Laboratory Analysis of Causative Factors for the Final Incision Size due to Intraocular Lens Injector Insertion

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Purpose: In intraocular lens (IOL) implantation, insertion of the IOL injector enlarges the clear corneal incision. A larger incision size (IS) is associated with a higher risk for surgically induced astigmatism and endophthalmitis. The goal of this study was to determine which parameters most influence the final IS.

Design: Experimental study.

Subjects: A total of 126 cadaver porcine eyes were included in this study.

Methods: We analyzed 409 clear corneal incisions made with 126 injectors from 13 injector models. We noted the vertical diameter and the tip angulation for every model. The corneal thickness of each incision location was measured using Scheimpflug tomography. The IS was measured before and after injector insertion and described as preoperative and final ISs, respectively. During surgery, the insertion depth and incision length were documented. A mixed effects model was applied to analyze the influence of the parameters on the final IS.

Main Outcome Measures: Influence on the final IS.

Results: Increases in the vertical diameter of the injector tip, the preoperative IS and the insertion depth, and a reduction of incision length were all significantly associated with increased final IS ($P < 0.05$). The conditional Pseudo-R^2-Measure was 0.92. The preoperative IS had the largest standardized estimated effect on the final IS, followed by the vertical diameter of the injector tip, insertion depth, and lastly, incision length. Neither corneal thickness nor the tip angle of the injector had a significant effect on the final IS ($P > 0.05$).

Conclusions: The IOL injector's vertical diameter should be as small as possible to ensure a minimal final IS. The injector's insertion depth may be minimized, and the incision length should be long enough to reduce the final IS. Further studies are needed to confirm the findings in human autopsy eyes and in clinical practice.

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Clear corneal incisions are used to gain access to the anterior chamber in intraocular lens (IOL) implantation procedures. A smaller corneal incision is associated with a reduced risk of endophthalmitis and less surgically induced astigmatism.[1–3] In order to implant an IOL into the eye, an IOL injector is used. The insertion of an IOL injector into the clear corneal incision is the main cause for intraoperative incision enlargement leading to a larger final incision size (IS).[4,5] This intraoperative enlargement impedes the previously mentioned positive effects of a small corneal incision.

Previous studies noted that some parameters, such as the vertical diameter of an IOL injector tip or the tip angle, were associated with an effect on the final IS.[6,7] However, these studies were mostly abstract models or a singular analysis of a causative factor. To our knowledge, no study has published an integrated model to determine the relative influence of these parameters on the final IS. Additionally, these earlier studies did not include factors such as the insertion depth of an injector, the incision length, or the local corneal thickness. A deeper insertion of a conical

injector tip could lead to a larger final IS due to the increase of the effective injector diameter.[7] A longer incision or a thicker cornea could stabilize the incision and prevent high intraoperative incision enlargement.

The purpose of this study was to perform an integrative approach to analyzing the influence of different parameters of injector insertion on the achievable final corneal IS. The parameters we included were of the IOL injector itself (vertical tip diameter and tip angle), the pachymetry at the site of incision and IS (preoperative IS and incision length) and the surgical procedure (insertion depth).

Methods

Study Materials

In this laboratory analysis, 126 IOL injectors from 13 different IOL injector models were included as shown in Table 1.

The surgical procedure was performed on 126 cadaver porcine eyes obtained from a local abattoir. The eyes were randomized into

13 test groups, 1 group for each IOL injector model. The exclusion criteria were a damaged or opacified cornea and any sign of trauma such as lens prolapse, iridodialysis, or a ruptured bulbus. The corneas were constantly humidified using a wet chamber. Attached orbital tissue was removed and the eyes were held immobile by embedding the posterior hemisphere in 3% agar solution. All surgeries and measurements were performed within 11 hours posthumously and the eyes were cooled to $+3°$ C. Before surgery, all eyes were examined with a Scheimpflug tomography (Pentacam AXL, Oculus Optikgeräte), allowing the corneal thickness of each peripheral quadrant to be obtained.

This study did not need an ethics committee approval due to the non-human and ex vivo nature of the study eyes.

