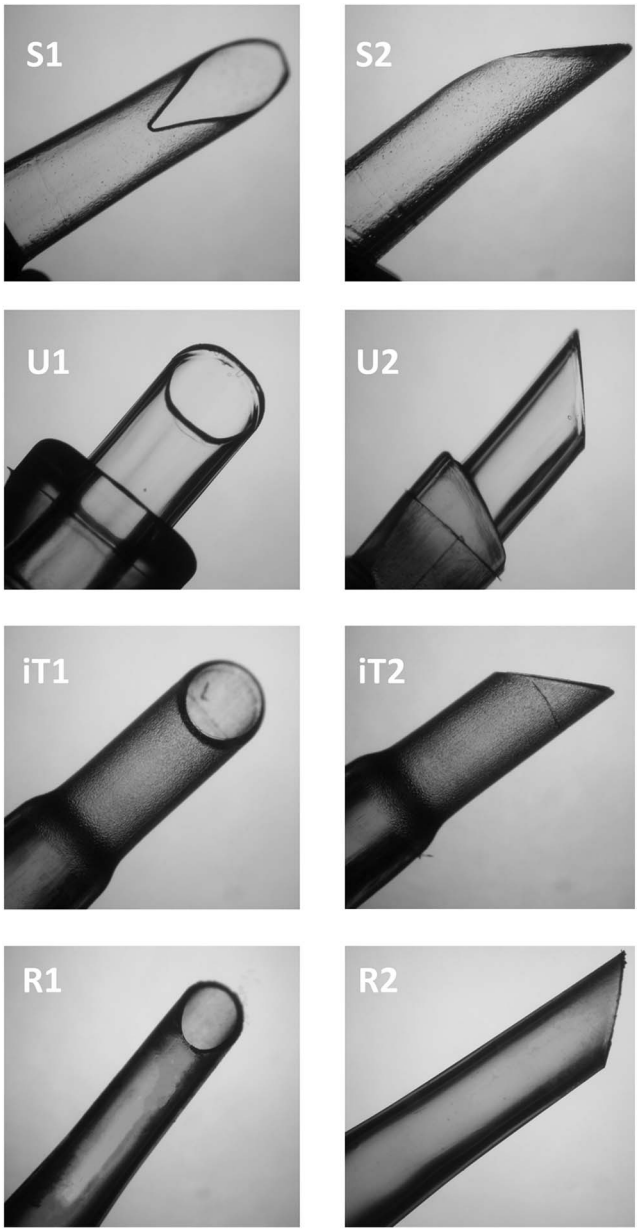


Figure 1. Representative microscopic images of 4 IOL injector nozzle tips. S1 and S2: Axial view and profile view of injector S, respectively. U1 and U2: Axial view and profile view of injector U, respectively. iT1 and iT2: Axial view and profile view of injector iT, respectively. R1 and R2: Axial view and profile view of injector R, respectively. S1 showing the v-shaped configuration at the exit. U1, iT1, and R1 showing the oval-shaped configurations at the exit.

haptic first exits the nozzle tip and the time when the trailing haptic fully exits the nozzle tip. The delivery time was calculated by the same observer (L.Z.) based on the Miyake-Apple view videos.

Statistical Analysis

Results were recorded as mean ± SD. The differences in the mean incision enlargements and the mean delivery time among 7 groups were assessed for statistical significance using 1-way analysis of variance with Tukey adjustment for post hoc comparison. The differences in the total occurrences of inadvertent events among 7 groups were assessed for statistical significance using Fisher exact analysis with Bonferroni adjustment for post hoc comparison. SPSS Statistics for Windows software (v. 23.0; SPSS, Inc.) was used for statistical analysis. A P value of less than 0.05 was considered statistically significant.

RESULTS

Parameters of the Nozzle Tips

In this study, 70 porcine eyes were used for IOL implantation study with 70 injector systems from 4 manufacturers. For each injector system, outer cross-section length, outer cross-section width, outer cross-section area, inner cross-section length, inner cross-section width, and inner cross-section area were measured and summarized in Supplemental Table 2 (http://links.lww.com/JRS/A417). In Figure 2, the top section shows the cross-section surface of each injector system, whereas the bottom section indicates each parameter measured in this study.

