Observational Study

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Comparison between using INTEGRA and manual method in determining axis for intraocular lens implantation

Preliminary retrospective study

Marcin Jaworski, MD[a,*], Dorota Wyględowska-Promieńska, MD, PhD[b,c], Piotr Jaworski, MD[a], Krzysztof Jaskot, PhD[d], Robert Bieda, PhD[d], Richard Packard, MD, PhD[e]

Abstract

The aim of this study was to explore the efficacy, repeatability, and efficiency of a new intraoperative contactless device (INTEGRA Optomed, Chorzów, Poland) for determining the axis for toric intraocular lens implantation and then to compare this with that determined using a manual method.

This study was conducted at the Ophthalmological Center for Children and Adults Optomed, Chorzów, Poland.

This nonrandomized, retrospective, observational study included 20 eyes of 12 patients (5 males and 7 females) who had toric intraocular lens implanted. A video recording of each surgery using the INTEGRA system was made showing the analysis. The surgeon and one of the researchers then independently assessed the location of the implant axes determined with both digital and manual slit-lamp methods, and compared them.

The implantation axes suggested for both the manual and INTEGRA methods were similar. The median axis disparities were 0.0 degree and 0.5 degree, and standard deviations were 0.61 and 0.81 for researcher 1 and 2, respectively. The dominant value was 0.0 in both groups. The INTEGRA axis designation was not statistically different from the manual method (level of significance: $\alpha < 0.01$).

The INTEGRA system is a digital ink-free device for image tracking scleral vessels. It was helpful for determining the implantation axis in a precise and repeatable manner, and measurements were comparable with a manual technique.

Abbreviations: IOL = intraocular lens, TABO = Technischer Ausschuss für BrillenOptik.

Keywords: automated surgical support system, axis designation, axis determination, computer-assisted surgery, digitally assisted surgery, integra, intraoperative device

1. Introduction

Automated surgical support systems have been used in ophthalmic surgeries for some years. Ventura found that correcting the astigmatism by proper determination of the right axis of implantation as well selecting the correct lens power were crucial for achieving the optimal effect.[1–5] A total of 84% of surgeons use manual systems to determine the Technischer Ausschuss für BrillenOptik (TABO) scale, whereas others, 8% use Verion and 8% use Callisto, use systems based on image tracking.[6] Available calculators suggest the optimal axis.[7] This is based on the use of TABO scale during refractive surgery (Fig. 1). These devices give reliable and reproducible axis designation during toric lens implantation. The scale represents a circular arc in the eye, determined by a central angle of 180 degrees. The radius of the semicircle is oriented at the

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INTEGRA is a proprietary system originating from the Ophthalmology Center for Children and Adults Optomed (Chorzów, Poland). The owner and project manager is one of the authors – Piotr Jaworski.

This study adheres to the tenets of the Declaration of Helsinki. The patients signed their consents for the use of images for further analysis by the INTEGRA system.

Piotr Jaworski, Krzysztof Jaskot, and Robert Bieda invented described medical device – INTEGRA (Optomed, Poland) and Piotr Jaworski possesses rights to the device.

The others authors report no conflicts of interest.

[a] *Ophthalmological Center for Children and Adults Optomed, Chorzów,* [b] *Department of Ophthalmology, University Clinical Centre, School of Medicine in Katowice,* [c] *Ophthalmology Clinic, University Clinical Centre, School of Medicine in Katowice, Medical University of Silesia in Katowice,* [d] *Department of Automatic Control and Robotics, Silesian University of Technology, Gliwice, Poland,* [e] *Arnott Eye Associates, Optegra Eye Hospital London, London, United Kingdom.*

[*] *Correspondence: Marcin Jaworski, Ophthalmological Center for Children and Adults Optomed, Katowicka 50, 41-500 Chorzów, Poland (e-mail: m.jaworski01@gmail.com).*

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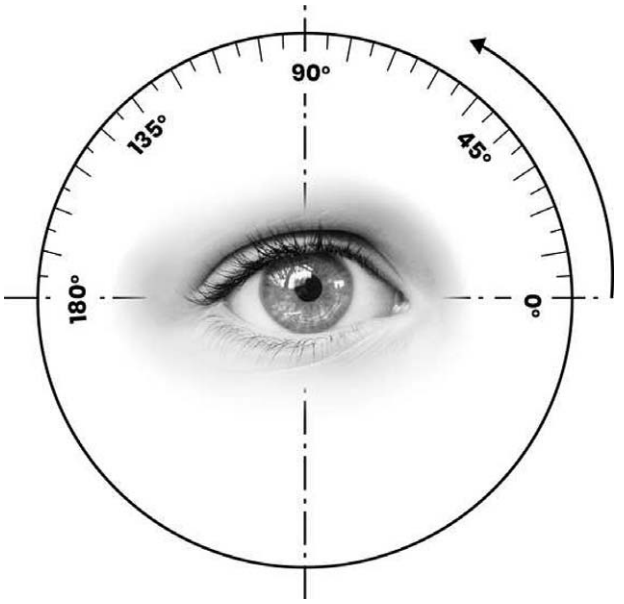

Figure 1. . Technischer Ausschuss für BrillenOptik scale.