Characterization of Injector Models

Five injectors of each injector model were microscopically examined and photographed from a side view using an Olympus BX50 microscope (Olympus) with an attached Olympus Camedia C-7070 Wide Zoom camera (Olympus). The vertical outer diameter and the tip angle of an injector tip was quantified using ImageJ software version 1.51 (United States National Institutes of Health) as shown in Figure 1A.

Surgical Procedure

The procedure followed one described in a previous study.[8] The same surgeon (M.F.) performed all surgeries. The eyes were humidified with balanced salt solution throughout the procedure. A triplane self-sealing rectangular clear corneal incision was created with a stainless-steel slit knife (Mani). The size of the knives ranged from 1.8 to 2.8 mm. After incision, the anterior chamber was filled with Pe-Ha-Visco 2.0% ophthalmic viscosurgical device (Albomed). Before every injector insertion, the preoperative IS was measured using an incision gauge set (Duckworth & Kent), which can obtain measurements from 1.0 to 3.0 mm with intervals of 0.1 mm. All injectors were prepared in accordance with the manufacturer's instructions for use. An injector was then inserted into the corneal incision and into the anterior chamber with an insertion depth comparable to the into-the-bag IOL implantation technique.

After the insertion of an IOL injector, the final IS was measured with an incision gauge set to assess the intraoperative incision enlargement due to the IOL injector insertion.

Afterward, the eye was rotated by 90° around the vertical axis and a second clear corneal incision with a different IS was created. Subsequently, the full surgical process of the previously mentioned injector insertion and measurements were repeated. After completion of the second surgical procedure, the eye was twice turned by another 90°, allowing surgery for a third and fourth time with different ISs. The intraocular pressure was maintained with a reapplication of ophthalmic viscosurgical device before every injector insertion. For one injector, the SkyJet (Carl Zeiss Meditec), only 3 incisions per eye were made as the enlarged final incisions exceeded the scale limit of 3.0 mm of the incision gauge set. In total, 499 clear corneal incisions were made in 126 eyes.

Insertion Depth and Incision Length Measurement

During each procedure, the maximum insertion of an IOL injector into the corneal incision was photographed using a DMC-G6 camera (Panasonic) attached to a Leica M220 microscope (Leica Microsystems). At the end of each insertion, the incision was stained with metallic particles and photographed. After calibrating each image with a scale on incision level, the insertion depth and incision length were also measured using ImageJ software version 1.51 as shown in Figure 1B, C. The exclusion criteria for image evaluation were evidence of reduced image quality and a high subjective uncertainty regarding the measurement.

Statistical Analysis

The statistical analysis was performed with SPSS for Windows (Version 29, IBM). A mixed effects model was fitted to determine the influence of the parameters on the final IS, because the data were grouped for each IOL injector model. The fixed effects were vertical tip diameter, preoperative IS, insertion depth, corneal thickness, and incision length. The random effect was the injector model. A P value < 0.05 was considered significant.

Results

In total, 409 of the 499 incisions (81.96%) had a complete dataset without missing values and therefore only these 409 were included in the mixed effects model.

Including measurements of vertical tip diameter, tip angle, corneal thickness, preoperative IS, insertion depth, and

Table 1. The IOL Injector Models Included in This Study and Their Respective Vertical Diameter and Tip Angle

IOL Injector Model	Manufacturer	N	Vertical Tip Diameter (mm)	Tip Angle (°)
Accuject 1.6-1P	Medicel	5	1.46	44.81
Accuject 1.8-1P	Medicel	12	1.66	55.74
Accuject 2.2-1P	Medicel	10	1.89	54.46
AutonoMe	Alcon	12	1.48	44.06
Bluemixs 180	Carl Zeiss Meditec	10	1.67	55.66
Ergoject 2.2-TL	Medicel	5	1.84	37.28
Kowa original injector	Kowa Company	10	1.78	45.42
MultiSert	Hoya Medical Singapore	10	1.69	33.30
RaySert PLUS	Rayner Intraocular Lenses	19	1.99	44.22
RayOne	Rayner Intraocular Lenses	8	1.68	46.74
SkyJet	Carl Zeiss Meditec	5	2.09	45.56
Ultrasert	Alcon	10	1.46	46.53
Viscoject-Bio 2.2	Medicel	10	1.76	49.86