Corneal Incision Size and Incision Enlargement

Incision enlargement was observed in all cases. The data of the final incision size and the incision enlargement after IOL delivery are shown in Figure 3. Injector system S1.8 resulted in the smallest incision size (2.18 ± 0.09 mm), whereas injector type iT led to the largest incision size (2.62 ± 0.11 mm). Injector system S2.0 produced the least enlargement (0.15 ± 0.07 mm), whereas injector system S1.8 generated the greatest enlargement (0.36 ± 0.08 mm). Injector system S2.0 caused the least degree of enlargement (7.25% ± 3.30%), whereas injector system S1.8 brought about the largest degree of enlargement (19.79% ± 4.47%).

As Figure 3 shows, when comparing the incision enlargements between 2 injector groups with the same corneal incision size, there were statistically significant differences between groups S2.0 and R2.0 (0.15 ± 0.07 mm vs 0.35 ± 0.11 mm; $P <$ .05), injector systems S2.2P and U2.2 (0.17 ± 0.12 mm vs 0.32 ± 0.09 mm; $P <$ .05), and injector systems S2.2P and iT2.2 (0.17 ± 0.12 mm vs 0.30 ± 0.08 mm; $P <$ .05). When comparing the same injector model with different incision sizes, injector system S1.8 led to a significantly larger enlargement than that of injector system S2.0 (0.36 ± 0.08 mm vs 0.15 ± 0.07 mm; $P <$ .05) and S2.2P (0.36 ± 0.08 mm vs 0.17 ± 0.12 mm; $P <$ .05).

Ease of Use

The ease of use was evaluated on a 5-point Likert scale, with 1 = very difficult, 2 = difficult, 3 = acceptable, 4 = easy, and 5 = very easy (Supplemental Figure 4, http://links.lww.com/JRS/A415). Injector system S2.2P got the highest total score (29.00), whereas injector system S1.8 obtained the lowest total score (23.00). Injector systems S2.0, S2.2S, U2.2, iT2.2, and R2.0 obtained similar total scores (25.00, 26.00, 26.00, 25.00, and 24.00, respectively).

Delivery Performance Based on Miyake-Apple View Videos

Table 1 summarizes the performance of different injector systems during IOL implantation. Statistically significant difference regarding total occurrences of inadvertent events among 7 groups was not observed ($P >$ .05). Figure 4 shows

Table 1. Delivery Performance of Injector Systems.

	S1.8 (n = 10)	S2.0 (n = 10)	S2.2P (n = 10)	S2.2S (n = 10)	U2.2 (n = 10)	iT2.2 (n = 10)	R2.0 (n = 10)
Abnormal leading haptic, n (%)	1 (10.00)[a]	1 (10.00)[a,b]	1 (10.00)[a,b]	1 (10.00)[a]	1 (10.00)[a,b]	0 (0.00)	2 (20.00)[a,b]
Trapped trailing haptic, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Optic–haptic adhesion, n (%)	4 (40.00)[b]	0 (0.00)	2 (20.00)[b]	0 (00.00)	5 (50.00)[b]	5 (50.00)[b]	0 (0.00)
IOL attachment to the plunger, n (%)	2 (20.00)[c]	0 (0.00)	1 (10.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Total occurrence of inadvertent events, n (%)	7 (70.00)[d]	1 (10.00)[d]	4 (40.00)[d]	1 (10.00)[d]	6 (60.00)[d]	5 (50.00)[d]	2 (20.00)[d]
Requiring second instrument, n (%)	4 (40.00)	1 (10.00)	3 (30.00)	0 (00.00)	6 (60.00)	5 (50.00)	2 (20.00)
No. of successful deliveries, n (%)	9 (90.00)	10 (100.00)	10 (100.00)	10 (100.00)	10 (100.00)	10 (100.00)	10 (100.00)
Gross damage to IOL (n, %)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)

[a]Leading haptic counterclockwise
[b]Requiring second instrument to achieve successful implantation
[c]In 1 of the 2 cases, IOL was unable to be delivered into the capsular bag because of IOL attachment to plunger
[d]No statistical significance was observed between groups as determined by Fisher exact analysis with Bonferroni adjustment for post hoc comparison, $P > .05$

the representative images of inadvertent events seen in Miyake-Apple view photographs during IOL delivery.

The mean delivery time for each injector system is shown in Figure 5. Injector system iT2.2 took the longest mean delivery time (13.20 ± 3.29 seconds), whereas injector S2.2S took the shortest (4.50 ± 0.71 seconds). There were statistically significant differences in the mean delivery time between injector system iT2.2 and all the other injector groups $P < .05$ (injector system iT2.2 longer than all the other injector groups). No statistically significant differences in delivery time were observed between other study groups.

