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Time–efficiency assessment of guided toric IOL cataract surgery: a pilot study

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AU3

Purpose: To compare the time spent on toric intraocular lens (IOL) implantation during cataract surgery using a manual-marking vs a digital image-guided system (the Verion) for toric IOL alignment.

Settings: All procedures were performed at the Instituto Oftalmológico Quirónsalud ophthalmology clinic (A Coruña, Spain).

Design: We designed an experimental and longitudinal (1-month follow-up) study.

Methods: A total of 98 eyes of 65 participants (68.2 ± 12.2 years) were divided into 2 groups: 49 eyes operated with toric IOL alignment using a manual-marking technique (manual group) and another 49 eyes operated using image-guided marking (Verion group). The primary variable for comparison between both groups was cataract surgery time. Other outcomes such as toric IOL misalignment, spherical equivalent, astigmatism, uncorrected

distance visual acuity, and corrected distance visual acuity were also measured.

Results: The total cataract surgery time was 2:09 minutes shorter ($P < .001$) with the Verion system ($12:12 \pm 2:20$) compared with the surgical procedure performed using manual marking ($15:27 \pm 3:04$). One month after surgery, there were no statistical differences in terms of toric IOL misalignment between the Verion ($3.38^\circ \pm 2.95^\circ$) and the manual group ($4.66^\circ \pm 3.95^\circ$). No statistical differences were observed between groups for refractive and visual outcomes either ($P \geq .05$).

Conclusions: The cataract surgery time was reduced when the procedure was assisted using the Verion system to align the IOL compared with manual marking, maintaining the same efficacy in terms of toric IOL misalignment, residual refraction, and visual acuity.

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Current cataract surgery procedures enable accurate correction of refractive errors to avoid spectacle use or dependence on other optical corrections. Implantation of spherical intraocular lenses (IOLs) is intended for patients with low levels of corneal astigmatism due to their minimal impact on postsurgical visual quality.^{1,2} Corneal reshaping with limbal relaxing incisions or excimer laser is a postsurgical alternative for those patients with low corneal astigmatism affecting their vision.^{3,4} However, corneal astigmatism of 1 diopter (D) or higher that negatively affects visual quality requires the implantation of toric IOLs to compensate for the astigmatism.^{1,5} Prevalence studies estimate that 30% to 37% of patients have corneal astigmatism of 1 D or higher, which constitutes a considerable number of patients for implantation of toric IOLs in clinical practice.^{6–8}

Toric IOL implantation has been shown to be safe and effective for both correcting corneal astigmatism and improving visual quality compared with spherical IOLs.^{9–11}

Nevertheless, there are some limitations associated with this procedure, such as toric IOL tilt, decentration, and misalignment that could compromise both optical and visual quality after surgery.^{12–14} Postoperative IOL misalignment is a combination of IOL placement during surgery and rotation.^{12,15,16} Given that a 5-degree rotation of the toric IOL means that around 17% of corneal astigmatisms will not be corrected, accurate marking of the intended axis placement is therefore critical and can be performed manually or assisted using a digital imaging system.¹⁷

The development of cataract surgery during the last decade has allowed the incorporation of digital image-guided systems for toric IOL alignment.¹⁸ The Verion system (Alcon Laboratories, Inc.) incorporates a measurement module for capturing high-resolution images of the eye and a digital marker for projecting the toric IOL alignment through the oculars of the surgical microscope in real time.

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AU1

One of the advantages of image-guided systems for toric IOL alignment is their potential to save time in cataract surgery. However, to our knowledge, there is no scientific evidence supporting this idea. For this reason, the purpose of the current study was to compare the time spent on the implantation of a toric IOL during cataract surgery when the procedure is performed with manual marking and with the Verion system. Other variables such as toric IOL misalignment, refraction, and visual acuity (VA) were also measured.