IOL = intraocular lens, N = number of injectors used in study.
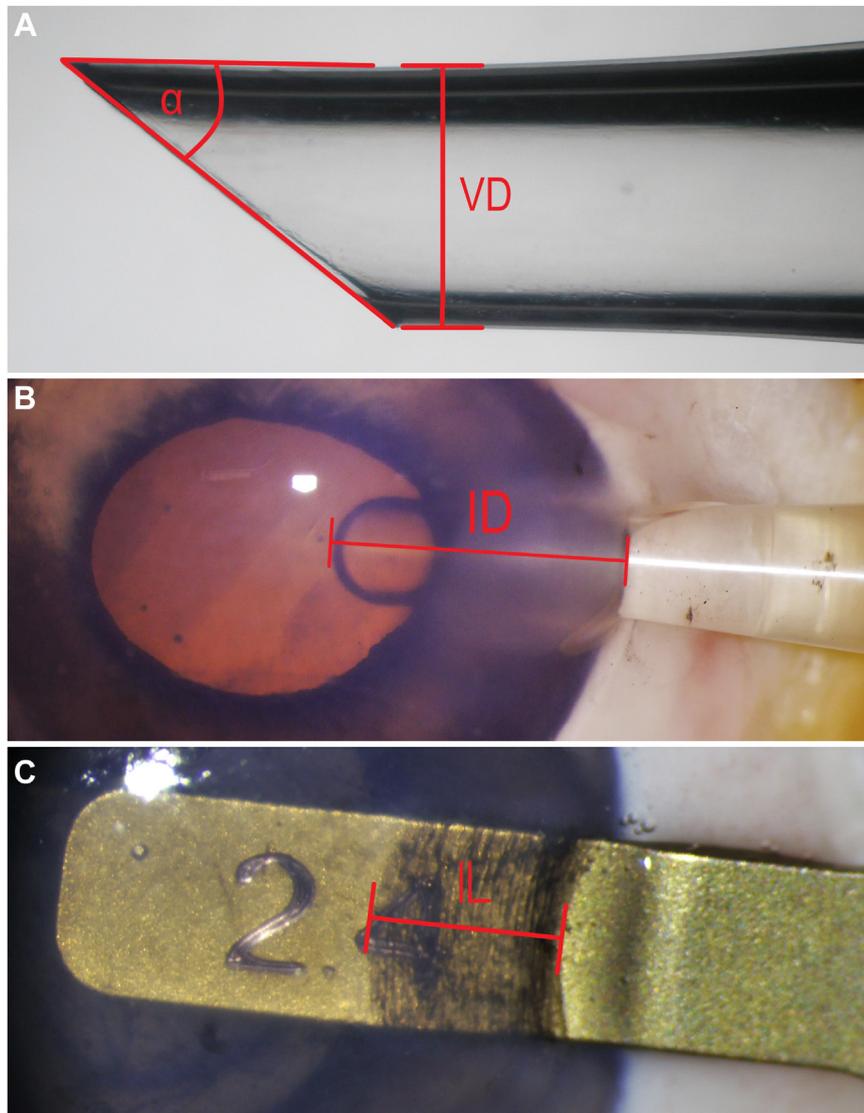
Figure 1. Illustration for the measurements of the parameters, (**A**) tip angle (α) and vertical diameter (VD), (**B**) insertion depth (ID), and (**C**) incision length (IL).

incision length, this model to predict the final IS resulted in a conditional Pseudo-R^2-Measure of 0.92. This means that roughly 92% of the variation of the final IS is explained by the model. As shown in Table 2, the vertical tip diameter, the preoperative IS, the insertion depth, and the incision length had a statistically significant effect on the final IS. The vertical tip diameter showed the highest absolute estimated effect on the final IS. Corneal thickness and tip angle did not have a significant effect on the final IS.