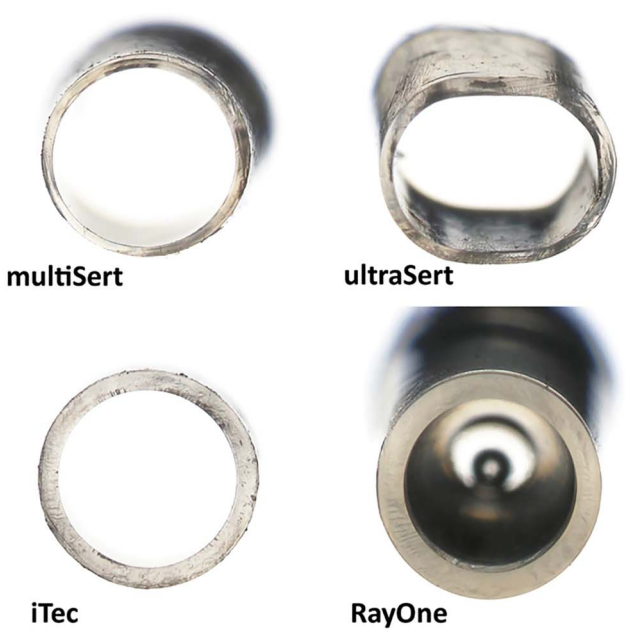
DISCUSSION

In our study, we aimed to compare a new IOL injector system (multiSert = S) with 3 other standard injector systems (UltraSert = U, iTec = iT, RayOne = R) using in vitro porcine eye models. The outcomes included parameters of the nozzle tip, final incision size, incision enlargement after IOL delivery, ease of use during preparation and implantation, delivery time, and performance evaluated from Miyake-Apple view videos. To the authors' knowledge, this is the first study that included multiSert injector system for injector comparison or evaluation and that evaluated the IOL delivery performance from a back perspective with Miyake-Apple view videos.

As noted in a previous study, the corneal incision is like a slit, and the injector nozzle tip is like a cylinder.[6] The insertion of a cylinder through a slit would always lead to some stretching or damage to the slit unless the diameter of the cylinder is significantly smaller than the slit width. Thus, it is not surprising that all the injector systems in our experiment led to incision enlargement after IOL implantation, ranging from 7% to 20% of the initial incision sizes. When a nozzle tip is fully inserted into a corneal incision, the corneal stretching is associated with the outer cross-section length, outer cross-section width, and the outer cross-section area. Although the outer cross-section length and the outer cross-section width of injector S and R are similar, injector S showed significantly smaller incision enlargement than injector R with the same incision size 2.00 mm. We speculate that the v-shaped design as opposed to the regular shapes (ie, round or oval) at the exit of the nozzle tip and the use of insert shield of injector S play an important role in incision reduction. As 1 previous literature has pointed out, the v notch nozzle tip design acts as a stretch absorber at the IOL insertion stage, thus leading to smaller incision enlargement.[6] Injector S showed smaller outer cross-section area than injector U. Previous studies showed that injector U yielded a smaller incision enlargement.[7,8] Such finding might be attributed to the depth guard design for injector U.[7] However, in our study, we did not use the insert shield for group S2.2P, which resembles the depth guard in injector U. But injector S2.2P caused significantly smaller incision enlargement than injector U. It seems that the smaller outer cross-section diameter and the v-shaped design of the nozzle tip of injector S played a more important role in reduction of the incision enlargement than the effect of depth guard.

Injector S and iT showed round-shaped configuration of the outer cross-section surface, whereas injector U showed oval-shaped surface (Figure 2, *top*). Injector S (push-mode) showed smaller outer cross-section area and significantly smaller incision enlargement compared with injector U with the same incision size 2.20 mm. Injectors iT and U showed similar outer cross-section areas, and no statistically significant difference regarding incision enlargement was found between iT and U with the same incision size 2.20 mm. It seems the incision enlargement was not affected by the round or oval shape as long as the cross-section areas were similar. Our finding in this study was in accordance with the study by Kleinmann et al.[10] In their study, they found that the shape (oval or round) had no influence on the induced stress if the external outer areas were the same. However, sophisticated studies need to be performed to confirm our speculation in this study.

