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ARTICLE

Enlargement of main corneal incision: clinical intraindividual comparison of two preloaded intraocular lens injectors

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Purpose: To compare the enlargement of the clear corneal incision from IOL implantation with 2 different intraocular lens (IOL) injectors: the AutonoMe preloaded with the Clareon IOL and the Multisert preloaded with the Vivinex IOL.

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

Design: Prospective randomized clinical comparative study.

Methods: 96 eyes of 48 patients with cataract were intraindividually randomized to treatment with 1 of the 2 injectors. For Multisert eyes, the insert shield (IS) was used in the advanced position in 23 eyes. The initial incision was 2.2 mm, and intraoperative measurements of the incision size were made before and after IOL injection. 3 months postoperatively, keratometry and uncorrected (UDVA) and corrected (CDVA) distance visual acuities were assessed.

Results: Results are reported for 96 eyes of 48 patients. The mean incision enlargement was 0.213 ± 0.068 mm in the Multisert with the IS group, 0.265 ± 0.055 mm in the fellow eyes (AutonoMe) ($P < .05$), 0.272 ± 0.060 mm in Multisert eyes treated without the IS, and 0.296 ± 0.066 mm for the fellow eyes (AutonoMe) ($P > .05$). The mean absolute surgically induced astigmatism was 0.42 ± 0.23 diopters (D), 0.50 ± 0.25 D, and 0.44 ± 0.18 D in the Multisert with the IS, Multisert without the IS, and AutonoMe group, respectively ($P > .05$). The UDVA and CDVA were comparable in all groups.

Conclusions: The Multisert was associated with less wound enlargement than the AutonoMe. All groups had comparable functional outcomes. Therefore, the observed difference in incision enlargement may be of limited clinical relevance.

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Over time, the development of improved instruments and techniques for cataract surgery has led to a steady improvement in outcomes and faster postoperative visual rehabilitation. Surgery through a clear corneal incision (CCI) is one of the preferred approaches today, as it is known to limit postoperative inflammation.[1] The trend is toward a further reduction in the incision size that minimizes surgically induced astigmatism (SIA), corneal aberrations, and the risk for postoperative endophthalmitis or wound leakage.[2–4] It is now accepted, however, that the initial incision size is not the final wound size because the incision is enlarged during many steps in the cataract surgery procedure.[5] Intraocular lens (IOL) implantation is a critical step, and advances in IOL injector technologies can reduce wound enlargement.[6] Surgeons can nowadays choose between different preloaded injector systems that allow them to inject an IOL through microincisions that are even smaller than 2.0 mm.[2,7,8]

Injector manufacturers recommend an initial incision size, which can vary from one model to another. This initial incision gets enlarged as the surgeon introduces, moves, and removes instruments through the opening. Thus, the wound is stressed and widens. Since the 1990s, it has been accepted that the incision size and its architecture and location influence the amount of SIA.[9] In this study, we investigated the enlargement of the CCI with 2 different preloaded IOL injectors, the AutonoMe (Alcon Laboratories, Inc.) and Multisert (Hoya Corp.). Of particular interest was the Multisert's insert shield (IS), which the surgeon can use optionally to limit the injector's advance

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into the eye and thus reduce the stress on the wound (Figure 1). We applied both modalities (IS in the default position and IS in the advanced position) to compare the shield's effect using this injector model.

METHODS

Patients and Surgical Procedure

This study was approved by the Local Ethics Committee of the University of Heidelberg and is registered at the German Clinical Trials Register (Deutsches Register Klinischer Studien; reference number: DRKS00007837). This study was performed in accordance with the tenets of the Declaration of Helsinki.

Power calculation indicated that at least 44 eyes per group were needed to detect a difference of 0.06 mm in corneal incision enlargement with a power of 0.80 and at the 5% significance level.

We recruited 48 patients with cataract who were scheduled for bilateral phacoemulsification and posterior chamber IOL implantation to participate in this study. Patients with a minimum of 18 years of age and clear intraocular media other than bilateral cataract as well as a calculated IOL power within the commercially available power range were enrolled after signing informed consent. Patients with systemic or ocular conditions that could affect the study outcome such as pupil abnormalities, previous surgery, or pseudoexfoliation were excluded. Also, patients with a difference of >1.5 diopters (D) of required IOL power between both eyes were excluded because the IOL power was considered a possible factor influencing the wound stretch.[9]

Patients' eyes were intraindividually randomized for implantation with the AutonoMe injector, which is preloaded with the Clareon IOL (Alcon Laboratories Inc.), or the Multisert injector that is preloaded with the Vivinex IOL (Hoya Surgical Optics, Inc.). For 50% of the eyes assigned to treatment with the Multisert injector, the use of the IS in the advanced position (with IS) was determined in randomly selected patients. The AutonoMe injector features a depth guard, which has a fixed position and also limits injector advancement.

