• Review Article •

Image-guided lens extraction surgery: a systematic review

Eirini-Kanella Panagiotopoulou, Panagiota Ntonti, Maria Gkika, Aristeidis Konstantinidis, Irfan Perente, Doukas Dardabounis, Konstantinos Ioannakis, Georgios Labiris

Department of Ophthalmology, University Hospital of Alexandroupolis, Dragana, Alexandroupolis 68100, Greece
Correspondence to: Eirini-Kanella Panagiotopoulou. Department of Ophthalmology, University Hospital of Alexandroupolis, Dragana, Alexandroupolis 68100, Greece. eipanagi@med.duth.gr
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Abstract

● **A systematic review of the recent literature regarding the current image-guided systems used for cataract surgery or refractive lens exchange was performed based on the PubMed and Google Scholar databases in March 2018. Literature review returned 21 eligible studies. These studies compared image-guided systems with other keratometric devices regarding their accuracy, repeatability and reproducibility in measurement of keratometric values, astigmatism magnitude and axis, as well as in IOL power calculation. Additionally, the image-guided systems were compared with conventional manual ink-marking techniques for the alignment of toric IOLs. In conclusion, image-guided systems seem to be an accurate and reliable technology with measurements of high repeatability and reproducibility regarding the keratometry and IOL power calculation, but not yet interchangeable with the current established and validated keratometric devices. However, they are superior over the conventional manual ink-marking techniques for toric IOL alignment.**

● **KEYWORDS:** image-guided systems; cataract surgery; toric intraocular lenses; systematic review

INTRODUCTION

In the last few years, technological progress has revolutionized the preoperative and intraoperative phase of cataract surgery. As a result, nowadays, only an excellent refractive outcome can meet high visual expectations of patients and increase their satisfaction[1-2]. According to the published experience, approximately 20% to 30% of patients prior to cataract surgery have corneal astigmatism of 1.25 diopters (D) or higher[3-4], while the prevalence of corneal astigmatism >2.00 D is 8%[5]. This prevalence varies according to the race and the country of origin of the different examined samples[6]. If this astigmatism is not corrected intraoperatively, patients will be probably spectacles dependent. There is a variety of methods for astigmatism correction during the lens extraction surgery. Among them, extended-on-axis incision (EOAI), limbal relaxing incisions (LRI), opposite clear cornea incision, femtosecond laser assisted keratotomy and the implantation of toric intraocular lenses (IOLs)[7-9]. Toric IOL implantation is an effective method for correction of higher astigmatism and results in a high proportion of spectacles independence for distant vision and high patient satisfaction[10-11]. An additional refractive option is the correction of astigmatism simultaneously with a good patient's vision for distance, intermediate and near with the implantation of multifocal toric IOLs[12-15].

One of the commonest reasons for patients' claims after cataract surgery is the insertion of a wrong power IOL due to incorrect keratometry[16]. There is a variety of devices that perform keratometry. Among them, partial coherence interferometry (PCI), rotating Scheimpflug camera, Placido disc-based corneal topography, autorefraction/autokeratometry optical low-coherence reflectometry (OLCR) and low-coherence interferometry. Additionally, image-guided systems are a new technology which is recently introduced and provides keratometry (K) measurements.

Another essential factor for a good postoperative refractive outcome and high patient satisfaction is accurate alignment of toric IOL. According to a great number of studies, it has been found that 1 degree of toric IOL misalignment leads to 3.3% reduction in the astigmatism correction, namely to residual astigmatism that is 3.3% of the initial corneal astigmatism magnitude if the cornea and IOL cylinders are equal[17-20]. Moreover, ocular cyclotorsion can cause a deviation in astigmatism axis. This deviation could result in residual astigmatism, too, and decrease the postoperative visual outcome.

Table 1 Studies design

Studies	Comparative studies	Descriptive studies	Prospective studies	Retrospective studies
References	1-2,22,24,26-41	25	1-2,25-33,41	22,24,34-38
No. of studies	20	1	12	7

In order the cyclotorsion to be compensated and toric IOL misalignment to be minimized, a number of different conventional manual marking techniques have been used for the alignment of these IOLs. However, image-guided systems, apart from keratometry, are able to provide digital image guidance for toric IOL alignment without preoperative manual marking.

In 2010, Osher[21] introduced the concept of iris-fingerprinting, which uses the landmarks of the iris, including iris crypts, nevi and brushfield spots in order to place the axis marks. Osher Toric Alignment System (OTAS, Haag-Streit, Koeniz, Switzerland) constituted the basis for the creation of a noticeable number of image-guided systems. The most common current surgical-guidance systems are the Alcon Verion Image-Guided System (Alcon Laboratories, Inc., Fort Worth, Texas, USA) and the Zeiss Callisto Eye and Z align (Carl Zeiss Meditec AG, Dublin, CA)[22-23]. Another similar system is TrueVision 3-D (3 dimensional) Surgical System (TrueVision Systems, Inc., Santa Barbara, California)[24]. However, these systems are recently introduced. As a result, there is a need for evaluation of the accuracy and the repeatability of their measurements as well as the interchangeability of such measurements with those obtained with other corresponding commonly used devices.

Within this context, primary objective of this study is to review the recently published literature regarding image-guided cataract surgery or refractive lens exchange (RLE), describing the current image-guided systems, comparing them with other conventional devices or techniques and examining if image-guided systems are suitable as alternative tools in clinical practice.

MATERIALS AND METHODS
A systematic search for relevant studies was performed based on the PubMed and Google Scholar databases using the following search terms: image-guided cataract surgery, Verion, Callisto AND cataract surgery, TrueVision. The search took place in March of 2018. Search filters and language restrictions were not used in this initial search. The results of this search were checked and only articles with a relative to the subject title were selected. Afterwards, the abstracts and full texts of these selected articles were reviewed thoroughly and the following data were extracted and assessed: keratometric measurements, astigmatism power, astigmatism axis, repeatability, reproducibility, interchangeability, toric IOL alignment, misalignment, rotation, ocular cyclotorsion,

preoperative examination and alignment time, surgery time, duration of preoperative examination, and patient comfort. Both comparative and descriptive studies in adult patients were included in this review. Articles not available in English or German language were excluded. When the eligible articles were not available in full text, abstracts were used as a source of information.

RESULTS
Studies' Design The present review included 1 descriptive[25] and 20 comparative[1-2,22,24,26-41] studies. Among them, 12 were prospective studies[1-2,25-33,41] and 7 retrospective[22,24,34-38], while there was not any relative statement in the rest 2 studies[39-40] (Table 1). Eight studies compared the accuracy of toric IOL alignment using image-guided systems versus different conventional manual marking techniques[24-28,34,39,41], whereas Hura and Osher[22] made a comparative evaluation of the alignment meridian generated by two different image-guided systems. Among the other objectives of Mayer et al study[28] was the comparison of the required time of cataract surgery with implantation of a toric IOL using digital and manual marking techniques, while the main objective in the study of Thomas et al[29] was the comparison of the duration of the preoperative examination and patient comfort between measurements with an image-guided system and other established keratometry devices. In addition, 7 studies[1-2,30,35-37,40] made a comparison in the keratometric measurements of image-guided systems with other devices used in current clinical practice, while two studies[31,37] compared an image-guided system with other devices regarding the IOL power calculation. Finally, the intraobserver repeatability[1,30,32-33,36,40], the reproducibility[32,36], and the interchangeability[1-2,33,36] of keratometric measurements obtained with image-guided systems were analyzed in some studies of this review.

Patients' Selection Criteria Patient selection was presented to be very crucial for the best possible assessment of the relatively recently introduced surgical-guidance systems and their objective comparison with other devices used in current ophthalmological practice. In this way, it will be evaluated if this new method has the potential to be an alternative complete assessment tool in clinical practice. Therefore, most studies dealt thoroughly with patients' inclusion and exclusion criteria. The most common inclusion criterion was a positive diagnosis of cataract with no other existing ocular pathologies[2,25-28,34-38,41]. However, there were a number of studies, which had as

inclusion criterion the existence of healthy eyes, namely eyes with healthy corneas, without cataract or any other prior ocular disease[1,29-31,33,36,40]. The latter studies in their majority examined the repeatability and/or the interchangeability of image-guided systems[1,30,32-33,36,40], while the rest of the studies that included healthy eyes evaluated the time that the preoperative examination with image-guided systems lasts and the patient comfort[29] or assessed the influence of corneal radii measured by these systems on IOL power calculation in comparison with other imaging modalities[31]. Moreover, Lauschke et al[36] included patients scheduled not only for cataract surgery, but also for RLE.