Inner and outer diameters determine the thickness of tube wall and space for IOL movement in the tube. If the space was too small, greater friction between IOL and tube could be anticipated. Greater friction could cause IOL and injector damage and inadvertent events during IOL implantation. The space (inner cross-section area) of injector R was smaller than those of all the other 3 groups. Although we did not find any IOL damage in our groups and the difference of inadvertent events among different injector



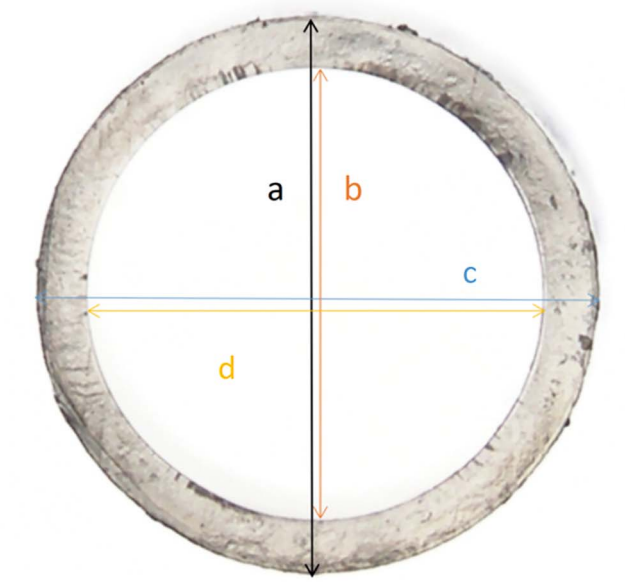


Figure 2. *Top*: Representative images of nozzle tips in cross-section view for all injector systems. *Bottom*: Representative image indicating each parameter measured in our study. *a* = outer cross-section length; *b* = inner cross-section length; *c* = outer cross-section width; *d* = inner cross-section width.

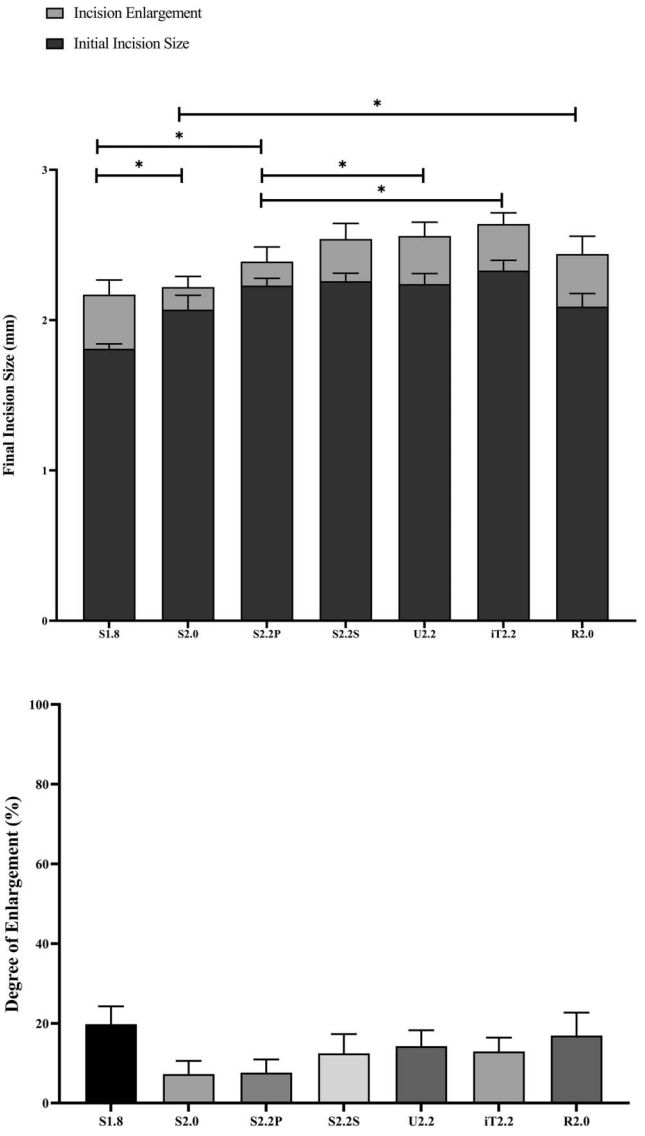


Figure 3. *Top*: Final incision size and incision enlargement of each injector group. Data are presented as the mean ± SD. *Statistical significance in incision enlargement between groups as determined by 1-way analysis of variance followed by Tukey post hoc analysis. *Bottom*: Degree of enlargement in percentage.