Preoperatively, we assessed subjective refraction and uncorrected (UDVA) and corrected (CDVA) distance visual acuities, and we performed slitlamp and dilated fundus examination. Optical biometry was obtained from the IOLMaster 700 (Carl Zeiss Meditec AG). We calculated the required IOL power targeting either emmetropia or −2.50 D according to the patient's preference. Keratometry was obtained from the Pentacam device (Oculus Optikgeräte GmbH).

The same experienced surgeon (R.K.) performed all the surgeries, with the patient choosing local or general anesthesia. To allow for microcoaxial phacoemulsification, he used a Centurion phacoemulsification machine and a 0.9 mm 45-degree ABS Intrepid Balanced phaco tip with a NanoSleeve (Alcon Laboratories, Inc.). The main corneal incision was 2.2 mm for both IOL injectors and was placed at the 12 o'clock position for all patients, following standard procedures at our clinic. The size of this incision was measured at 3 different timepoints during surgery using the Storz ET-2418 incision gauge set with titanium blades from 1.0 to 3.0 mm (Bausch & Lomb, Inc.). The first measurement was performed directly after the incision was created, the second was performed after phacoemulsification and complete removal of the crystalline lens, and the third took place after through-the-wound IOL implantation. To measure the incision size, incision gauges of increasing sizes were advanced through the wound. The procedure of intraoperative measurements is depicted in Figure 2. The difference between the second and third measurement was used to calculate the incision enlargement that we attributed to IOL implantation. For both injectors, a cartridge insertion technique was used. For the Multisert injector, the push mode was used for all implantations. The outer diameter of the Multisert injector tip is 1.70 mm according to the manufacturer, and the outer cross-section length is 2.05 mm, whereas the outer cross-section width is 1.49 mm for the AutonoMe.[10]

Follow-up

At the 3-month follow-up visit, we assessed manifest refraction, UDVA, and CDVA. Postoperative keratometry measurements were obtained using the Pentacam device. Slitlamp examination and dilated fundoscopy were also performed, focusing on IOL material changes, including the presence or absence of glistenings.

Data Analysis

All data were collected in an Excel file (v. 14.7.7; Microsoft Corp.). For demographic data and outcome measures, we calculated mean values and SDs. The Shapiro-Wilk test was used to test for normal distribution. The Wilcoxon signed-rank test for dependent parameters or the Mann-Whitney *U* test for independent parameters was used when appropriate to test for differences in the mean corneal incision size enlargement. The SIA was calculated from the preoperative and postoperative keratometry values obtained with the Pentacam and analyzed as described by Holladay et al.[11] The centroids of SIA for the 3 groups are presented on a double-angle plot using MATLAB software (Mathworks, Inc.). A *t* test for dependent or independent parameters was used when appropriate to test for differences in the mean SIA, UDVA, and CDVA. A *P* value less than 0.05 was considered statistically significant for all tests.

RESULTS

The patients' mean age was 72 ± 13 years. Twenty-two (45.8%) of 48 patients were male.

The mean power of the implanted IOLs was 21.65 ± 2.72 D (range 16.0 to 25.0 D) for the AutonoMe group (n = 48), 21.83 ± 2.41 D (range 17.0 to 26.0 D) for the Multisert patients treated with the IS (n = 23), and 21.28 ± 2.72 D (range 16.0 to 26.0 D) for Multisert patients treated without the IS (n = 25). There was no statistically significant difference between groups.

The preoperative astigmatism was −0.74 ± 0.37 D for the AutonoMe group, but for the Multisert with and without the IS, it was −0.74 ± 0.37 D and −0.85 ± 0.38 D, respectively.