Additionally, some of the studies took into consideration the preexisting corneal astigmatism. Three studies included patients with corneal astigmatism greater than or equal to 1.25 D[26-28], whereas in another study the corneal astigmatism should be 1 D or higher[41]. Corneal astigmatism in the study of Raucau et al[25] had to be 0.75 D or more against-the-rule (ATR) or oblique (OBL), or at least 1 D with-the-rule (WTR). The astigmatism should be stable[25,28] and regular[25-28,35,38]. Patient with either irregular or progressive astigmatism were excluded from analysis. Ruiz-Belda et al[33] included patients with refraction error between +5 D and -10.00 D. Zhao et al[39] set a best-corrected distance visual acuity (BCDVA) restriction of 0.02 or higher with fixation capability, while Velasco-Barona et al[1] included patients with BCDVA of 20/20. Finally, the retrospective study of Davison and Potvin[38] included only patients with implanted AcrySof® IQ Toric hydrophobic single-piece acrylic lenses and accurate measurements from IOLMaster (Carl Zeiss Meditec AG) and Pentacam (Oculus Optikgeräte GmbH, Germany).

Some common exclusion criteria, apart from irregular astigmatism, were previous ocular or intraocular surgery[1-2,26,28-31,33-34,36], previous or current ocular disease[29-31,33], acute or chronic corneal infection or inflammatory conditions[34,41], ocular trauma[1-2,30], glaucoma[1,26,28,41], maculopathy due to age-related macular degeneration (ARMD), diabetic retinopathy (DR) or other causes[25-26,28,35,41], other retinal diseases[35], any anterior segment disease that could affect the accuracy of keratometric measurements[2,35,40] and contact lens wear history 2wk before the examination[1-2,29-31,40].

Some additional exclusion criteria were amblyopia[25,41], central corneal scars[25,33], ectatic corneal disease[33], keratoconus[37] or pterygium[35] that could cause irregular astigmatism, previous corneal surgery[26] including refractive surgery, namely laser-assisted in situ keratomileusis (LASIK) or photorefractive keratectomy (PRK), and corneal transplantation[37], corneal opacities[28,33,35], and generally any type of corneal pathology[1-2,36] that could affect the keratometric outcome.

Furthermore, patients with high or special refractive errors[33,35], nystagmus[34-35], and poor cooperation[35] were excluded from some studies. Velasco-Barona et al[1] excluded also patients with current taking of any kind of ocular medicine other than eye lubricant. Davison and Potvin[38] excluded the eyes with a toric IOL misaligned more than 10 degrees and eyes with 4.25 D or higher of anterior corneal astigmatism. Zhao et al[39] did not include patients with systemic or ocular diseases which may cause ocular myopathy. The unavailability of data for any of the examined parameters due to noncompletion of all measurements was another cause of rejection[35-37].

Regarding patients' age, only studies on adults were included in this review. The participants' age varied from 18[1,29-31] to 91[34] years old. The age of patients was considered as an exclusion criterion in four studies[1,26,30,33]. For example, three of them included patients 18 years old or older[1,26,30], while Ruiz-Belda et al[33] included only patients >30 years old. In the study of Velasco-Barona et al[1], patients older than 60 years old were excluded. Thomas et al[29] divided patients into three age-groups and analysed comparatively their parameters.

Finally, in some studies only right eyes were examined[1-2,32,35-36], in other studies one eye was chosen randomly[26,29-31,33,40-41], while other researchers included both eyes[25,27-28,34,37-39].

Image-Guided Systems Surgical-guidance systems are a recently introduced technology used for cataract surgery and RLE. They have been designed to help the surgeon with a preoperative planning of the size and location of the surgical incisions and capsulorrhexis, as well as correct placement of IOLs and accurate alignment of toric IOLs. These systems give the opportunity to the surgeon to see in real time intraoperatively the aforementioned measurements.

SensoMotoric instruments GmbH An earlier version of current image-guided systems was the Surgery Guidance platform SensoMotoric Instruments GmbH (SMI)[32]. This platform is an automated keratometer that consists of the following two units: the SMI Reference Unit, which makes the preoperative measurements, and the SMI Surgery Pilot, which is used for the intraoperative alignment of the toric IOL. SMI Reference Unit is a non-contact modality that photographs the eye and simultaneously performs automated keratometry. It uses the reflection of 12 concentric light emission diodes within a ring of 1.9 mm diameter in order to measure corneal curvature.

VERION A descendant of SMI Reference Unit is the recently introduced VERION image-guided system (Alcon Laboratories, Inc., Fort Worth, TX, USA) which was evaluated for the first time by clinical trials in 2013. The VERION, like the SMI Surgery Guidance Platform, is composed of two units: the VERION Reference Unit and the VERION Digital Marker (VDM). The Reference Unit includes two modules: the Measurement Module, and the Vision Planner[42].

VERION Reference Unit

Measurement module The measurement module of the VERION Reference Unit is a non-contact point-based keratometry device. This module captures a high-resolution preoperative reference image of the eye which can be used to document the center of the undilated pupil, corneal reflex position or eccentricity of the visual axis, scleral vessels and iris structures. It can be also used to measure biometric ocular parameters including keratometric measurements, corneal radii, the magnitude of astigmatism, limbus position and diameter, white-to-white (WTW) horizontal distance, and pupillometry[42].

Examination procedure During the examination, subjects were seated in an upright position with their chin on the chinrest and their forehead against the Measurement Module. The operator instructs them to look at the red fixation light and targets the center of the cornea by using the joystick. During the adjustment, arrows on the screen show the direction the examiner needs to move the Measurement Module (forwards or backwards). During the phase of adjustment (focusing phase), the device takes several infrared pictures and when a green circle appears in the center of the cornea, the examiner pushes the button of the joystick in order to take a snapshot (snapping phase). During the adjustment, four signals appear on the monitor, namely "Centration", "Corneal Power", "Focus" and "Fixation". If they are green, the setting is accurate. On the taken snapshot, three signals are displayed called "Astigmatism", "Vessel" an "Corneal Power" showing the quality of the photo. Ideally, these signals should be green as well. It is recommended for operators to repeat this procedure three times consecutively in each eye[1-2,40].

Light-emitting diode The VERION Reference Unit uses 1 red light-emitting diode (LED; 624 nm) for patient fixation. It calculates the curvature and power of the cornea by calculating the position and shape of 15 projected light reflections on the cornea created by 3 near-infrared LEDs (830 nm) and 12 white LEDs (450 nm). The measurement procedure takes place in two steps. During the first step, the reflections of the 3 near-infrared LEDs, which cover a diameter of 0.8 to 1.2 mm, are used to calculate the corneal spherical power during the focusing phase. In this phase, the examiner varies manually a few times the distance between the device and the cornea. During the second step, the reflections of the 12 white LEDs, which cover a diameter of approximately 2.8 mm on the central cornea, are used to determine the corneal cylinder and astigmatism axis.

Vision planner Vision planner is the second component of the Verion Reference Unit. It enables planning the cataract surgery steps, namely it allows the import of the keratometric data measured by the Measurement Module of the image-guided system as well as the modification of K values by manually entering the keratometric measurements performed by another keratometry system. Additionally, Vision Planner enables calculating the power of toric or multifocal IOL using different formulas, selecting the optimum location of corneal and limbal incisions by providing an astigmatism planner, selecting the preferred diameter and centration of capsulorrhexis as well as IOL centration and position after the visual identification of the optical axis[30,33].

VERION digital marker After the planning of the surgical procedure, the operator exports the data to a universal serial bus (USB) stick or uploads them onto a network in order to transfer them to the digital marker. VERION digital marker (VDM) is located in the operating room and allows the surgeon to see in one of the oculars of the operating microscope in real-time a digital tracking overlay picture after the intraoperative image registration. This system corrects automatically the cyclotorsion by recognising scleral vessels and landmarks of the iris and visually guides the surgeon for the size and location of corneal incisions and capsulorrhexis. Moreover, it assists the surgeon in controlling the IOL centration and performing accurate IOL alignment in case of toric IOL implantation, calculates surgically induced astigmatism (SIA) and optimizes the constant of the IOL in case of postoperative follow-up and repeated measurements which are taken by this system[30,33,40].