groups was not statistically significant, the smaller space for IOL movement of injector R might still be a consideration when choosing IOL preloaded systems. As mentioned earlier, the thickness of the tube wall of the nozzle tip is associated with the inner and outer diameters, thus also associated with the incision size. If the wall of the nozzle tip was too thick, the smoothness for IOL movement would be compromised, and the corneal incision size might be enlarged. If the wall of the nozzle tip was too thin, the corneal incision size could be reduced, but the possibility of nozzle tip burst might increase. Hence, a balance has to be found between reducing the corneal incision size and smoothing IOL implantation.

Injector system S2.2P caused a statistically significantly smaller incision enlargement than injector system iT2.2, whereas no statistically significant difference was observed between S2.2S and iT2.2. This result may be attributed to the screw method adopted by iT2.2 and S2.2S. The screw method could cause pauses in the advancement of IOL through the incision. The pauses can generate potential reexpansion and unfolding of the IOL, leading to a greater damage to the incision.[11] In addition, turning the screw handle of the IOL injectors tends to cause a small amount of rotation to twist the injector tip in the incision and, thus, might result in more stretching.[12]

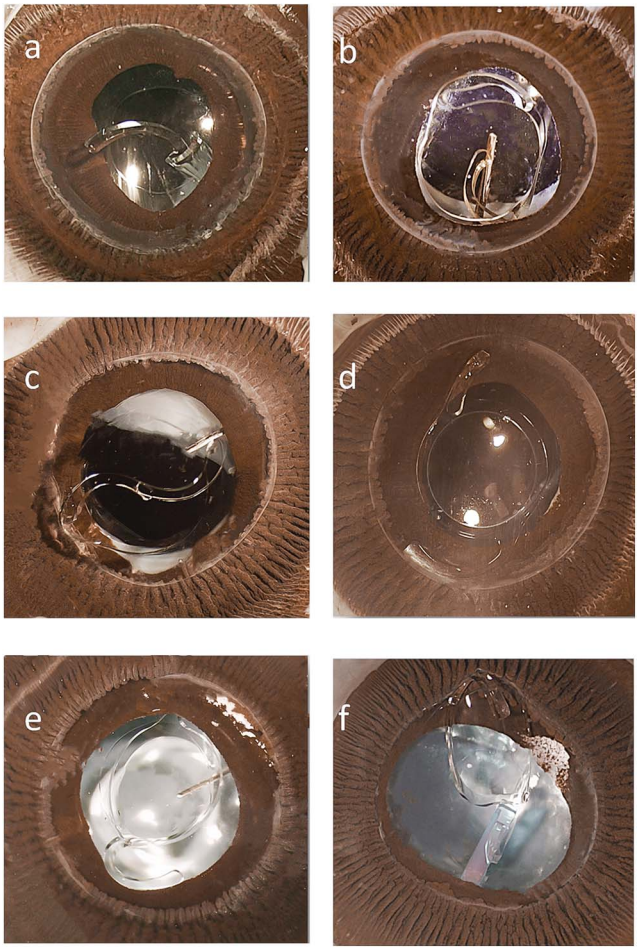


Figure 4. Miyake-Apple view images showing IOL delivery performances. *a* and *e*: counterclockwise leading haptic. *b*, *c*, and *d*: optic–haptic adhesion. *f*: IOL attachment to the plunger.