In a standardized model with a subtraction of the scale of all parameters, the preoperative IS had the largest relative effect with a standardized estimated fixed effect of 0.10. The standardized estimated fixed effect of the vertical diameter of an injector was slightly lower (0.09). The other significant parameters, insertion depth and incision length, had a standardized estimated fixed effect of 0.06 and −0.01, respectively. However, these values should only be used for comparing the relative size of influence of these causative effects on the final IS.

Figure 2 visualizes the influence of all parameters on the final IS without assessing the injector group. Those parameters, which had a significant effect on the final IS, show a positive slope and a small uncertainty. It can be noted that the incision length, which has a negative estimated effect on the final IS, has a positive slope. This could be explained by the ungrouped visualization of the data, which does not assess the repeated measures of an injector model. The corneal thickness and the tip angle demonstrate a minimal slope indicating their insignificant results using the mixed effects model.

As shown in Figure 3, the fitted mixed effects model resulted in an accurate prediction of the final IS and was roughly consistent in all IOL injector models. The similar slopes with varying intercepts show how the grouped

Table 2. Estimated Effects of the Included Parameters on the Final Incision Size

Parameter	Estimate	Standard Error	P Value	95% Confidence Interval	
				Lower Bound	*Upper Bound*
Intercept	0.663	0.363	0.097	−0.144	1.470
Vertical tip diameter	0.481	0.163	0.014	0.119	0.843
Tip angle	< 0.001	0.005	0.961	−0.011	0.010
Corneal thickness	0.035	0.021	0.096	−0.006	0.077
Preoperative incision size	0.404	0.014	< 0.001	0.377	0.431
Insertion depth	0.045	0.006	< 0.001	0.034	0.057
Incision length	−0.014	0.007	0.044	−0.028	−0.001

A P value < 0.05 is considered statistically significant.

structure in this model accounted for the differences between the injector models. For better visualization, the position of the data points is displayed with a small horizontal displacement factor.