METHODS

Study Design

An experimental and longitudinal study was conducted in compliance with Good Clinical Practice guidelines, European review board regulations, and the Declaration of Helsinki, revised in 2013.¹⁹ All procedures were performed on patients undergoing cataract surgery at the Instituto Oftalmológico Quirónsalud ophthalmology clinic (A Coruña, Spain). All patients provided written informed consent after having been informed about the procedures and were free to leave the study at any time, even after surgery, without their postoperative evaluation being affected.

The following variables were measured at different time points: time spent on cataract surgery was measured during the procedure; refraction and VA were measured 1 month after surgery; and toric IOL misalignment was measured 1 week and 1 month after surgery. The results of these variables were compared after use of the manual-marking procedure and the Verion system.

Sample

A total of 98 eyes of 65 participants were included in the study. By using a simple, nonblinded randomization method, the sample was divided into 2 groups with similar characteristics: 49 eyes operated using manual toric marking (manual group) and another 49 eyes operated using image-guided toric marking (Verion group). Patient demographic characteristics are summarized in

T1 Table 1.

Inclusion criteria were corneal astigmatism higher than ± 1.00 D, regular corneal astigmatism, and understanding and signing the written informed consent. Exclusion criteria were irregular corneal astigmatism, previous ocular surgeries that could affect visual outcomes, the presence of ocular or systemic diseases that could also affect outcomes, allergy to mydriatics, noncontrolled cardiac or hypertensive history, and any other contraindication for cataract surgery.

Preoperative Evaluation and IOL Calculation

The preoperative evaluation consisted of the following series of tests: uncorrected distance VA (UDVA), subjective refraction followed by corrected distance VA (CDVA), biometry with the IOLMaster 700 biometer (Carl Zeiss Meditec AG), corneal topography with the Orbscan II topographer (Bausch & Lomb, Inc.), high-resolution images of the eye obtained using the Verion reference unit or measurement module, and surgical planning.

An Acrysof toric IOL (model SN6AT3-9) was implanted in all patients. This IOL has an aspheric design with spherical powers from +6.00 D to +30.00 D, whereas its cylindrical powers are from -1.50 D (T3) to -6.00 D (T9) in 0.75 D steps at the IOL plane. The IOL power was calculated based on optical biometry data and the Barrett Universal II formula (http://calc.apacrs.org/barrett_universal210) targeting the first negative expected spherical refraction. The cylinder of the IOL base power was calculated using the manufacturer's online toric calculator from data obtained with the optical biometry, the theoretical surgically induced astigmatism, and the position of the corneal incision. For a corneal incision of 2.2 mm, the surgically induced astigmatism was assumed to be 0.10 D.²⁰

Surgical Procedure

All surgeries were performed by the same experienced surgeon (E.B.L.) under topical anesthesia. Furthermore, the same equipment was used, and the same operating room team participated in all cases. The phacoemulsification technique was assisted by the Vision Infiniti system. A 2.2 mm clear corneal incision was made (at 45° in the left eye and 135° in the right eye) for aspirating and irrigating the cortex. Similar incisions were performed in all patients to reduce potential variabilities due to differences at the incision site. The toric IOL was implanted with a hydraulic injector in the capsular bag through a self-sealing incision.

As for surgeries, manual marking of the astigmatism was performed by the same surgeon (E.B.L.). Marking was performed using the 3-step technique. First, with the patient seated, the horizontal corneal meridian (0°-180°) was marked with a Storz toric bubble marker assisted by slitlamp observation. Subsequently, with the patient supine on the operating table, the axis of astigmatism was marked with a Whitman axis marker. Finally, the toric IOL was aligned during the surgery by matching the mark of the lens and the axis of astigmatism.

For the image-guided digital marking, the Verion system captures high-quality images of the eye (conjunctival vessels, limbus, and iris) with the measurement module. These images are transferred to the digital marker of the system, which obtains a real-time image of the alignment axis through the right ocular of the microscope. The eye-tracking system minimizes the effect of ocular cyclotorsion and movement while the IOL is being aligned with the axis of astigmatism.