The target refraction was −0.62 ± 0.92 D, −0.73 ± 0.97 D, and −0.49 ± 0.77 D for the AutonoMe, Multisert with the IS, and Multisert without the IS groups, respectively. The difference between the achieved and the targeted spherical equivalent was +0.04 ± 0.70 D for the AutonoMe patients, whereas it was −0.18 ± 0.33 D and +0.05 ± 0.43 D, respectively, for the Multisert group with and without the IS. Patients with myopic target refraction were included in this analysis.

Corneal Wound Size

The mean corneal wound enlargement from IOL implantation was 0.281 ± 0.063 mm for the AutonoMe group and 0.244 ± 0.070 mm for the Multisert group; the difference reached the significance level (P = .002). The mean incision enlargement in the Multisert patients treated with the IS was 0.213 ± 0.068 mm vs 0.265 ± 0.055 mm in the fellow eyes treated with the AutonoMe injector (P = .002). In the Multisert patients treated without the IS, the mean incision enlargement was 0.272 ± 0.060 mm and 0.296 ± 0.066 mm in the fellow eyes (P = .173). The incision enlargement in the Multisert with shield group was significantly lower than that in the Multisert without shield group (P = .007). The mean corneal wound size during the course of surgery is depicted in Figures 3 and 4.

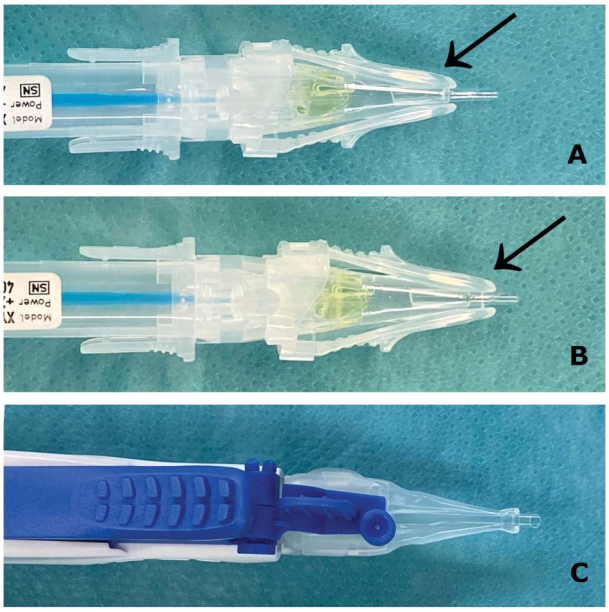

Figure 1. Tips of the injector models used in this study. *A*: Tip of the Multisert injector with the IS in the default position (*arrow*). *B*: Tip of the Multisert with the IS in the advanced position (*arrow*). *C*: Tip of the AutonoMe injector. IS = insert shield

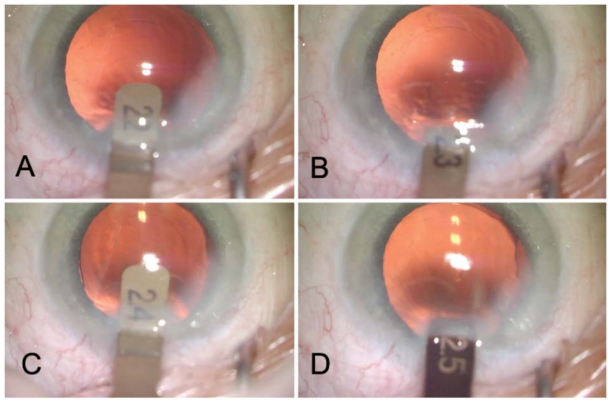

Figure 2. Intraoperative measurement of the corneal incision using incision gauges of increasing sizes. *A*: The incision gauge of 2.2 mm can be advanced through the corneal wound. *B*: The incision gauge of 2.3 mm is too large to be inserted. *C*: After IOL implantation, the incision gauge of 2.4 mm can be advanced, but *D*: the 2.5 mm incision gauge is too large.

Functional Results

The mean absolute SIA was lowest in the eyes treated with the Multisert injector using the IS (0.42 ± 0.23 D), followed by the eyes treated with the AutonoMe (0.44 ± 0.18 D). Slightly higher values were found in patients treated with the Multisert injector without the IS (0.50 ± 0.25 D). The differences between groups did not reach the significance level, however ($P > .05$). Figure 5 shows the mean absolute SIA for all groups. The double-angle plot shows the 3 centroids distributed around the against-the-rule axis, which may result from superior (12 o'clock) CCIs (Figure 6).