CALLISTO The Zeiss Callisto Eye (Carl Zeiss AG, Dublin, CA) constitutes a computer assisted cataract surgery system that helps the surgeon to plan in advance of surgery the location and the size of the surgical incisions, including the position of LRI (Incision/LRI Assistant) and capsulorrhexis, as well as the position of the implant according to the optical axis of the patient's eye (Rhexis Assistant). A preoperative image is captured with the IOLMaster 500 or 700 and the report with the relevant biometry data can be transferred and be available for review in the operating room. An additional assistance function performed with Z Align-Toric assistant is the use of reference axis from the ZEISS IOLMaster and the use of target axis in the microscope eyepiece in order to provide accurate markless alignment of toric IOLs[43].

TrueVision 3D Surgical System TrueGuide® Computer-Guided Surgery is a 3-dimensional (3D) visualization system contributing in the dynamic, real-time optimization of incision placement, capsulorrhexis location, IOL centration, and precise toric implant alignment taking into consideration the SIA and cyclotorsion. TruePlan® is a surgical planning application that collects and stores all diagnostic variables that are necessary for the creation of a customized surgical plan which is afterwards sent to the TrueGuide in the operating room. TruePlan can collect data from a variety of preoperative devices, such as i-Optics Cassini corneal LED topographer,

OCULUS Keratograph 5M and OCULUS Pentacam AXL, as well as Haaf-Streit Lenstar[24].

Comparison of keratometric measurements/corneal power between VERION and other keratometric devices Among the available image-guided systems, only the VERION Reference Unit is able to perform keratometry measurements. Therefore, this is the only surgical-guidance system that is compared in this review with the current established keratometry devices regarding the accuracy in measurement of keratometry as well as astigmatism magnitude and axis. The total of studies examining keratometry are presented in Table 2.

Comparison between VERION and IOLMaster IOLMaster is an optical biometer which uses autokeratometry in order to measure the anterior curvature of the cornea. It is based on PCI and is considered to be the gold standard for keratometry and preoperative calculation of IOL power. In contrast with the VERION, which uses 12 light reflections in the central 2.8 mm of the cornea for the calculation of corneal cylinder and 3 LEDs which cover a diameter of 0.8 to 1.2 mm of the central cornea for the determination of corneal spherical power, the IOLMaster 500 collects keratometric data projecting 6 LEDs onto the central 2.3-2.5 mm of the cornea in a hexagonal pattern[2,30-31,36-37,40]. There are numerous studies which compare the VERION with the IOLMaster and examine the level of agreement regarding the keratometric measurements obtained by these devices. Asena et al[2] found that keratometric values [flat K readings (K1), steep K readings (K2) and mean K readings (Km)] obtained by the VERION system were significantly higher than the values obtained by the PCI biometer (K1, K2: P=0.01, Km: P<0.05). Nevertheless, the mean difference was quite small (<0.20 D). Therefore, it was not expected to have a relevant clinical effect. Additionally, in the same study[2], although the power of the astigmatism between these devices were very similar, the variation of astigmatism axis was not acceptable and the difference was clinically relevant. As a result, an unexpected refractive error could be possible in case of toric IOL implantation.

On the contrary, in the study of Thomas et al[31], flat (R1), steep (R2) and average (R) corneal radii were found to be significantly flatter with the VERION image-guided system than with the PCI device (P<0.01). A possible explanation for these results is the difference in measurement methods, namely VERION provides 12 light reflections in a central corneal diameter of 2.8 mm, while the IOLMaster 500 uses 6 light reflections on the central 2.5 mm. Due to the fact that a normal cornea is steeper in the center than in its periphery, it is expected that more central measurements, like with IOLMaster, can produce steeper curvature readings[44]. Mueller et al's study[30] showed that the R1 and R measured by the image-guided system was significantly higher than the

Table 2 Comparison of keratometric devices in measurement of keratometry parameters

Compared devices	References
VERION *vs* IOLMaster	2,30,31,36,37,40
VERION *vs* Pentacam	30,36,37
VERION *vs* Lenstar	30,31,35
VERION *vs* Topcon KR-8800/KR-8900	2,35,36
VERION *vs* OPD-Scan III	35,37
VERION *vs* AL-Scan	35,37
VERION *vs* Tonoref II	37
VERION *vs* Aladdin	33

IOLMaster. However, the steep axis of astigmatism did not differ between the two keratometry systems.

On the other hand, there are a number of studies[36-37,40] which did not found any significant difference between the VERION system and the IOLMaster as regards the K values, magnitude and axis of astigmatism, as well as vectors J0 and J45. Additionally, in one of these studies[37], where the participants were placed in a WTR and an ATR astigmatism group, the IOLMaster measured the biggest astigmatism power, while the image-guided device measured the second highest power among 6 keratometry devices (VERION, IOLMaster, AL-Scan, Pentacam, OPD-Scan III, Tonoref II). Moreover, the highest axis of astigmatism was obtained with the VERION.

Comparison between VERION and Pentacam A second keratometry module which is compared in many studies with image-guided systems is Pentacam. This is a corneal topography device, which uses a rotating Scheimpflug camera to measure, among other parameters, both the anterior and posterior corneal curvature and to calculate the corneal thickness. During the rotation of the Scheimpflug camera, 25 separate images of the eye are recorded resulting in a composite image, which is focused across the whole surface of the cornea. Pentacam is particularly useful for screening before refractive surgery and for the diagnosis of keratoconus. However, it provides keratometry measurements which have been repeatedly compared with these of other established keratometry systems.

In two studies of the literature[30,37], it was observed that R1 and R2 were significantly lower when they were measured with the Scheimpflug device than with the image-guided system. However, Lauschke et al[36] did not found any significant difference between the VERION system and the Pentacam as regards the Km, corneal cylinder, axis and vectors J0 and J45 (P>0.05). In Schultz et al's study[37], the smallest astigmatism power of the ATR group was measured with the Pentacam among 6 keratometry devices (VERION Reference Unit, IOLMaster, Pentacam, AL-Scan, OPD-Scan III and Tonoref II).

Comparison between VERION and Lenstar The Lenstar LS900 device (Haag-Streit AG, Köniz, Switzerland) is a system based on optical low-coherence reflectometry (OLCR). It provides 2 concentric rings of 32 (2×16) light reflections (infrared light, 950 nm) in a central array of the anterior corneal surface with each zone having a diameter of 1.65 mm and 2.30 mm. These lights are used for keratometry. Furthermore, the OLCR device measures WTW dictance, central corneal thickness (CCT), anterior chamber depth (ACD), pupil diameter (PD) and axial lenght (AL). According to the literature, all studies[30-31,35] reported similar results as regards the comparison of flat, steep and average corneal radii between the image-guided system and OLCR device showing no significant differences. In addition, the measured steep axis did not differ significantly between the two devices[30,35].

Comparison between VERION and Aladdin Aladdin system (Aladdin, Topcon, Tokyo, Japan) is an optical biometer based on non-contact optical low-coherence interferometry and Plasido-disc topography. Actually, it can perform numerous measurements. Among them, AL, ACD, corneal topography, pupillometry, WTW distance, CCT, keratometry, lens thickness, corneal diameter and corneal wavefront analysis. It uses a superluminescent diode with wavelength of 830 nm that can penetrate high-density cataracts[33,45]. Finally, it can make IOL power calculations for cataract surgeries. The keratometry comparison of the Aladdin with the VERION was performed by one article in the literature. Ruiz-Belda *et al*[33] found significant but clinically acceptable differences in K1, K2 and astigmatism power, whereas the axis of the flattest corneal meridian measured from the VERION was significantly similar with this one measured from the Aladdin biometer, but a clinical relevance was observed (mean difference: 15.74 degrees).

Comparison between VERION and Topcon KR-8800/KR-8900 The Topcon KR-8800 and KR-8900 (Topcon Corp., Tokyo, Japan) are two auto-keratorefractometers (AKRs). They are rotary prism systems which use reflections projected on the anterior corneal surface within a 3 mm diameter. The keratometric measurements of these AKRs were evaluated in many studies in comparison with the image-guided system. Asena *et al*[2] found significantly higher K1, K2, Km and mean magnitude of astigmatism with VERION *vs* KR-8900 (*P*<0.05). Nevertheless, their mean difference was <0.25 D. Therefore, it was not expected to have a relevant clinical effect. A possible explanation for this difference is the smaller diameter of the region that is measured by the VERION (2.8 mm) comparing to the AKR (3.00 mm). It is known that a normal cornea is steeper in the center than in its periphery. Consequently, more central measurements can result in steeper curvature readings[43].