To facilitate an accurate prediction of the final IS, 2 novel intraoperative parameters—incision length and insertion depth—were measured. The mean incision length was 2.56 mm with a standard deviation of 0.49 mm, as shown in
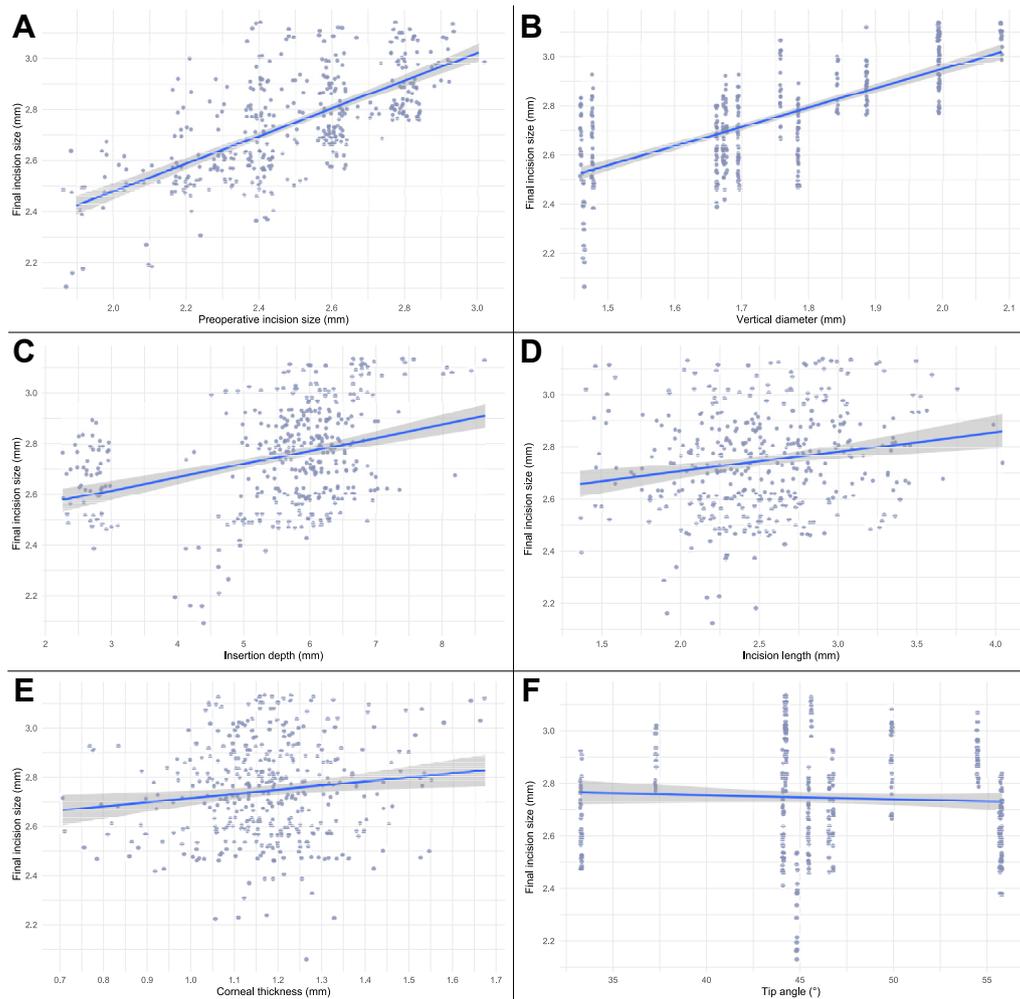
Figure 2. Overview of the correlation of the analyzed parameters regarding the final incision size (IS). The 95% confidence interval is visualized in gray. **A,** Influence of the preoperative IS on the final IS. **B,** Influence of the vertical diameter of an injector tip on the final IS. **C,** Influence of the insertion depth of an injector into a corneal incision on the final IS. **D,** Influence of the incision length on the final IS. **E,** Influence of the corneal thickness on the final IS. **F,** Influence of the tip angle of an injector on the final IS.
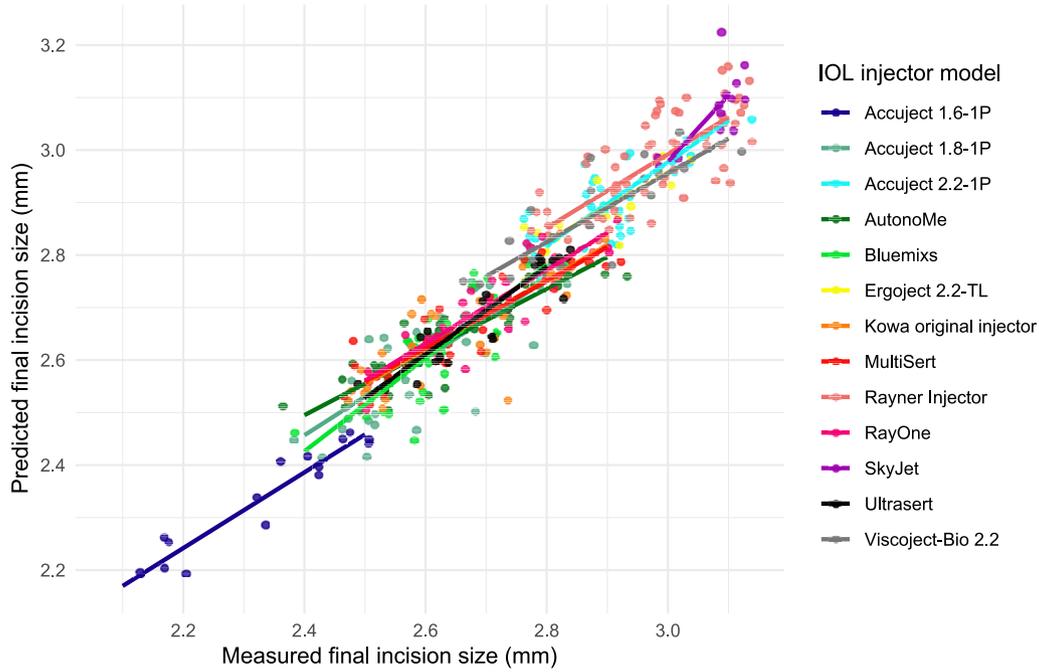
Figure 3. The accuracy of the predicted final incision size (IS) regarding the measured final IS grouped by intraocular lens (IOL) injector model. For better visualization the data points were horizontally dispersed.