Three-month postoperative UDVA and CDVA were comparable in all groups, with a UDVA of 0.07 ± 0.15 logMAR, 0.15 ± 0.13 logMAR, and 0.11 ± 0.15 logMAR and a CDVA of −0.02 ± 0.16 logMAR, 0.05 ± 0.11 logMAR, and −0.02 ± 0.10 logMAR, respectively, for the AutonoMe, Multisert with shield, and Multisert without shield groups. Patients with myopic target refraction were excluded from the UDVA analysis.

Differences in UDVA and CDVA between groups were not statistically significant ($P > .05$).

DISCUSSION

In this prospective clinical study, we found a greater corneal wound enlargement caused by IOL implantation with the AutonoMe compared with the Multisert injector; the difference reached the significance level. When using the IS in the advanced position, the Multisert caused significantly lower wound stretch compared with not using the IS. Despite the statistically significant differences in wound size after IOL implantation, the functional results, including SIA, were similar in all groups.

It has been previously reported that each step during cataract surgery leads to irreversible stretching or tearing of the CCI.[5] Phacoemulsification is known to account for a relatively small amount of wound enlargement. Values ranging from 0.03 to 0.09 mm have been reported.[5,12,13] We found even lower values of 0.01 mm incision enlargement from phacoemulsification. The lower value is most likely

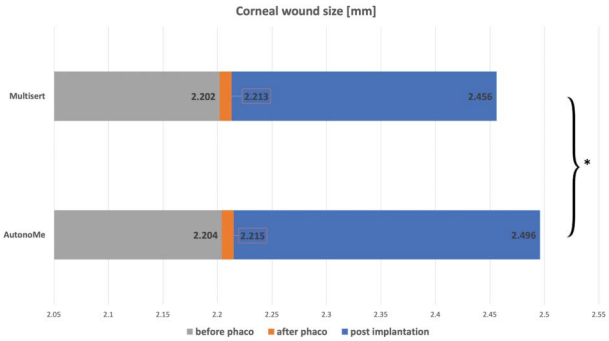

Figure 3. The change in corneal wound size during surgery in the Multisert vs AutonoMe group. *The difference between both groups was statistically significant.

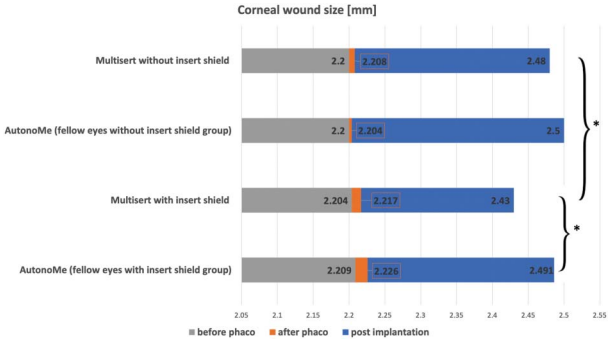

Figure 4. Corneal wound size in patients treated with and without the IS and of fellow eyes treated with the AutonoMe injector. *Statistically significant differences.

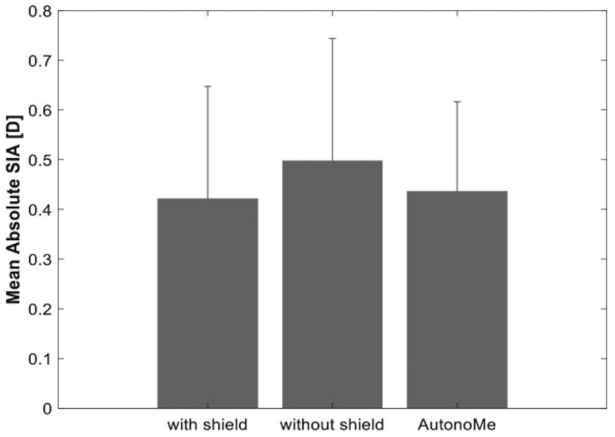

Figure 5. The mean absolute SIA for all 3 groups did not differ significantly. SIA = surgically induced astigmatism