Furthermore, there was a significant difference (>20 degrees) in the axis of astigmatism between the two instruments in 17% of patients. This is an unacceptable, clinically relevant difference, with VERION having higher axis, and could lead to unpredictable refractive errors in case of toric IOL implantation. In the study of Lin *et al*[35], the corneal cylinder value was significantly higher measured with VERION than with KR-8800 (*P*<0.05), whereas K1, K2 and Km did not showed any significant difference. Additionally, it was found that these two devices had the largest width for the 95% limits of agreement (LOA) in the measurement of astigmatism axis among 5 keratometry devices (VERION Reference Unit, OPD-Scan III, LenStar LS900, AL-Scan, and KR-8800). Some other researchers[36] did not observe any significant difference between the VERION and the AKR regarding Km, corneal cylinder, steep axis and vectors J0 and J45.

Comparison between VERION and OPD-Scan III The OPD-Scan III wavefront aberrometer (Nidek Co., Ltd.) is a Placido-based corneal topography and measures wavefront error using dynamic sciascopy. It has a built-in Placido disc that is composed by 33 blue rings with 11 880 data points. This instrument can provide keratometry measurements and determine the aberrometry of the whole eye, the cornea, and the difference[35,37]. In this review, two articles comparing the VERION and the OPD-Scan III were examined. In the first article[35], it was mentioned that significant differences were observed in K1, K2 and Km with greater values obtained with the VERION, but there was not any significant discrepancy in corneal astigmatism magnitude and corneal astigmatism axis between the two compared modules. Schultz *et al*[37] also found that K2 values of the VERION were significantly higher than those of the OPD-Scan III, and astigmatism magnitude measured with the VERION was significantly lower.

Comparison between VERION and AL-Scan The AL-Scan (Nidek Co., Ltd.) is an optical biometer that uses PCI technology to provide keratometric measurements *via* projection of monochromatic LEDs on the cornea (2 rings with diameter 2.4 and 3.2 mm respectively). Some additional capabilities of this device is the measurement of WTW, CCT, ACD, PD, and AL values[35,37]. The AL-Scan was compared with the VERION in some studies of the literature. In one of them[35], corneal astigmatism power and axis, K1, K2, and Km from VERION had no significant difference from the corresponding parameters of AL-Scan (2.4 mm zone). As regards the astigmatism axis, the AL-Scan showed the smallest difference from the VERION among three other keratometric devices (Lenstar, OPD III, KR-8800). Schultz *et al*[37] found that the AL-Scan both with a 2.4 and 3.2 mm zone showed no difference with the VERION in K1 and K2 values. However, the K2 measured by the VERION were slightly higher than

those measured by the AL-Scan (2.4 mm zone). Moreover, in the same study, it was found that there was no difference in the axis of astigmatism between the VERION and AL-Scan (2.4 mm), while the difference was significant when the AL-Scan 3.2 mm radius was compared to the VERION. The optical biometer (3.2 mm) measured the smallest astigmatism axis angle (83.5 degrees) in the group with ATR astigmatism.

Comparison between VERION and Tonoref II The Tonoref II (Nidek Co., Ltd.) combines an auto refractometer, auto keratometer and non-contact tonometer in one unit. It is enable to measure K values *via* projection of 4 infrared LEDs on a diameter of 3.3 mm of the cornea. One study of the literature studied the differences in the keratometric measurements and astigmatism between the VERION and the tonometer-refractometer[37]. It showed that there was no significant difference between the VERION and the Tonoref II regarding the K1 and power of astigmatism. On the other hand, it was found that K2 values of the VERION were higher than those of the tonometer-refractometer.

IOL Power Calculation: comparison between VERION and other keratometric devices A precise preoperative calculation of IOL power plays a pivotal role in the best possible refractive outcome of a cataract surgery and RLE. Gold standards for the calculation are the IOLMaster PCI device and the recently introduced Lenstar OLCR device. The VERION is a new module which also enables calculating the power of IOL.

In some studies of this review, researchers examined in how many cases surgeons would have been chosen the same IOL power with different keratometry modules (Table 3). The target refraction was emmetropia (0.0 D)[31,37]. If emmetropia was not feasible, the choice of the IOL power was defined as the nearest negative target refraction[31]. The calculation of the IOL power using the image-guided system, in one study[31], showed significant differences compared to the IOLMaster. The SRK/T formula gave the lowest mean difference. However, there was not any significant difference in the study of Shultz *et al*[37]. Additionally, the VERION calculated significantly different IOL power than the Scheimpflug camera and wavefront aberrometer[37]. In particular, the average IOL power calculated by the former is significantly lower than this calculated by the Pentacam HR and OPD Scan III[37]. Finally, no differences were found when the VERION was compared with AL-Scan optical biometer (2.4 mm and 3.2 mm)[37] and OLCR device[31]. Nevertheless, in both studies, the mean difference among all devices and different IOL calculation formulas was smaller than the typically provided step for IOL power (<0.50 D). In the study of Thomas *et al*[31], the same IOL power would have been chosen in approximately two thirds of cases when the surgeon used the image-guided system and the PCI device or

Table 3 Comparison of keratometric devices in IOL power calculation

Compared devices	References
VERION *vs* IOLMaster	31,37
VERION *vs* Pentacam	37
VERION *vs* Lenstar	31
VERION *vs* Topcon KR-8800/KR-8900	NA
VERION *vs* OPD-Scan III	37
VERION *vs* AL-Scan	37
VERION *vs* Tonoref II	NA
VERION *vs* Aladdin	NA

NA: Not applicable.

the OLCR device, an IOL power differing ±0.5 D would have been chosen in one third, while in about 3%-4%, the surgeon would have chosen a more than ±0.5 D different IOL power[31]. Similarly, in another study[37], 3% of cases had an imaginary IOL power that differed ≥2 D. Davison and Potvin[38] investigated if the total corneal refractive power (TCRP) value, which is based on measurement of the corneal power of the anterior and posterior surface, could provide valid and reliable measurements for the most accurate toric IOL calculation. In this retrospective study, operated eyes with toric IOLs were included. The IOLMaster was used for the calculation of IOL spherical power. The TCRP keratometry measurement of the Pentacam was used in the AcrySof Toric IOL Calculator. Moreover, a theoretical toric IOL calculation model was created using keratometry data from the VERION Reference Unit. It was observed that the VERION usually suggested a greater toric power than the TCRP-based calculator when the anterior cornea had WTR astigmatism, while it was less likely to suggest a greater toric power when astigmatism of the anterior cornea was ATR. As a result, the consideration of posterior corneal astigmatism, rather than a population-averaged value, for the toric IOL calculation was proposed by the writers.

TORIC IOL ALIGNMENT
It is well known that the three main factors that affect refractive performance in a toric IOL implantation are preoperative measurement, accurate alignment of the IOL and its stability in the bag[25]. The accurate alignment of toric IOLs is crucial for the best possible postoperative refractive outcome and high patient satisfaction. However, for the best possible alignment, the consideration of the ocular cyclotorsion plays a pivotal role. A considerable number of studies were conducted in order to evaluate the accuracy of image-guided systems in toric IOL alignment and compare them with different conventional manual ink-marking techniques (Table 4). Among them, horizontal slit beam marking (HSBM)[34], subjective direct visual marking (SDVM) on the table (using a bevel knife tip)[34], marking with pendulum-attached marker[41] and with

Table 4 Comparison of image-guided systems in toric IOL alignment

Toric IOL alignment	VERION	Callisto	TrueVision
Alignment meridian	22	22,25	NA
Cyclotorsion	34,39	25	NA
Misalignment	22,26,27,34	22	NA
Rotation	26	25	NA
Error in alignment	26,27,41	28	24
Visual acuity	26,27,41	25,28	NA
Residual refractive cylinder	26,27,41	25	NA
Deviation from TIA	41	28	NA
Alignment time-Surgical time	NA	28	NA

NA: Not applicable.

bubble marker instrument[26,28]. For the assessment of image-guided systems in the alignment of toric IOLs, a variety of parameters were taken into consideration, including the mean toric IOL misalignment and rotation (the difference between the axis of the toric IOL 1h postoperatively and at consecutive follow-up timepoints)[26], the mean residual refractive cylinder, the mean uncorrected distance visual acuity (UDVA) as well as the BCDVA, the mean deviation from the target-induced astigmatism (TIA), and the mean overall time required for the alignment and for the whole cataract surgery.