Table 1. Demographic Characteristics of the Study Participants in Both Groups.

Variable	Total sample (N = 98)	Group		P value
		Manual (n = 49)	Verion (n = 49)	
Age (y)	69.4 $\pm$ 11.3	68.9 $\pm$ 9.4	69.9 $\pm$ 13.0	.529 ^a
Men	52.0%	42.9%	61.2%	.069 ^b
Women	48.0%	57.1%	38.8%	
Right eye	43.9%	46.9%	40.8%	.541 ^b
Left eye	56.1%	53.1%	59.2%	
With-the-rule astigmatism	35.7%	40.8%	30.6%	.514 ^b
Against-the-rule astigmatism	46.9%	44.9%	49.0%	
Oblique astigmatism	17.3%	14.3%	20.4%	

Values are expressed as mean $\pm$ SD or frequency (%)

^aStatistical comparison between groups, Mann-Whitney U test

^bStatistical comparison between groups, Chi-square test

Measurement of Cataract Surgery Time

The total time spent on the cataract surgery was measured as the sum of 3 different periods (T1, T2, and TQx) using a timer. In the case of manual marking, the time was estimated from the moment the patient took a seat in front of the slitlamp to the time they got up (T1, corneal marking), then from the moment the eye speculum was positioned with the patient located on the operating table to when the manual marking was completed (T2, astigmatism marking), and finally from T2 to the moment the eye speculum was removed (TQx, surgical procedure), which comprised the intraoperative time.

With the procedure assisted by the Verion system, T1 represented the time from which patients took a seat in front of the measurement module to capture of the ocular images, T2 was the time spent by the digital marker to recognize the eye, and TQx represented the same period as in the surgery performed with manual marking.

Measurement of Toric IOL Misalignment

Toric IOL misalignment was measured 1 week and 1 month after the cataract surgery under mydriatic conditions obtained by topical instillation of 1% tropicamide combined with 10% phenylephrine. An image of the position of the toric IOL mark was taken with the IM600 slitlamp (Haag-Streit AG), and the angle of misalignment was quantified using the EyeSuite software, which can detect axis deviations up to 0.1° (Figure 1).

F1 can detect axis deviations up to 0.1° (Figure 1).

Analysis of Refractive Results

The refractive errors were obtained by conventional subjective refraction. The aim of this refraction was to achieve the maximum positive sphere for maximum VA. The refraction was analyzed in terms of spherical equivalent (SE) and astigmatism. Double-angle plots for astigmatism were drawn to compare the preoperative corneal astigmatism and the postoperative refractive astigmatism within each group.

Analysis of Visual Acuity

Both UDVA and CDVA were measured under photopic conditions by using the high-contrast (100%) Early Treatment Diabetic Retinopathy Study chart (VectorVision, Inc.), placed at 6 m. The units of measurement were expressed in decimal scale to calculate both the safety index and efficacy index as follows²¹:

Safety index = post-CDVA/pre-CDVA.

Efficacy index = post-UDVA/post-CDVA.

Statistical Analysis

Statistical analysis was performed using the IBM SPSS Statistics 25 software (IBM Corp.). The normality of all the study variables was assessed with the Kolmogorov-Smirnov test. For the quantitative comparison between groups, the Mann-Whitney *U* test was used for non-normal distributions, and the *t* test for independent samples for normal distributions. For the qualitative comparison, the Chi-square test was used. A statistical significance of 95% ($P < .05$) was established for all the statistical tests.

RESULTS

A total of 98 eyes of 65 participants (68.2 ± 12.2 years, range 35 to 91 years) in the study were assigned to either the manual or Verion group (Table 1). Mean age of the manual group was 68.9 ± 9.4 years, and for the Verion group was 69.9 ± 13.0 years, with no statistically significant differences between groups ($P = .529$). No statistical differences between groups were observed either in the rest of the demographic variables, such as sex ($P = .069$), eye selected for the surgery ($P = .541$), and direction of corneal astigmatism ($P = .514$). Therefore, there was no bias between groups before cataract surgery. No adverse events occurred during the study.