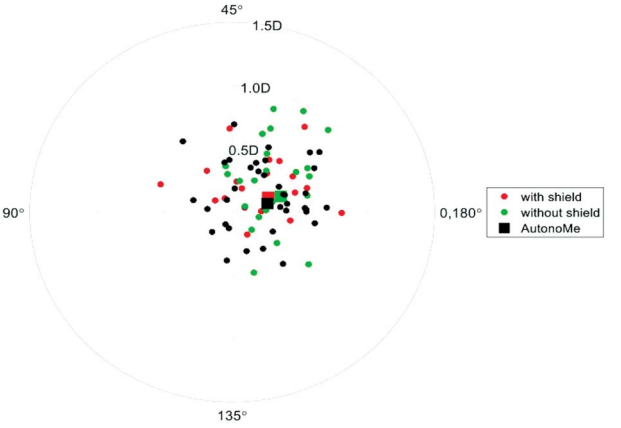

Figure 6. Double-angle plot of the surgically induced astigmatism: The squares indicate centroids of the AutonoMe (*black*), with shield (*red*), and without shield (*green*) groups.

due to the initial incision size of 2.2 mm and the phacoemulsification machine that we used, with its bevel tip and sleeve.

A much larger proportion of wound enlargement is attributed to IOL implantation, and we confirmed this point.[5] A clinical study by Haldipurkar et al. examined the incision enlargement of both predecessor models of the injectors used in this study. For the UltraSert injector, which is the predecessor of the AutonoMe injector, they reported a mean value of 0.167 mm, and for the iSert injector, which is the predecessor of the Multisert injector, the mean value was 0.168 mm with an initial incision size of 2.2 mm in all cases.[13] For the same injectors, Oshika et al. found mean values of 0.15 mm (UltraSert) and 0.24 mm (iSert) in a laboratory study using porcine cadaver eyes and initial incision sizes of 2.2 mm for the UltraSert and 2.0 mm for the iSert.[14]

To the authors' knowledge, this is the first study examining corneal incision enlargement from IOL implantation with the Multisert. We found a mean enlargement of the CCI of 0.24 mm for the Multisert and of 0.28 mm for the AutonoMe, with an initial incision size of 2.2 mm for both injectors. A previous study comparing the AutonoMe with the iSert (Hoya Corp.) revealed values of 0.20 mm and 0.29 mm, respectively, for the AutonoMe and iSert injector; the initial incision sizes in this study were 2.2 mm for the AutonoMe and 2.0 mm for the iSert.[12] Liu et al. compared 4 different IOL injectors regarding the incision enlargement in a laboratory study using human cadaver eyes. Each injector was used in a sample of 16 freshly enucleated eyes. Despite the in vitro setting, the results for the AutonoMe were very comparable with our findings: they found a mean enlargement of the CCI of 0.29 mm for this injector model. The other implantation systems assessed showed similar or higher values of incision enlargement.[15]

Several factors influencing corneal incision enlargement have been identified: Arboleda et al. in an animal model examined 13 different IOL injector models with different diameters, tip angles, and cone angles and found that the most important parameter determining the final incision size is the diameter of the injector nozzle. The tip angle also affects the corneal incision enlargement but to a lesser extent. All injectors caused wound enlargement during IOL injection between 0.1 mm and 0.65 mm. None of the injectors used in their study could implant a lens through a 1.8 mm incision, so they recommended that the surgeon chooses an initial incision size according to the injector tip diameter to avoid excessive wound stretch.[16]

The injectors we used had a diameter of 2.05 mm for the AutonoMe and 1.70 mm for the Multisert, according to each manufacturer.[10] It seems plausible that the larger nozzle tip diameter of the AutonoMe causes greater incision enlargement than the Multisert with a smaller diameter. For the predecessor model of the Multisert, the iSert injector, which has the same diameter, a higher amount of wound enlargement with a mean value of 0.29 mm was reported.[12] However, the recommended initial incision size was smaller for this injector with only 2.0 mm. Smaller incision sizes may result in the wound being subjected to more wound tearing from manipulation of injector systems for which the incision is too tight, whereas adequately sized incisions show less damage from manipulation.[14,17,18]

It has been previously reported that designs limiting the advancement of injectors into the eye can help limit wound stretch.[14,15,19] Wang et al., using porcine cadaver eyes, compared an injector with a depth guard design against several injectors without such a feature, and they found a significantly lower amount of incision enlargement using the depth guard compared with the other models. They reasoned that an inadvertent advancement of the injector during IOL implantation may cause excessive wound stretch.[19] They also concluded that the depth guard increases the mechanical strength of the injector tip, which protects the wound better during the advancement of the IOL in the nozzle.[14,19] In this study, the mean incision enlargement was significantly lower with a mean value of 0.213 mm for the group treated with the IS in the advanced position vs 0.272 mm for the group treated without the IS. This result supports the idea that limiting injector insertion contributes to wound protection.