Comparison of the Automated and Manual Axis Alignment
It is well known that the precise axis alignment of toric IOLs is very important for a good postoperative refractive outcome and high satisfaction of patients. Automated axis alignment is considered to be a highly accurate alignment method. Only one study comparing computer assisted cataract surgery systems (Callisto) and conventional manual ink-marking techniques is available in the literature[25]. The primary goal of this study, in which 50 eyes of 38 patients were examined, was the comparison of the 0°-180° axes of alignment, provided by the two techniques. Their mean difference was 4.7°. It is interesting that the mean difference for right eyes was 5.6°, while for eyes was 3.5°. However, the maximum difference between automated and manual alignment was 12°. Hura and Osher's study[22] was the only study of this review that compared the VERION with the Callisto. Specifically, no identical photographs from the 16 included eyes were found regarding the target meridian. The 53% had a significant variation of <3°. The authors suggested that the accuracy of the two sophisticated technologies was similar, but none of them showed superiority over the other.

Ocular Cyclotorsion Ocular cyclotorsion is a rotation of the eye around its visual axis and takes place during the transition from seated to supine position. It is a physiological phenomenon which contributes to the maintenance of binocular single vision when the head is tilted. Every cataract and refractive surgeon should take always into consideration the fact that cyclotorsion is a factor which could affect negatively

the postoperative refractive outcome if it is not taken into account during the implantation of a toric IOL. As regards the manual marking of the horizontal meridian, this should be performed in a seated rather than a supine position. Image-guided systems are an alternative solution for the accurate detection of horizontal meridian, since they take automatically the cyclotorsion of the eye into consideration by comparing the preoperative photograph of the eye, which is taken with the patient seated, with the intraoperative image (supine position) under the surgical microscope.

Different studies have analyzed the cyclotorsion (clockwise or counterclockwise) of the eye scheduled for lens extraction surgery using surgical-guidance systems. In one study[25], the mean cyclotorsion was found to be 4°, while in approximately one third the cyclotorsion was over 5°. In only two eyes, it was 10.4°. Lin et al[34] compared the measured cyclotorsion with HSMB and SDVM using as reference meridian the VDM measurement. A higher relative cyclotorsion was detected with the SDVM (-3.46°±7.32°) than with the HSBM (0.41°±4.92°) compared with the reference meridian. An additional comparison was performed between right and left eyes regarding the cyclotorsion measured with each method. According to the results, the left eyes showed a greater difference in relative excyclotorsion, in comparison with the right ones.

According to Zhao et al[39], the orientation of ocular cyclotorsion seemed to be connected only to eye laterality, while age, gender, AL, BCDVA, astigmatism magnitude, astigmatism axis and anaesthesia did not seem to affect the degree or the orientation of cyclotorsion. In particular, excyclotorsion (positive cyclotorsion degree) was predominant (70%) in right eyes, whereas incyclotorsion (negative cyclotorsion degree) was predominant (57%) in left eyes.

Misalignment Misalignment, namely the difference between the desired axis of toric IOLs and the achieved axis 1h postoperatively[26], in other words "incorrect placement"[28], is a factor that could cause unexpected residual astigmatism after the implantation of a toric IOL. Misalignment could be created by both imprecise prediction of the desired axis of IOL alignment preoperatively and imprecise alignment intraoperatively. According to the literature, every 10° of axis misalignment during toric IOL implantation could lead to a 33% increase in residual astigmatism. Respectively, a 30° misalignment would yield a 100% rate of residual astigmatism[17-20]. In order to estimate the misalignment, some researchers compared the desired toric IOL axis with the achieved axis immediately after the surgery as it was measured with slitlamp photography[26-27,34].

Lin et al[34] observed a mean misalignment of 3.66° and 6.94° with HSBM and SDVM, respectively, using the VERION

to determine the horizontal reference meridian. As a result, the VDM and the HSBM, according to the writers, were considered to be similarly reliable marking methods, while the SDVM exhibited much lower reliability. An additional observation was the significant difference in the measured axis misalignment between right and left eyes. A possible explanation for this was the fact that the same right-handed surgeon used their dominant hand to mark both right and left eyes. In two studies of Webers *et al*[26-27], in which 36 eyes of 24 patients were recruited (18 eyes for the image-guided group and 18 eyes for the manual group), the average toric IOL misalignment was significantly lower in the VERION group than in the bubble marker group 1h postoperatively (1.3°±1.6° *vs* 2.8°±1.8°, *P*=0.02).

Rotation   The difference between the axis of the toric IOL immediately (*e.g.* 1h) postoperatively and during follow-up period is characterized as "rotation"[26]. The follow-up timepoints in different studies were 1wk[26], 3wk[41], 1mo[25-26], and 3mo[26-27]. Several studies suggest that the most of rotations of toric IOLs happen early, within the first 14 postoperative days[46-48].

In the study of Webers *et al*[26], 27 out of 36 enrolled eyes were evaluated with anterior slitlamp photographs at follow-up visits (1wk, 1mo, 3 mo) in order the postoperative rotation to be determined. The rotation in the image-guided (VERION) group was lower than in the manual in these three timepoints, but without a significant difference. Raucau's *et al* study[25] calculated the mean rotation after a comparison of a slitlamp photograph captured at the follow-up visits with the final alignment verified on the photos taken with Callisto from the end of surgery. In this study, all IOL alignments took place with a manual technique. It was mentioned that the average observed rotation was 4.3° (0°-29°). Eleven eyes experienced an IOL rotation between 5° and 10°, while 4 eyes had a rotation of over 10° (11°, 12°, 13°, and 29°).

Error in Alignment   The mean error in alignment of a toric IOL, namely the absolute difference between intended versus achieved axis[26], is another way to estimate the final success of the IOL alignment. It derives from the sum of the directly postoperative misalignment and of the postoperative rotation in the capsular bag[49]. Toric IOL misalignment and rotational stability can be affected by a variety of factors. Among the described factors are the material (silicone) and the design of IOLs (three-piece lenses with polypropylene loop haptics), inadequate removal of the ocular viscosurgical devices (OVDs) from the bag postoperatively, the long AL, the unsuitable size and centration of capsulorrhexis, variations of the intraocular pressure after the surgery, the vertical axis of implantation, as well as imprecise preoperative marking of the axis[28,48,50-52].

All studies exhibited a significant difference between image-guided groups (VERION or Callisto) and manual groups in total misalignment 1wk[26], 1mo[26,41], and 3mo[26-28] after the surgery. In the examined studies of this review, the mean misalignment 3mo postoperatively in the digital group had a range between 1.7° and 2.4°, while in the manual group the average misalignment extended between 3.1° and 4.33°. However, one study[24] analyzed the accuracy of toric IOL alignment with the TrueVision 3-D computer guided system combined with femtosecond laser intrastromal marks compared with a manual marking method. The mean 3-D imaging alignment error was found to be -0.58°±3.90°, while the mean alignment error for manual group was -0.27°±3.65°, without any significant difference with the first group.

Visual Acuity   A common method of clinical practice to evaluate the accuracy of toric IOL alignment is the measurement of visual acuity after the surgery during the follow-up period. It was observed that all studies that compared digital with manual groups appeared comparable UDVA and BCDVA without any significant difference at every follow-up timepoint[26-28,41]. The range of the mean postoperative UDVA in the studies of this review was 0.03 to 0.12 logMAR for the image-guided group and 0.04 to 0.18 logMAR for the manual marking group, while the range of the mean postoperative BCDVA was -0.05 to 0.05 logMAR for the image-guided group and -0.04 to 0.07 logMAR for the manual one.

Elhofi and Helaly[41] explained that 93.3% of the 30 eyes included in the image-guided group of the study had postoperative UDVA≤0.3 logMAR, while the postoperative UDVA was 0.3 logMAR or better in 9 per 10 eyes of the manual group. Moreover, 100% of the eyes in both groups appeared a BCDVA of 0.3 logMAR or better. It is worth to mention that no eyes had a worse line of visual acuity (VA) after the implantation of the toric IOL in comparison with their preoperative VA. Raucau *et al*[25] correlated the VA with the rotation and cylinder power of the toric IOL. Specifically, it was referred that most of the eyes (77%) with UDVA of 10/10 had an IOL rotation of ≤5°, while the VA without correction in eyes with rotation of more than 10° had a range from 7 to 10/10. Additionally, eyes implanted with IOLs having cylinder power between 1 D and 1.5 D had an average UDVA of 9/10. Actually, the majority (92%) of eyes with UDVA of 10/10 received a cylinder of lower than 3 D. On the other hand, 6 out of 50 eyes operated with the use of Callisto appeared cylindrical correction of more than 3 D. The UDVA in 5 of them was satisfying (7/10).