Table 3. The mean insertion depth was 5.50 ± 1.33 mm and varied between different IOL injector models. For example, the Accuject 1.6-1P (Medicel), AutonoMe (Alcon) and Ultrasert (Alcon) had a feature to hinder a deep insertion of the respective injector into an incision. The mean insertion depths of these 3 IOL injector models were, therefore, smaller compared to the other injector models.

The mean vertical tip diameter of the IOL injectors was 1.73 ± 0.18 mm. As shown in Table 1, the smallest vertical tip diameter could be observed in the Accuject 1.6-1P (Medicel) and Ultrasert (Alcon), both with 1.46 mm, and largest in the SkyJet (Carl Zeiss Meditec) with 2.09 mm.

The tip angle of the IOL injectors ranged from a minimum of 33.30° in the MultiSert (Hoya Medical Singapore) to a maximum of 55.74° in the Accuject 1.8-1P (Medicel). However, 11 of 13 IOL injector models had a tip angle > 44.00°. In Figure 2B, F, the grouped nature of the injector parameters is visualized.

Table 3. Descriptive Statistics of the Parameters Included Into the Mixed Effects Model

	N	Mean	SD	Minimum	Maximum
Vertical tip diameter	499	1.73 mm	0.18 mm	1.46 mm	2.09 mm
Tip angle	499	46.86°	0.28°	33.30°	55.74°
Corneal thickness	493	1.18 mm	0.15 mm	0.71 mm	1.69 mm
Preoperative incision size	499	2.48 mm	0.24 mm	1.90 mm	3.00 mm
Postoperative incision size	499	2.74 mm	0.20 mm	2.10 mm	3.10 mm
Insertion depth	423	5.50 mm	1.33 mm	2.27 mm	8.63 mm
Incision length	488	2.56 mm	0.49 mm	1.37 mm	4.30 mm

N = number of successful measurements; SD = standard deviation.

The porcine cornea is thicker than the human cornea; the mean thickness at each incision location was 1.18 ± 0.15 mm, measured in 98.80% of all incisions.

The preoperative ISs ranged from 1.90 to 3.00 mm, representing a wide range of commonly used ISs in manual small incision cataract surgery. The incisions enlarged intraoperatively, with a mean of 0.26 ± 0.18 mm to a mean final IS of 2.74 ± 0.20 mm. Note that the injector models SkyJet (Carl Zeiss Meditec) and RaySert PLUS (Rayner Intraocular Lenses) reached the maximum measurement capacity of the incision gauge set (3.0 mm). Thus, in this study, it was not possible to accurately assess the maximum final IS for these injector models.

Discussion

We developed, for the first time, an accurate model to predict the final IS in IOL injection (Pseudo-R^2-Measure = 0.92). A significant influence on the final IS was observed for preoperative IS and vertical diameter of an IOL injector tip, and for the novel intraoperative parameters insertion depth of an IOL injector into an incision and incision length. However, 2 measurements, corneal thickness and tip angle of an injector, did not significantly correlate with the final IS.

Previous studies mainly analyzed the final IS in regard to the injector model that was used [4,9,10] or its dimensions.[7] Other causative factors that could influence the final IS and their attributable effects were neglected. In this study, an integrated approach to find the determining factors for the final IS was employed to reduce spurious correlations.

A reduction of the vertical diameter in an IOL injector correlated with a smaller final IS. This is congruent with

previous findings.[6,7,11–13] Kleinmann and Kleinmann hypothesized in their finite element calculation model that the stress onto the incision margins is dependent on the outer circumference of an IOL injector and the preoperative IS.[6] With a higher diameter of an IOL injector pulling apart the horizontal incision margins during an insertion, the lateral incision angles are increasingly stressed and tend to tear and widen the incision.[6,13] They concluded that IOL injector manufacturers should do their utmost to advance injector and lens technology to reduce the necessary vertical diameter to a minimum, while ensuring a safe IOL implantation. However, simply reshaping the injector tip to be more elliptical by reducing the vertical diameter might be insufficient. During IOL insertion, elliptical shaped injector tips could change to a more circular shape, hence increasing the vertical diameter and limiting aforementioned advantageous effects. The vertical diameter needs to be minimized consistently during every surgical step.