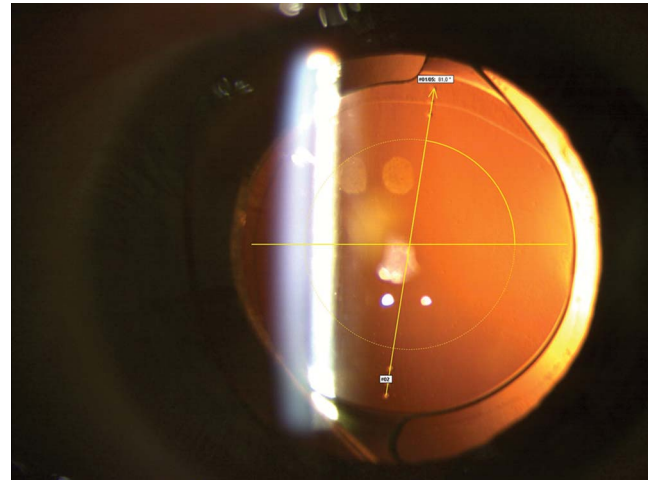


Figure 1. Slitlamp image of the toric IOL for calculating the angle of misalignment using the EyeSuite software. The axis of the toric IOL was calculated from the angle between the horizontal line and the line joining both marks of the lens.

Cataract Surgery Time

For the time spent on cataract surgery, the results of the differences between groups are expressed as minutes:seconds (min:s) (95% CI) (Table 2). The Verion system **T2** was 1:89 min:s faster on average in capturing the ocular images than the manual procedure for marking the horizontal corneal meridian (T1: $P < .001$). It was also 1:01 min:s faster on average in recognizing the eye than the surgeon for marking the desired axis of astigmatism (T2: $P < .001$). However, no statistically significant differences were observed between both groups for the rest of the surgical procedure (TQx: $P = .418$), which includes the phacoemulsification and toric IOL implantation. Thus, the mean of total time spent on cataract surgery was 3:15 min:s faster with the Verion system compared with the surgical procedure performed with manual marking ($P < .001$).

Toric IOL Misalignment

One week after surgery, the toric IOL misalignment was slightly higher in the manual group compared with the Verion group, but there were no statistically significant differences between groups ($P = .154$) (Table 3). After **T3** 1 month, the misalignment values remained similar in both groups, with no statistical differences between groups either ($P = .125$).

Refractive Results

The postoperative results of refraction showed that 85.7% of participants in the manual group reached an SE between ± 0.50 D, slightly less than 87.8% in the Verion group ($P = .766$) (Figure 2, A). The percentage of participants who **F2** obtained values between ± 1.00 D was 93.9% in the manual group and 98.0% in the Verion group ($P = .307$).

In addition, 79.6% and 89.8% of participants achieved astigmatism values between ± 0.50 D in the manual and Verion groups, respectively ($P = .161$), whereas 95.9% and

Table 2. Results of the Spent Time in Corneal Marking (T1), Astigmatism Marking (T2), Surgical Procedure (TQx), and Total Time in Both Groups.

Variable	Group		P value
	Manual	Verion	
T1 (min:s)	2:27 ± 0:43	0:38 ± 0:21	<.001 ^{a,*}
T2 (min:s)	1:26 ± 0:51	0:25 ± 0:11	<.001 ^{a,*}
TQx (min:s)	11:34 ± 2:49	11:08 ± 2:19	.418 ^b
Total time (min:s)	15:27 ± 3:04	12:12 ± 2:20	<.001 ^{b,*}

^aStatistical comparison between groups, Mann-Whitney *U* test

^bStatistical comparison between groups, *t* test for independent samples

**P* < .05

98% of participants obtained values between ± 1.00 D (*P* = .558), respectively (Figure 2, B). Figure 3 shows the double-angle plots for refractive astigmatism of both groups. In the manual group, the mean preoperative corneal astigmatism was 2.06 ± 0.69 D, and the postoperative refractive astigmatism was reduced to 0.29 ± 0.36 D after surgery. Similar results were found in the Verion group, showing a mean preoperative corneal astigmatism of 1.89 ± 0.80 D that was reduced to 0.23 ± 0.33 D for postoperative refractive astigmatism.