Residual Refractive Cylinder   The toric IOL misalignment or rotation after the surgery leads to the creation of a new cylinder in a new axis, in other words creates residual refractive astigmatism. Residual subjective astigmatism is the

lowest possible cylinder to achieve BCDVA[25]. Therefore, the accuracy in the toric IOL alignment plays a significant role in the best possible postoperative refractive outcomes and the reduction of residual refractive astigmatism. As a result, automated conjunctival registration contributes to the determination of the target axis, in which the toric IOLs are implanted during the surgery, reduction of unexpected residual refractive cylinder and improvement of postoperative UDVA. In this review, no study demonstrated significant difference in residual postoperative refractive cylinder between image-guided and manual groups. However, in all of them, image-guided groups had lower residual subjective astigmatism than manual groups[25-27,41]. A study conducted by Raucau et al[25] observed that residual astigmatism due to misalignment becomes higher proportionally to the cylinder power of the toric IOL.

Deviation from Target-induced Astigmatism For the best evaluation of the postoperative refractive outcome, beyond the residual refractive cylinder, deviation from TIA should be taken into consideration, as well. The comparison of the level of TIA achievement between computer-assisted and manual toric IOL alignment was one of the objectives in a variety of studies[25,28,41].

Mayer et al[28] and Elhofi et al[41] demonstrated a significantly lower deviation from TIA in the digital marking group (Callisto and VERION, respectively; 0.10 D) compared with manual marking group (around 0.2 D). All eyes belonging in the first group of Elhofi and Helaly's study[41] were within +0.5 D of the TIA. These results validated the superiority of image-guided systems in the toric IOL alignment over manual marking techniques.

Alignment Time and Surgical Time The transition from the manual ink-marking alignment to the image-guided alignment of toric IOLs leads not only to the reduction of the risk of anterior chamber bacterial contamination, but also to the decrease of the toric IOL alignmnet time as well as the overall time required to perform the surgery. The only study of this review comparing the alignment and surgical time was conducted by Mayer et al[28]. According to this study, the average IOL alignment time was significantly shorter in the Callisto group (37.2±11.9s) than in the bubble marking group (59.4±15.3s). Furthermore, the Callisto group was significantly faster (727.2±198.4s) than the manual marking one (1110.0±382.2s) as regards the overall surgical time. In particular, for the accurate comparison of the two examined methods a number of parameters were evaluated. Among them, regarding the manual marking group, the time required for assembling the marking device and corneal marking in advance of surgery, and intraocular IOL rotation, alignment, and realignment after the manual toric axis control during

the surgery. Concerning the computer-assisted group, the parameters included in the assessment were the time to import of biometry data into the Digital Marker and to match the reference image preoperatively, as well as the time for IOL alignment. Manual control of the toric axis and IOL realignment are not necessary for the image-guided method. Therefore, this is one of the reasons for the faster IOL implantation and better surgical workflow using digital marking.

Intraobserver Repeatability of Image-guided Systems For the spherical assessment of the measurement accuracy of image-guided systems, the evaluation of their intra-session repeatability is indispensable. Intra-session repeatability is the variability, namely the level of agreement between the results of experiments conducted by the same individual, with the same measuring instrument, at the same location, with the same measurement procedure, under the same conditions and repeated within a short period of time[53]. For the more precise estimation of repeatability, healthy volunteers were chosen in all studies examining this parameter[1,30,32-33,40]. According to Bland and Altman[54], the within-subject standard deviation (Sw), an estimate of the size of the measurement error[1,32-33,36], as well as the intraclass correlation coefficient (ICC)[1,30,36,40], its 95%CI value[30,40], the value of Cronbach's alpha[40], and intra-subject precision (Pr, ±1.96×Sw)[33] were determined for repeatability calculation. Three consecutive measurements were performed by the same physician using the image-guided systems to assess their intra-session repeatability.

To evaluate the repeatability of image-guided modules, the repeatability for a variety of variables was examined, including mean K, K1, K2[1,33,36,40], (or mean R, R1 and R2)[30], corneal astigmatism magnitude and flat or steep axis[30,32-33,36,40], Jackson's cross cylinder power vector components (J0 and J45)[36,40], and WTW distance[30,40].

Visser's et al study[32], whose purpose was the comparison of corneal astigmatism measurements of the SMI Reference Unit, a precursor of the VERION, with other keratometry devices, found an acceptable repeatability of astigmatism magnitude of the SMI Reference Unit (Sw=0.14 D), but a moderate repeatability of astigmatism meridians (Sw=24 degrees). According to the writers, acceptable values of Sw for the repeatability were less than 0.25 D for the astigmatism power and less than 5 degrees for the astigmatism axis. These limits are consistent with the results obtained by Ruiz-Belda et al[33] with the VERION. This study demonstrated a good repeatability for all keratometric measurements with Sw<0.26 D for K1, K2 and astigmatism magnitude and Sw of 4.29 degrees for the axis of the flat meridian. Similarly, Nemeth et al[40] reported a high repeatability with Crobach's alpha values ranging from 0.950 to 0.998 for all parameters.

In general, the majority of studies demonstrated an excellent (ICC>0.9)[1,30], or high (ICC>0.85)[36,40] repeatability for all parameters measured by the VERION.

Interobserver Repeatability (Reproducibility) of Image-guided Systems There is no doubt that every device should perform as accurate and reliable measurements as possible regardless of the operator, even when these measurements are obtained by inexperienced users. Interobserver repeatability refers to the variability in repeated measurements when observer is varied[53]. For this reason, the determination of image-guided systems' interobserver repeatability constitutes a significant part of their general evaluation. In this review, two studies analyzed the reliability and reproducibility[32,36] of two image-guided systems by comparing the outcomes of sets of three consecutive measurements obtained from healthy eyes by an experienced and inexperienced operator.

Visser et al[32] estimated the interobserver repeatability of the SMI Reference Unit after the comparison of the mean astigmatism vectors, the mean difference, and the Sw of measurements taken by the two categories of observers. The writers concluded that there was no influence of the operator's experience on the measurements performed with the computer-assisted system. Lauschke et al[36] assessed the interoperator reproducibility of the VERION Reference Unit by comparing the Sw and ICC for experienced and inexperienced users. Reproducibility and reliability were not found to have significant differences between experienced and inexperienced technicians. Both types of technicians achieved high reproducibility for mean keratometry, corneal astigmatism, axis of the steepest meridian and vector analysis measurements.

Interchangeability Undoubtedly, a question is raised as to in which degree image-guided systems could equally replace the current, conventional, validated keratometry devices. For this reason, several studies have examined the interchangeability of the VERION System with IOLMaster, Pentacam, Aladdin and KR 8900[1-2,33,36].

Asena et al[2] came to the conclusion that VERION was not completely interchangeable with IOLMaster and KR-8900 in performing keratometric and astigmatic measurements. Nevertheless, the mean difference was small enough (<0.25 D) to influence the final astigmatic correction. Moreover, Ruiz-Belda et al[33] concluded that results derived from the measurement of axis of the flattest corneal meridian obtained from VERION were not completely interchangeable with the optical biometer Aladdin, particularly in low and OBL astigmatism. Similarly, according to Velasco-Barona et al[1], the interchangeable use of the VERION with AKR was discouraged due to the wide spread of data for all evaluated variables. On the contrary, in the study of Lauschke et al[36], a broad interchangeability of the

VERION was observed in comparison with the Topcon AKR, the IOLMaster and the Pentacam.

Duration of Preoperative Examination: patient comfort Last but not least, a significant characteristic that every device should have is the relatively short examination time for the best possible comfort and cooperation of the patient. The evaluation of these features was the object of Thomas et al's study[29], in which the duration of preoperative examination and patient comfort in measurements taken by the VERION were compared with the corresponding parameters of IOLMaster 500, Lenstar LS900 and Pentacam HR. Only healthy subjects were included and were classified according to their age into 3 groups (young, middle, old). The objective exam duration was measured with a chronometer. With regard to patient comfort, the whole measurement procedure, light brightness, head posture and subjective duration were evaluated with questionnaires.

A significant difference in examination time was found only between the first and second measurement with the VERION. The three age groups did not showed any significant difference in the analyzed variables. Concerning the subjective patient comfort, the mean value was classified as "not uncomfortable" or "slightly uncomfortable" for all questions. Therefore, the researchers came to the conclusion that the VERION could be satisfactorily compared with the other established keratometric devices regarding the duration of preoperative examination and patient comfort, and could be easily integrated in clinical practice. However, the only negative parameter that should be taken into consideration is the fact that there is a need for calculation of AL and ACD with another biometric module because the VERION cannot measure these values. As a result, IOL calculation takes extra time beyond the time for the keratometric measurements.