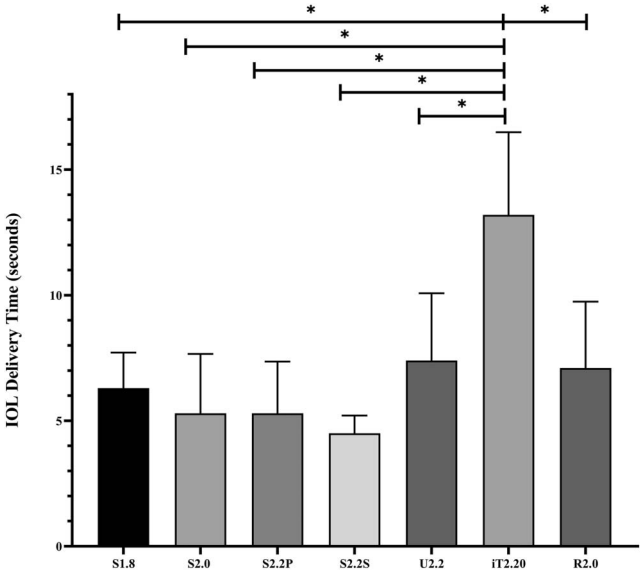


Figure 5. IOL delivery time for tested injector systems. Data are presented as the mean ± SD. *Statistical significance in IOL delivery time between groups as determined by 1-way analysis of variance, followed by Tukey post hoc analysis.

Among injectors with different incision sizes for the same injector model S, a smaller preimplantation incision (S1.8) generated a statistically significantly larger amount of enlargement than a larger preimplantation incision (S2.0 and S2.2P). This is in accordance with the study by Oshika et al., which showed that UltraSert 2.2 mm and iTec 2.2 mm yielded more stretching than UltraSert 2.4 mm and iTec 2.4 mm, respectively.[5] There is an increasing trend toward smaller incisions in practice because of the association of a smaller incision size with reduced surgically induced astigmatism (SIA).[13,14] However, the benefits of smaller incision may be compromised if the incision is too small to accommodate the IOL to its delivery system. One study found that starting with a well-constructed 2.3 mm incision is better than an initial 2.1 or 2.2 mm incision that stretches to a 2.3 mm but then has irregularities and distortions along its surfaces and edges.[15] Another study also showed that IOL implantation through a very tight incision would lead to an increased stress on the wound structure.[10] Therefore, it is necessary to choose an appropriate incision size that best fits the injector system chosen for surgery.

The typical Likert scale is a 5- or 7-point ordinal scale used for respondents to rate the degree to which they agree or disagree with a statement.[16] Some previous studies used this method to rate IOL delivery injector systems.[6,17] In this study, higher Likert scores indicate better performance regarding ease of use. The injector system S2.2P achieved the best result because of the following advantages: the packing box of injector S was easy to open, the 2.2 mm incision could achieve an easy nozzle tip insertion, and the push mode of injector S was smooth and required a smaller force. However, one more step to prime the injector S is needed compared with the other 3 injector systems (3 steps); injector system S got a lower score for advancing into nozzle." In the same injector system S with different incision sizes, smaller incision sizes made insertion more difficult and required more force, resulting in lower score on the Likert scale.

Compared with the push mode injectors S1.8, S2.0, S2.2P, U2.2, and R2.0, screw-mode injectors S2.2S and iT2.2 required both hands in IOL implantation. Using both hands on the injectors would lead to instability of the eyes under operation. The sharp blister pack of injector R can scratch one's hand with a higher probability when the pack is opened. Since injector R needs to be immersed in the saline in a blister tray, the liquid might leak from the blister tray and fall everywhere when the pack is opened. Injector R was made inconvenient by all these factors and obtained the lowest score for opening pack.

Several inadvertent IOL behaviors were perceived during implantation based on Miyake-Apple view videos. Hand shaking fashion of haptics (categorized as optic–haptic adhesion for occurrence collection) was observed simply in the iTec group (40%) (Figure 4, *c*). This result is higher than 25% observed by Auffarth et al.[18] In a similar study, only 1 case (10%) of trapped trailing haptic was observed in group iTec and none in the group UltraSert.[7] Optic–haptic adhesion and

intrawound IOL manipulation were not seen in any of the study groups. In 1 study evaluating the delivery performance of the preloaded injector system AcrySert, in the total number of 85 cases, there were 47 (55%) with abnormal leading haptic, 6 (7%) with trapped trailing haptic, and 1 (1%) with optic–haptic adhesion.[19] All these 54 cases (64%) needed further manipulation to achieve a successful delivery. In this study, optic–haptic adhesion accounted for 40% in S1.8, 20% in S2.2P, 50% in U2.2, and 50% in iT2.2. Trapped trailing haptic did not occur in any of our study groups. Regarding abnormal leading haptic, 1 case (10%) in each group of S1.8, S2.0, S2.2P, S2.2S, and U2.2 was observed and 2 cases (20%) in R2.0. In addition, 40% in S1.8, 10% in S2.0, 30% in S2.2P, 60% in U2.2, 50% in iT2.2, and 20% in R2.0 required second instruments to help achieve a successful delivery. Although IOL delivery could mostly be achieved with the help of a second instrument, previous studies found that use of a second instrument may enlarge the wound stretching by intrawound manipulation and increase the risk for damage to the IOL or the capsular bag.[7,20] No statistical significance regarding total occurrences of inadvertent events was noted. This finding might be due to the small sample size for each injector group in this study. However, we noticed a trend of more inadvertent events in the smallest incision group (S1.8). We speculate this was because smaller incision size caused more lateral stress inside the injector tube, thus leading to more inadvertent events. Further studies need to be conducted to confirm whether there is a correlation between the number of the inadvertent events during IOL implantation and the smaller corneal incision sizes.