Visual Acuity

The postoperative results for UDVA showed that 59.2% of participants in the manual group achieved values of 0.8 (decimal units) or better compared with 77.6% in the Verion group (*P* = .051) (Figure 4, A). In addition, 83.7% and 93.9% of participants achieved values of 0.5 or better in the manual and Verion groups, respectively (*P* = .110).

With respect to CDVA, 79.6% of participants in the manual group achieved values of 0.8 or better compared with 85.7% in the Verion group (*P* = .424) (Figure 4, B). Finally, 93.9% and 98.0% of participants obtained values of 0.5 or better in the manual and Verion groups, respectively (*P* = .307).

With respect to both the safety and efficacy indexes, there were no statistically significant differences between groups. The safety index was 1.89 ± 1.12 in the manual group and 1.75 ± 1.75 in the Verion group (*P* = .254), whereas the efficacy index was 0.86 ± 0.16 in the manual group and 0.90 ± 0.15 in the Verion group (*P* = .136).

DISCUSSION

The current study examines the possibility of reducing the time spent on cataract surgery when assisted by a digital image-guided system for toric IOL alignment, the Verion. The outcomes obtained with this system were compared with those obtained using the manual-marking technique. For the first time, we report a statistically significant reduction in the time spent on cataract surgery with the Verion system, although there were no statistical differences between both methods for toric IOL marking in terms of toric IOL misalignment and postsurgical VA and refraction outcomes.

Because the visual and refractive advantages of these new digital systems are still unclear, the automation of toric IOL

Table 3. Results of Toric IOL Misalignment in Both Groups After Cataract Surgery (1 Week and 1 Month).

Misalignment (°)	Group		P value
	Manual	Verion	
1 wk	4.49 ± 3.94	3.30 ± 2.84	.154 ^a
1 mo	4.66 ± 3.95	3.38 ± 2.95	.125 ^a

Values are expressed as mean ± SD

^aStatistical comparison between groups, Mann-Whitney *U* test

marking with the Verion system could help to both minimize human error during cataract surgery and to reduce surgery times.^{17,22–24} As explained previously, the Verion system captures an image of the eye that is immediately imported to a recognition module in real time during the surgery. Using this procedure, we were able to reduce the cataract surgery time by more than 2 minutes compared with the manual-marking method described herein (Table 2). Thus, considering the total time required by both methods for toric IOL marking, and in the case of simultaneously working in 2 operating rooms, around 5 cataract surgeries could be performed in 1 hour with the Verion system compared with 4 with the manual-marking method. This would be possible because capturing an image