DISCUSSION

There is no doubt that PCI constitutes the gold standard for measurement of AL and the calculation of power of IOLs, monofocal, monofocal toric, multifocal and multifocal toric. In the attempt to find equivalent systems for this purpose, numerous keratometry devices have been introduced. However, the large variety of these currently existing modules means that none of them is able to replace equally PCI.

In this context, in the past few years, the technology of image-guided surgery has been introduced mainly for the calculation of toric IOL power and planning optimal alignment. For both of these purposes, accurate measurement of corneal astigmatism is necessary.

In this review, all major studies regarding cataract surgery and RLE guided by computer-assisted technology were assessed. After an intensive research, several studies were elected from the scientific literature. Most of these studies[2,29-31,33,35-37,40]

compared image-guided systems with other existing keratometry devices that are used widely for keratometry measurement and IOL power calculation. Some of them examined keratometric values, including K1, K2, Km, R1, R2, Rm, astigmatism power and axis, vectors J0 and J45, and WTW distance, as well as the power of the IOL calculated by each module, the duration of the preoperative examination and the patients' comfort during the examination. In addition, a comparison between image-guided systems and conventional manual ink-marking methods for alignment of toric IOLs as regards the alignment accuracy as well as the time of alignment and cataract surgery was performed[22,24-28,34,39,41]. Furthermore, evaluation of the intraobserver and interobserver repeatability was conducted[1,30,32-33,36,40].

With reference to keratometry values and IOL calculation, it was noticed that the only image-guided system analyzed in this review is the Alcon VERION Reference Unit, which is composed by the Measurement Module and the Vision Planner, because this is the only system that combines keratometry measurements and IOL calculation with toric IOL alignment guidance. However, with regard to toric IOL alignment, beyond the VERION Vision Planner and Digital Marker, the Zeiss Callisto Eye and the TrueVision 3-D Surgical System are also evaluated in the present review.

The present review contrasted the VERION with the IOLMaster, a device based on the technology of PCI. With reference to keratometry values, the analysis of the results showed that there was no agreement among the different studies comparing these two modules. In particular, one study[2] found significantly steeper keratometric measurements with the VERION, however with a small mean difference (<0.20 D), namely without any clinical significance. On the other hand, other researchers[30-31] mentioned that they found significantly flatter keratometric values with the VERION versus the IOLMaster, whereas, according to other studies[36-37,40], no significant difference between the two devices respecting keratometry was observed. Therefore, it seems that there is no consistency in the results and no obvious conclusion about the comparability between VERION and IOLMaster can be reached.

In regard to anterior corneal astigmatism power, the majority of studies[2,36-37,40] found no significant difference between the VERION image-guided system and the IOLMaster. However, one researcher[37] mentioned that despite the absence of a statistical significance, the IOLMaster demonstrated the biggest astigmatism power between 6 currently available compared modules (Verion Reference Unit, IOLMaster, Tonoref II, AL-Scan, Pentacam, and OPD Scan III), whereas the VERION had the second highest power of astigmatism. With respect to anterior corneal astigmatism axis, different findings resulted

from this review which range from a high, unacceptable, clinically relevant difference[2] to absence of a significant difference indicated by most of studies[30,36-37,40].

The second keratometry device, with which the VERION was contrasted, was the Pentacam, which is a rotating Scheimpflug camera system for anterior segment analysis. The research of the literature indicated that in most of the studies[30,36-37], the VERION appeared significantly flatter keratometric values than the Pentacam, while one writer[36] did not detect significant differences in K values and corneal cylinder axis. However, the number of available studies was relatively small for a precise conclusion.

With regard to the contrast of the VERION with the Lenstar LS900 device, a system based on OLCR, no significant difference was revealed regarding both keratometric values and astigmatism axis[30-31,35].

Another device compared to the VERION was the Aladdin system, an optical biometer based on non-contact optical low-coherence interferometry and Plasido-disc topography. Only one article[33] in the literature performed this comparison and concluded that although the VERION performs consistent keratometric measurements, the measurement of the axis of the flattest corneal meridian did not showed interchangeability with the Aladdin's measurements especially when low or OBL astigmatism is present.

In addition, during the comparison of the VERION with the AKRs Topcon KR-8800 and KR-8900, the literature sources were divided in these that pointed out significantly steeper K values[2], higher magnitude[2,35] and axis of astigmatism[2] in measurements with the VERION, and the sources that did not indicate any difference between these systems in the same parameters (K values[35-36], astigmatism power[36] and astigmatism axis[36]).

An additional comparison took place between the VERION and OPD-Scan III wavefront aberrometer. The existing studies[35] did not reveal a clear view of the degree in which these two modules measure keratometric values and astigmatism power and axis without any significant difference. The VERION was found to give either significantly higher keratometric values[35,37], and lower astigmatism power[37] or similar K values[37] and cylinder power and axis[35].

As regards the comparison of the optical biometer AL-Scan with the VERION, although only two sources of literature[35,37] comparing these systems were available, it was clear that the AL-Scan performs especially similar measurements of keratometric values, astigmatism power and axis with the VERION. Actually, it seemed that AL-Scan gives the smallest difference with the VERION regarding the cylinder axis in contrast with other keratometric devices[35].

A final comparison that performed in the present review, evaluated the similarity of the VERION with the Tonoref II, which is a module combining an auto-refractometer, auto-keratometer and non-contact tonometer in one unit. Few research data suggested that no significant difference existed about K1 and astigmatism power, but the VERION measured higher K2 in contrast with Tonoref II[37].

To summarize, it seemed that the VERION Reference Unit, AL-Scan and Lenstar did not present any significant difference in the measurement of K-values as well as astigmatism power and axis. This could be explained by the fact that all these three modules are automated keratometers that are based on the projection of lights on the surface of the cornea to measure keratometric parameters. The KR-8800, the KR-8900 and the Tonoref II, which are also autokeratometers, did not showed a clear relationship with the VERION. Some studies pointed out no difference, while some other indicated that the VERION performed steeper keratometry. A possible explanation for this is that KR-8800, KR-8900 and Tonoref II create a larger diameter of light-reflexions on the central cornea (3 mm and 3.3 mm, respectively), in comparison with the VERION that projects LEDs onto the central 0.8-1.2 mm of cornea for the corneal spherical power measurement and onto the central 2.8 mm for the calculation of the corneal cylinder (corneal power and axis).

However, in cases of irregular astigmatism or severe peripheral deformations of corneal shape, measurement of K-values and astigmatism could be influenced. For this reason, surgeons should perform measurements such as topography or pachymetry by an additional module based on different principle as well as multiple measurements with each module in order to obtain more complete reference data[55]. The combination of the devices that would be used should be evaluated in each individual patient. When the steep corneal meridian is similar on different devices, the implantation of a toric IOL is advisable. On the contrary, a significant variability in axis and power of toric IOL among different devices should discourage refractive surgeons to implant such a lens or they should be very cautious and look for coexistent ocular comorbidities. Otherwise the visual outcome could be disappointing.

A crucial step in lens extraction surgery is a precise preoperative calculation of IOL power. In some studies, it was examined whether surgeons would have chosen the same or different IOL power for healthy volunteers[31] or patients scheduled for a cataract surgery[37] when they were measured with the VERION and other keratometric devices. Researchers found that VERION calculated significantly lower power of the IOL compared to the Pentacam and OPD Scan III[37], while the image-guided system did not differed significantly with

the AL-Scan and Lenstar in the proposed IOL power[31,37]. Nevertheless, no clear view was formed about the agreement between the IOLMaster with the VERION. Specifically, some researchers did not found any significant difference, whereas other writers indicated a significantly bigger IOL power when it was calculated with the VERION than with the IOLMaster[31]. The SRK/T formula proposed the most similar outcomes about IOL's power calculation. However, in general, the mean difference among all compared devices and IOL calculation formulas was smaller than 0.50 D, which is the typically provided step for IOL power.

For the achievement of an effective astigmatic correction, the axis of the toric IOL should be aligned exactly with the axis of the corneal cylinder. Since the introduction of the toric IOL, several manual marking methods have been used for the toric IOLs' alignment. However, the introduction of digital image guidance systems has allowed the alignment of toric IOLs without preoperative manual marking. For the finding of the best method of toric IOL alignment, a significant number of studies were conducted. In these studies, three image-guided systems, Alcon VERION Digital Marker[26-27,34,41], Zeiss Callisto Eye[25,28] or TrueGuidance Software (TrueVision 3-D computer-guided visualization system) were compared with the currently existing conventional manual ink-marking techniques, including SDVM[34], HSMB[34], marking with pendulum-attached marker[41] and with bubble marker instrument[26,28]. The two of the available image-guided systems, VERION and Callisto, were also compared to each other[22].