The mean delivery time, to some extent, indicates the speed of IOL insertion. Injector system iT showed the longest mean delivery time, approximately 13 seconds, which is similar to the finding in a previous study (approximately 11 seconds).[7] Although the screw method may be a reason why the iT systems took a longer delivery time, the S2.2S group with the screw method took a shorter delivery time, suggesting that different designs of screw injector systems also varied in the delivery time. Previous studies associated a faster IOL delivery with a smaller incision enlargement: the more rapidly the IOL is injected through the incision, the less time it will take for IOL to begin to reexpand toward its natural shape.[12,21] Another study also found that a reduction in the transit time of the IOL haptic through the incision could limit incision enlargement.[7] In this study, although group iT2.2 showed significantly longer delivery time than all the other groups, it did not cause the largest incision enlargement. Thus, the speed of IOL delivery is not the only factor that determines the wound stretching. The other injector systems (excluding injector iT) presented a similar delivery time without a statistically significant difference between groups, making no significant impact on the incision sizes.

Several limitations in our study must be addressed. First, although the porcine corneas presented less stiffness and greater thickness than the human corneas (both central cornea and the limbus), a previous study has shown that the porcine corneas could be the substitutes of human cornea when the corneal elastic property is investigated.[22–24] Many previous studies also used the porcine eyes to evaluate different injector systems and incision sizes.[1,6,7] In addition, porcine eyes were easier to acquire and cost much less. Second, a rim of the corneas was preserved for incision making. In this study, we did not experience any tearing during incision making or IOL insertion. We speculate this was due to the greater thickness of porcine cornea. Third, it is true that lack of the central cornea may change the dynamics of the implantation process and the results of incision sizes, and resistance forces could be different from the clinical situations. However, the aim was not to acquire exact values but rather to compare among different injector groups in the study. Finally, the use of different OVDs could influence the performance of different injector systems. However, we wanted to make sure that we completely followed the instructions for operation from each company, including the use of a specific OVD.

In this study, 70 IOL injectors from 4 models were thoroughly evaluated. The results suggest that injector systems varied in the parameters of the nozzle tip, incision enlargement, ease of use, delivery time, and performance. All findings arising from this study would shed light on our understanding about the characteristics of different injector systems, which could be much beneficial for eye surgeons' decision-making in surgery. More clinical studies are warranted to confirm our findings in this study.

WHAT WAS KNOWN

- Preloaded IOL injectors can make a more standardized, faster, and easier loading procedure possible.
- Using porcine eye model to evaluate the performance of IOL injector systems in certain aspects have been performed in previous studies; however, to our knowledge, comprehensive evaluation of IOL injector systems with Miyake-Apple view videos has not been studied.

WHAT THIS PAPER ADDS

- Compared with the depth guard or insert shield design, the configuration (ie, oval, round or v-shaped) of the nozzle tip at the exit and the diameters of the outer cross-section surface seem to play a more important role in the reduction of corneal incision size.
- It is important to choose an incision size that best fits the injector system. Starting with merely smaller sizes as opposed to appropriate sizes will eventually cause significantly larger incision stretching.
- With the smallest incision size of 1.80 mm, injector S generated the largest incision enlargement, lowest score on the ease of use Likert scale, and most occurrences of inadvertent events during IOL implantation. There was an indirect relationship between incision size and inadvertent events.