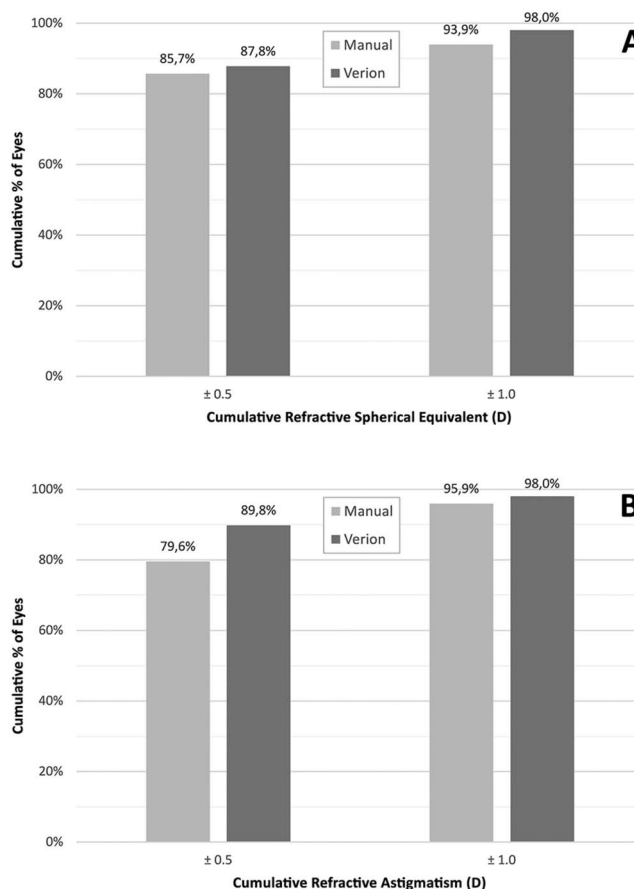


Figure 2. Cumulative percentage of eyes with different spherical equivalent (A) and astigmatism (B) values 1 month after cataract surgery.

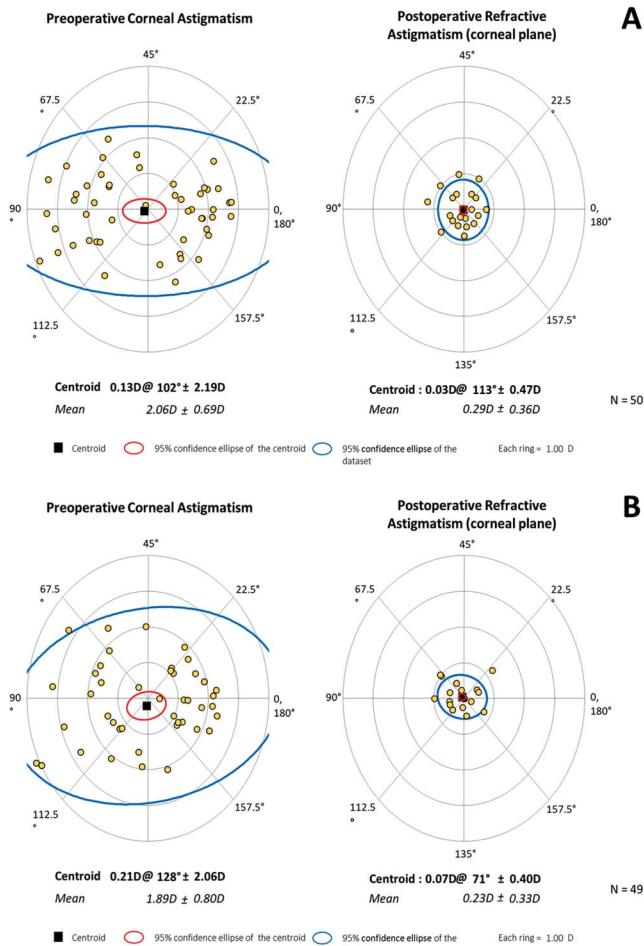


Figure 3. Double-angle plots for preoperative corneal astigmatism and postoperative refractive astigmatism in the manual group (A) and the Verion group (B). There was a similar correction of astigmatism in both groups after cataract surgery.

of the eye by the Verion system (T1) and its subsequent recognition (T2) is faster than the horizontal marking (T1) with the manual procedure, plus subsequent marking of the IOL axis (T2). No studies evaluating the time spent on cataract surgery assisted by the Verion or other similar digital systems were identified in the scientific literature.