Regarding the comparison of image-guided systems with manual marking techniques, the agreement in axis alignment[25], IOL misalignment[26-27,34], rotation[25-26], and total error in alignment[24,26-28,41], as well as the VA[26-28,41], residual refractive cylinder[25-27,41], deviation from TIA[28,41], alignment and surgical time[28] after the implantation of toric IOLs with automated or manual alignment techniques was examined. In all aforementioned parameters, VERION and Callisto indicated superiority over manual methods, while in TrueVision 3-D system no superiority was found. However, only misalignment, deviation from TIA, alignment and surgical time showed significant difference[26-27]. Additionally, the VA was correlated with the rotation and toric IOL cylinder[25], and it was observed that the higher the IOL rotation or the cylinder power the worse the postoperative VA. Another correlation occurred was this one between cylinder power of the implanted toric IOL and the residual refractive cylinder due to misalignment[25]. This revealed that residual refractive cylinder increases with the power of the implant.

Finally, in one study[22], the misalignment degree and the alignment meridian generated by the VERION image-guided system was compared with the Callisto. Generally,

it was concluded that the two devices are not currently interchangeable and none of them is superior over the other.

As a great ocular cyclotorsion is able to generate deviation of astigmatism axis and postoperative astigmatism, it would be helpful if we could understand the factors related with this phenomenon or predict the degree of cyclotorsion. For this reason, several researchers used image-guided systems to better understand cyclotorsion because of its accuracy and simplicity[25,34,39]. It was concluded that measuring cyclotorsion of left eyes by right-handed surgeons using SDVM could give especially inaccurate results[34]. Furthermore, only eye laterality was considered to be a factor that can affect the degree or the orientation of cyclotorsion[39].

After the evaluation of all parameters, obviously, the possibility for an interchangeable use of VERION with the rest validated keratometry modules should be examined. The majority of studies concluded that the interchangeable use of the image-guided systems with IOLMaster, KR-8900 and Aladdin optical biometer is not yet advisable despite the high correlation of their values[1-2,33]. Nevertheless, there is one study supporting the good interchangeability of the VERION with the IOLMaster, Pentacam and Topcon AKR[36]. Additionally, the VERION and the Callisto did not prove to be interchangeable. However, none of them is superior over the other[22].

There is no doubt that the estimation of the ability of any device to provide repeatable, reproducible and reliable outcomes is equally significant as the evaluation of its other characteristics. Many researchers evaluated precision of the image-guided systems, VERION[1,30,33,36,40] or its initial version, SMI Reference Unit[32] by estimating their intraobserver and interobserver repeatability. The conclusion of all authors was that the intraoperator repeatability was excellent or high for all parameters measured with the VERION. The measurements performed with the SMI Reference Unit showed an acceptable intrasession repeatability for astigmatism magnitude, but a moderate repeatability for the meridians of astigmatism[32]. With reference to the interoperator repeatability and reproducibility of measurements taken with the VERION or SMI Reference Unit by experienced and inexperienced operators, writers concluded that both devices are significantly similar and the experience of the user does not affect noticeably the reliability of measurements[32,36].

As regards the VERION system, beyond its various advantageous capabilities, there are some limitations to consider. Actually, the VERION cannot measure eye's AL and ACD. Considering that measuring the AL and ACD is required for the completion of the calculation of IOL power, the determination of the IOL diopter planning is impossible unless a second biometry device is available, such as IOLMaster, Lenstar, AL-Scan or Aladdin. As a result, the VERION cannot be independently used for

IOL calculation and should be combined with the use of a further module measuring AL and ACD. Moreover, this leads to a larger duration of the preoperative examination and less comfort[29].

Another remarkable disadvantage of the VERION Reference Unit is that measurement of posterior corneal surface is impossible. It has been recently shown that the consideration of posterior corneal astigmatism is very important for planning astigmatism correction and calculation of total corneal astigmatism[56-62]. It is well known that posterior cornea acts as a minus lens and has almost always a constant orientation of astigmatism, independently of the orientation of anterior astigmatism. The vertical meridian of the posterior corneal surface is usually steeper and remains steeper with age. Consequently, measured TCRP astigmatism is generally lower in eyes with WTR anterior corneal astigmatism and higher when the astigmatism of anterior corneal surface is ATR or OBL[38]. As a result, if posterior part of the cornea is neglected for the determination of toric IOL corneal power, the preexisting corneal astigmatism of patients with WTR astigmatism will be overcorrected, whereas the cylinder will be undercorrected in presence of ATR anterior corneal astigmatism[26,31,38]. Nevertheless, first-generation toric calculators, that are used nowadays for choosing toric IOL cylinder power, neglect posterior astigmatism as well as the effective lens position (ELP)[26-27]. Therefore, the consideration of the TCRP could play a pivotal role in the more precise determination of toric IOLs' cylinder power and in preventing the surprising residual astigmatism that sometimes appears postoperatively.

A considerable limitation of the included studies was that researchers calculated the IOL power that they would use in each case of patient, but they did not implanted these IOLs. As a result, the IOL power was compared to the power calculated by other established devices, but it would be impossible to assess with high accuracy if the used IOL was the appropriate. Therefore, the reliability of an image-guided system in IOL power calculation could be accurately evaluated only if, in future studies, the IOLs calculated with that system would be implanted and the refraction outcomes would be analyzed postoperatively.

Another point that could limit the reliability of a number of studies included in the present review is the fact that they recruited, instead of young healthy volunteers, old patients having cataract, some of whom being partially hearing impaired and with unstable tear film. This could justify some of the discrepancies between the different studies. Therefore, in the future, the type of individuals who will be recruited in corresponding studies should be carefully evaluated. To specify, from the one hand, healthy volunteers could contribute

in more reliable measurements. From the other hand, cataract patients constitutes the majority of eligible subjects for a lens extraction surgery. So, it would be logical if the measurements were performed in patients selected for cataract surgery. Moreover, management of the ocular surface, in particular the dry eye disease and the tear film quality, should play a pivotal role and should not be neglected in the future studies.

An additional notification that should not be neglected is the lack of corresponding studies in the literature concerning multifocal or toric multifocal IOLs. Multifocal IOLs could lead to spectacles independence making the activities of daily living (ADLs) easier and, as a result, increase patients' satisfaction[63-65]. It is well known that the high accuracy in keratometry, IOL calculation and IOL alignment is of paramount importance, and the inaccuracy in one of these parameters could lead to poorer outcomes in comparison with the corresponding monofocal IOLs.

A considerable limitation of this review that should be highlighted is the impossibility of access to the full text of various articles[22,27]. As a result, highly interesting and important information, mainly about the comparison of the VERION with the Callisto, was not available for thorough review.

A final point that should be taken into consideration is the fact that in some studies evaluating toric IOL alignment only right eye of patients were recruited[1-2,32,35-36], in other studies both right and left eyes were used[25,27-28,34,37-39], while in other ones the recruited eye was selected at random[26,29-31,33,40-41]. This could contribute to the consideration of factors that could be affected by eye laterality. No significant difference in keratometry was detected between right and left eyes[36]. On the other hand, studies assessing the alignment in both eyes could reveal discrepancies caused by the fact that the surgeon uses only the dominant hand for incisions in both eyes.

Unfortunately, image-guided systems are not panacea for all lens-based refractive surgeries because there are different factors that may limit the widespread usage of this technology. In particular, it should be taken into consideration that the financial cost for supplying of this equipment is considerable. Additionally, some other limitations that can make the preoperative measurements or the intraoperative registration impossible are uncooperative patients, chemosis, hemorrhage or ballooning of the conjunctiva, and difficult anatomy of the orbit. For this reason, every surgeon performing lens-based refractive procedures should be capable of taking accurate keratometric measurements and calculating the appropriate IOL power with the traditional keratometry technologies, as well as performing the best possible toric lens centration and alignment using conventional centration and manual ink-marking methods.

CONCLUSION

In conclusion, image-guided systems seem to be an accurate and reliable technology with measurements of high repeatability and reproducibility regarding the keratometry and IOL power calculation, but not yet interchangeable with the current established and validated keratometric devices. However, they are superior over the conventional manual ink-marking techniques for toric IOL alignment.

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