Postoperative corneal astigmatism is influenced by various factors, most notably the size of the CCI. Wang et al. varied the incision size to see what effect it had on SIA.

They found that a reduction from 3.0 to 2.6 mm led to a statistically significant decrease of SIA. However, a further reduction from 2.6 to 2.2 mm did not lead to a further decrease of SIA. With decreasing incision size, the authors observed a faster stabilization of refraction.[20] Masket et al. compared incision sizes of 3.0 mm and 2.2 mm and found that the SIA could be reduced from a mean value of 0.32 to 0.10 D with the smaller incision size.[21]

Apart from the size, the placement of the main incision is also of great importance. A temporal approach is known to induce less astigmatism than using a superior incision site.[22,23] Sonmez et al. examined the additional effect of tunnel length on different incision sites and found that a shorter tunnel may be beneficial for a superior CCI to limit the SIA.[24] Apart from that, wound stretching was suggested to be a contributing factor.[12] Vasavada et al. compared corneal incision enlargement and SIA using CCIs of 1.8 mm and 2.2 mm. They found higher mean values for incision enlargement in the group with the smaller CCI and interestingly also higher SIA values in this group, although the difference in SIA was not statistically significant.[25] In our analysis, we did not find statistically significant differences in SIA between the studied conditions. We noticed, however, that the Multisert eyes treated with the IS in the advanced position tend to have the lowest SIA. This may have resulted from less corneal incision enlargement seen in this group compared with the AutonoMe and Multisert (without the IS) eyes, but the observed difference did not reach the significance level.

Reducing the size of the CCI can improve the postoperative outcome including SIA and lead to a lower risk for postoperative complications. It is important, however, to choose an incision size that is appropriate for the diameter of the injector, phacoemulsification tip, and sleeve to avoid excessive wound enlargement. The previously mentioned study by Vasavada et al. found a higher rate of endothelial misalignment and wound gaping in patients with a smaller incision size of 1.8 mm, suggesting that the integrity of the wound and its self-sealing properties can be compromised from pronounced wound stress.[25] Further reduction of the CCI to sizes as small as 1.8 mm may lead to a more difficult surgery without an improvement in clinical results. To avoid excessive wound stress during IOL implantation, we consider that the most important factor is choosing an appropriate initial incision size that matches the injector. Oshika et al. found very low values of CCI enlargement for incision sizes of 2.4 mm of 0.04 for the UltraSert and 0.10 mm for the iTec injector.[14] When we consider that in all study cases, the final incision size was larger than 2.4 mm, it seems reasonable to select 2.4 mm as an initial incision size for the 2 assessed injectors.

A limitation of our study is that the use of the IS was not compared intraindividually. Instead, the IS was used in randomly selected patients, and the results were compared with the patients who were treated without the IS. Interindividual differences in tissue properties and wound healing might bias the results. Furthermore, this was a secondary exploratory hypothesis-generating analysis because sample size calculation was based on the comparison of the 2 different injector models.

In conclusion, eyes treated with the Multisert showed less corneal incision enlargement from IOL implantation than eyes treated with the AutonoMe injector. Using the Multisert IS contributed to wound protection and led to a significantly lower wound enlargement compared with not using the shield. Despite the differences in incision enlargement, the functional outcomes including SIA and visual acuity were similar in all groups. We conclude that the observed difference in incision enlargement may be of limited clinical relevance.

Acknowledgments

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WHAT WAS KNOWN

- There is a trend toward smaller clear corneal incisions for standard cataract surgery procedures.
- The initial size of the clear corneal incision is not the final wound size because the incision is enlarged during many steps of cataract surgery.
- Different injector models are associated with different amounts of incision enlargement from IOL injection.

WHAT THIS PAPER ADDS

- The Multisert injector was associated with a significantly lower corneal incision enlargement than the AutonoMe injector.
- Multisert eyes treated with the insert shield in the advanced position showed significantly less incision enlargement than eyes treated without the insert shield.
- Functional outcomes were comparable in all groups, leading to the conclusion that the differences in incision enlargement are of limited clinical relevance.

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