With respect to toric IOL misalignment, there were no statistical differences between the Verion group and the manual group 1 week and 1 month after cataract surgery (Table 3). The misalignment values were less than 5° and remained stable in both groups during the follow-up visits. However, the SD was higher in the manual group, which suggests that toric IOL misalignment higher than 5° could be found in a larger number of participants operated using this manual procedure. This difference, although small, could be clinically significant in cases of high astigmatism in which it could have an impact on the final visual result and on the patient satisfaction. Thus, the higher the lens astigmatism, the worse the effects resulting from IOL misalignment. It should be noted that toric IOL misalignments higher than 5° would generate undesirable residual astigmatism that could affect the visual

quality.^{12,15,16} The main advantage of the Verion system to prevent this misalignment is that it incorporates an eye-tracking sensor to minimize the effect of ocular cyclo-torsion during cataract surgery.²⁵

Although there were no differences in terms of toric IOL misalignment between both groups, other studies with a larger sample size have reported better results with the Verion system compared with the manual-marking technique.^{17,22} Webers et al. found a toric IOL misalignment of $1.70^\circ \pm 1.50^\circ$ with the Verion system 3 months after cataract surgery, which was statistically lower than the one obtained using manual marking ($3.10^\circ \pm 2.10^\circ$).¹⁷ They obtained lower misalignment values with both methods compared with the current study, also reporting a higher SD with the manual procedure. Elhofi et al. also showed toric IOL misalignment with the Verion system ($2.40^\circ \pm 1.96^\circ$) that was statistically lower than the manual procedure ($4.33^\circ \pm 2.72^\circ$) 5 weeks after surgery; these findings are consistent with the aforementioned study by Webers et al.²² Several authors have also reported mean misalignment values less than 5° —considered as clinically acceptable—with other different methods for toric IOL marking.^{26–30}

As regards refractive results, there were no statistical differences in the number of patients who achieved SE and astigmatism values equal to or lower than ± 0.50 D or ± 1.00 D

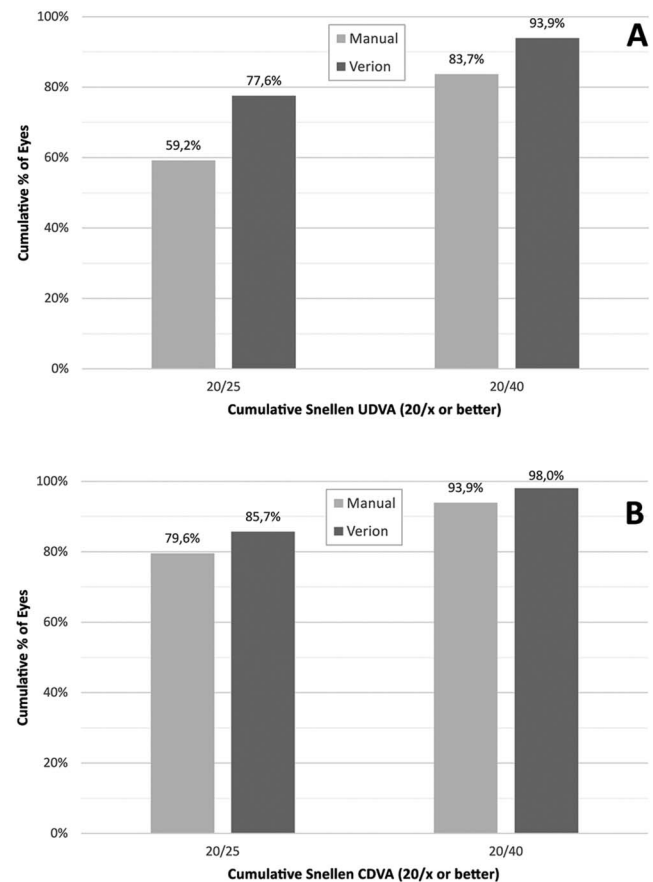


Figure 4. Cumulative percentage of eyes with different uncorrected distance visual acuity (A) and corrected distance visual acuity (B) values 1 month after cataract surgery.