Other studies hypothesized that a more acute tip angle of an IOL injector would cause more trauma in an incision.[7,11] In our study, the tip angle did not have a significant influence on the final IS. This supports the hypothesis that the vertical diameter is the most important parameter of an IOL injector regarding the final IS.

In the present study, a smaller preoperative IS was significantly associated with a smaller final IS and it had the largest effect in relation to the other parameters. In comparison to other studies that compared the use of different IOL injector models in a *specific* IS for each model, our study used *different* preoperative ISs for the same IOL injector model.[9,12,14] This allows us to first describe the positive correlation of the preoperative IS on the final IS for various IOL injector models.

Nevertheless, smaller preoperative incisions are also associated with a higher intraoperative incision enlargement and a lower postoperative endothelial cell count.[8,15] Future studies need to compare the visual outcomes of surgeries with a minimal final IS and a minimal intraoperative incision enlargement.

The insertion depth of an IOL injector into a corneal incision varies depending on different IOL implantation techniques. Kohnen and Klaproth found a direct implantation of the IOL into the capsular bag (into-the-bag implantation technique) to have a higher intraoperative enlargement than wound-assisted implantation techniques.[16] In the present study, an injector insertion was only performed using the into-the-bag implantation technique with an insertion depth between 2.27 and 8.63 mm. A deeper insertion of an IOL injector into the incision was positively correlated with the final IS and could be explained by a conical injector tip.[11] As the injector is inserted more deeply, a larger diameter influences the incision, and therefore, enlarges the incision more. According to this result, surgeons may hold the depth of injector insertion to a minimum while ensuring a safe and successful IOL implantation.

In other studies, the incision length was analyzed regarding the postoperative intraocular pressure or the wound architecture, but not the final IS.[17] Our study showed that a greater incision length correlates with a smaller final IS, which could be explained by a higher stability of a long incision. However, the effect of the incision length was small compared to the other significant parameters that influence the final IS. Additionally, Hayashi et al[18] found a longer, clear corneal incision to be associated with more surgically induced astigmatism. Therefore, we need further studies to compare the postoperative outcome when using different incision lengths.

We hypothesized that a higher corneal thickness would stabilize the incision and reduce intraoperative incision enlargement. However, the mixed effects model showed no significant correlation between the corneal thickness and the final IS.

The main limitation of this study was the execution of the experiments on cadaver porcine eyes. While the porcine eyes often replace human eyes in laboratory research, their anatomical properties differ in comparison to the human eye.[19] For example, the mean corneal thickness in our study was 1.18 ± 0.15 mm compared to a normal human corneal thickness of around 0.53 mm.[20]

Another considerable limitation is the applicable range of a mixed effects model. In general, a regression model is mainly applicable in the range of the values from which it was fitted.[21] The presented mixed effects model included IOL injector parameter dimensions similar to those included in previous studies.[6,7] If new injectors, new procedures, or patients with a corneal thickness of the described ranges are being evaluated with this model, this may produce inaccuracy. Nevertheless, the purpose of this study was to determine significantly-relevant parameters for the final IS with an integrated model. The values described in this study should be interpreted only in relation to each other and not as absolute numbers.

Finally, only the influence of the insertion of an injector into a clear corneal incision was analyzed. Other surgical steps, for instance phacoemulsification, may enlarge the corneal incision independently of the injector insertion and lead to an even higher final IS. However, we conclude that the insertion of an IOL injector accounts for the most intraoperative incision enlargement and it was, therefore, properly the focus of this study.[4,5]

The results indicate several leverage points to reduce the final IS and the complications associated with an enlarged incision. The vertical tip diameter of an IOL injector, the preoperative IS, the incision length, and the insertion depth of an injector into an incision have a significant influence on the final IS. Therefore, the vertical diameter in IOL injectors should be as small as possible to ensure a minimal final IS. The insertion depth of an injector may be held to a minimum and the incision length may be long enough to reduce the final IS. Further studies are needed to confirm the present findings in human eyes.

Footnotes and Disclosures

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