REFERENCES

1. Shimizu K, Kobayashi K, Takayama S, Zhaobin G. Preloaded injector for intraocular lens implantation without the use of ophthalmic viscosurgical devices. J Cataract Refract Surg 2008;34:1157–1160
2. Simon JW, Ngo Y, Khan S, Strogatz D. Surgical confusions in ophthalmology. Arch Ophthalmol 2007;125:1515–1522

3. Centers for Disease Control and Prevention (CDC). Toxic anterior segment syndrome after cataract surgery—Maine, 2006. MMWR Morb Mortal Wkly Rep 2007;56:629–630
4. Schmier JK, Halpern MT, Covert DW, Lau EC, Robin AL. Evaluation of Medicare costs of endophthalmitis among patients after cataract surgery. Ophthalmology 2007;114:1094–1099
5. Oshika T, Wolfe P. In vitro comparison of delivery performance of 4 preloaded intraocular lens injector systems for corneal and sclerocorneal incisions. J Cataract Refract Surg 2019;45:840–846
6. Nanavaty MA, Kubrak-Kisza M. Evaluation of preloaded intraocular lens injection systems: ex vivo study. J Cataract Refract Surg 2017;43:558–563
7. Wang L, Wolfe P, Chernosky A, Paliwal S, Tjia K, Lane S. In vitro delivery performance assessment of a new preloaded intraocular lens delivery system. J Cataract Refract Surg 2016;42:1814–1820
8. Mendicute J, Amzallag T, Wang L, Martinez AA. Comparison of incision size and intraocular lens performance after implantation with three preloaded systems and one manual delivery system. Clin Ophthalmol 2018;12:1495–1503
9. Apple DJ, Lim ES, Morgan RC, Tsai JC, Gwin TD, Brown SJ, Carlson AN. Preparation and study of human eyes obtained postmortem with the Miyake posterior photographic technique. Ophthalmology 1990;97:810–816
10. Kleinmann G, Kleinmann I. Intraocular lens injector-induced stress on the corneal incisions during lens implantation. Am J Ophthalmol 2014;158:185–191
11. Mencucci R, Favuzza E, Salvatici MC, Spadea L, Allen D. Corneal incision architecture after IOL implantation with three different injectors: an environmental scanning electron microscopy study. Int Ophthalmol 2019;39:397–403
12. Allen D, Habib M, Steel D. Final incision size after implantation of a hydrophobic acrylic aspheric intraocular lens: new motorized injector versus standard manual injector. J Cataract Refract Surg 2012;38:249–255
13. Loriaut P, Kaswin G, Rousseau A, Meziani L, M'nafek N, Pogorzalek N, Labetoulle M. Induced astigmatism after corneal suture removal after cataract surgery. J Fr Ophtalmol 2014;37:226–230
14. Kim YK, 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;28:130–131
15. Espiritu CR, Bernardo JP Jr. Incision sizes at different stages of phacoemulsification with foldable intraocular lens implantation. J Cataract Refract Surg 2009;35:2115–2120
16. Sullivan GM, Artino AR Jr. Analyzing and interpreting data from likert-type scales. J Grad Med Educ 2013;5:541–542
17. Anderson S, Feuchter L, Pohl R, Amon M, Findl O, Sauder G. Performance of a new preloaded insertion system for a 1-piece hydrophobic-acrylic, aspheric intraocular lens. Invest Ophthalmol Vis Sci 2013;54:1846
18. Auffarth GU, Merz PR, Choi CY, Giers BC. CSI Heidelberg: unfolding the characteristics of pre-loaded IOL-systems. Available at: https://www.youtube.com/watch?v=9K9q0lU1AeU&t=385s. Accessed September 30, 2020
19. Ong HS, Subash M, Sandhu A, Wilkins MR. Intraocular lens delivery characteristics of the preloaded AcrySof IQ SN60WS/AcrySert injectable lens system. Am J Ophthalmol 2013;156:77–78.e2
20. Chung B, Lee H, Choi M, Seo KY, Kim EK, Kim TI. Preloaded and non-preloaded intraocular lens delivery system and characteristics: human and porcine eyes trial. Int J Ophthalmol 2018;11:6–11
21. Ouchi M. Effect of intraocular lens insertion speed on surgical wound structure. J Cataract Refract Surg 2012;38:1771–1776
22. Elsheikh A, Alhasso D, Rama P. Biomechanical properties of human and porcine corneas. Exp Eye Res 2008;86:783–790
23. Martola EL. Central and peripheral corneal thickness. A clinical study. Arch Ophthalmol 1968;79:28
24. Zeng Y, Yang J, Huang K, Lee Z, Lee X. A comparison of biomechanical properties between human and porcine cornea. J Biomech 2001;34:533–537

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