between both groups (Figure 2). Nevertheless, the percentage of patients was slightly lower in the manual group for all the variables compared with the Verion group. In addition, the postoperative refractive astigmatism reached values close to 0.25 D in both groups, which is considered satisfactory after cataract surgery (Figure 3).² As previously mentioned, part of this manifest residual astigmatism could be associated with the toric IOL misalignment, since 5° of difference would imply an undercorrection of astigmatism of around 17%.^{12,15,16}

In agreement with our findings, both Webers et al. and Elhofi et al. found no statistical differences between the Verion system and manual marking in the number of patients with residual astigmatism.^{17,22} Other studies that evaluated the Verion system, albeit not in comparison to manual marking, reported both lower and higher numbers of patients with residual astigmatism compared with the current study.^{23,24} Furthermore, the toric IOL calculation with the Verion system should be done carefully because different studies have demonstrated that its keratometry is not completely interchangeable with other commercial devices.^{31–34} Nonetheless, in the current study, it should be noted that keratometry for calculating the toric IOL was measured with the IOLMaster 700 biometer, instead of with the Verion system.

Regarding visual analysis, as expected in cataract patients, the safety index showed that CDVA improved almost twofold after surgery compared with presurgical values in both groups. The efficacy index also showed that VA with and without optical correction was similar after toric IOL implantation, which would indicate the low spectacle dependence of these patients. Nevertheless, the latter statement should be interpreted carefully because other visual function variables (eg, low contrast VA and contrast sensitivity) or a questionnaire for assessing spectacle dependence were not evaluated. It should be noted that there were no statistical differences between both groups in terms of their safety and efficacy indexes or in the percentage of patients who achieved UDVA and CDVA values equal to or worse than 20/40 or 20/25 (Figure 4). However, although there were no statistical differences in UDVA, the percentage of patients who achieved values above 20/25 was more than 15% in the Verion group, reaching a *P* value close to 0.049 (*P* = .051). The studies by Webers et al. and Elhofi et al. found no statistical differences between the Verion system and manual marking for either UDVA or CDVA.^{17,22} Finally, it is also important to highlight that VA could be affected due to residual astigmatism derived from toric IOL misalignment, especially in those patients with medium or high presurgical corneal astigmatism.^{12,15,16}

One of the limitations of the current study is the short follow-up of only 1 month, so monitoring the stability of the different variables for a long-term period is needed. However, the main objective was to evaluate the improvement in the cataract surgery time with the Verion system. Another limitation is that the results obtained with the Verion system have not been compared with other

image-guided systems for toric IOL alignment. Accordingly, the advantages or disadvantages of the Verion system compared with other commercially available devices are still unknown.

In conclusion, the Verion system reduced the time spent on cataract surgery compared with the procedure assisted by manual marking for toric IOL alignment, maintaining the same efficacy in terms of toric IOL misalignment, residual refraction, and VA. The Verion system could therefore be a useful tool to save time in cataract surgery, with the consequent benefit for clinical practice.

WHAT WAS KNOWN

- Toric IOL implantation has been shown to be safe and effective for both correcting corneal astigmatism and improving visual quality compared with spherical IOLs.
- Given that a 5-degree rotation of the toric IOL means that around 17% of corneal astigmatisms will not be corrected, accurate marking of the intended axis placement is therefore critical.
- The development of cataract surgery during the last decade has allowed the incorporation of digital image-guided systems for toric IOL alignment with advantages as their potential to save time in cataract surgery. However, to our knowledge, there is no scientific evidence supporting this idea.

WHAT THIS PAPER ADDS

- The Verion digital system is safe and efficient when used to toric IOL alignment in cataract surgery.
- As using Verion digital system reduces the time spent in cataract surgery, it is worth considering using digital systems to toric IOL alignment.

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000 Time—efficiency assessment of guided toric IOL cataract surgery: a pilot study

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We show, ~~to our knowledge, for the first time~~ a significant reduction in the time spent on cataract surgery when using the Verion system compared with the surgical procedure performed by manual marking.