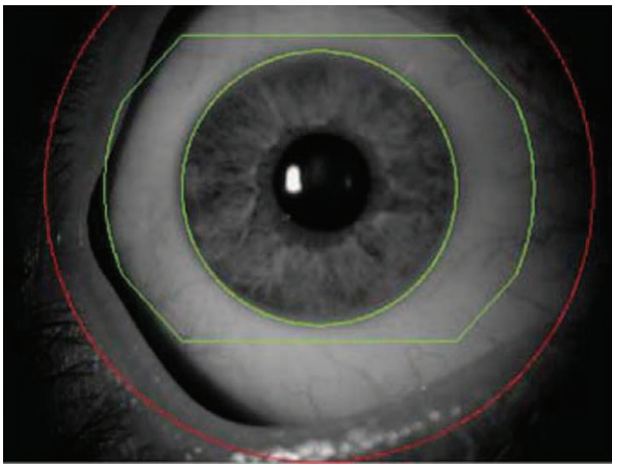

Figure 2. . Image prior to INTEGRA processing. Area inside the red circle indicates analyzed area; area limited by green lines indicates region of interest.

level of the eye, where 0 degrees is always on the right side of the semicircle.[7,8]

Proper toric lens alignment has a significant effect on postoperative uncorrected visual acuity.[1–5,7,9] The American Society of Cataract and Refractive Surgery conducted a survey, which indicated that for most surgeons, an incorrect implant axis greater than 10 degrees from that determined preoperatively was unacceptable.[6] In the majority of patients, cyclotorsion of about 2 degrees is found when changing from a sitting position (in which position the designation is made) to a lying position (in which the surgery is performed).[10] This study is to explore the effectiveness and accuracy of a new device called INTEGRA, the characteristics of which are described below, and to compare it with the measurements made manually.

Although methods of manual marking of axes are effective and reasonably precise, it should be remembered that the inks used in the markers may fade or get dispersed, which might lead to 10-degree differences in axis determination.[7,10] The principle of the INTEGRA system reported here was to define the eyeball mathematically, and thus determine the implant axis, based on characteristic points in the digital image in real time.

Modern image-tracking systems analyze the active area, the so-called region of interest. During the procedure, the eyeball may be rotated, deformed, and obscured by instruments or liquids, in particular, by impermeable ones, such as blood. Any negative impact on the analysis due to the lid speculum used during the procedure was ignored. The following key points were proposed:

- a ring segment, restricted internally by the cornea and externally by the eyelids;
- scleral vessels (Fig. 2).

The vessels may become narrowed by pharmacotherapy; however, as long as their outline remains visible, in accordance with the preliminary tests carried out, the algorithm used for tracking should be maintained. Conjunctival vessels may constrict but scleral vessels do not and their outline remains visible (Fig. 2). At the same time, these devices give a stable and repeatable designation, which is not affected by blurred ink or blood obscured marks (Fig. 2).

2. Materials and methods

This was a nonrandomized, retrospective, observational study. Twenty eyes of 12 Caucasian patients (5 males and 7 females) who had toric intraocular lens (IOL) implantation (phakic implants or combined with cataract phacoemulsification) were included in the study. Age range was 21 to 70 years old, with an average age of 40 years old. The group that had phakic implantation consisted of 6 female and 6 male eyes, age range was 21 to 34 years old, and the average age was 27 years old. The group of 7 eyes having a phacoemulsification procedure with primary toric IOL implantation consisted of 6 female and 1 male patients, age range was 40 to 70 years old, and the average age was 61 years old. The system is noninvasive and serves as a supporting tool for checking the position of the implant axis and the TABO scale in relation to the reference methods. The patients signed their consents for the use of images for further analysis by the INTEGRA system.

The scale-invariant feature transform algorithm, proposed by D. Lowe, which allows definition and description of scleral vessels in the region of interest was applied. The analysis was divided into 3 separate stages: the preliminary analysis, detection and selection of key points, and description of key points.[8]

On the basis of the captured images, the algorithm constructed a pyramid of Gaussian images in order to reduce their resolution by 50%. Next, filtration with various degrees of image blur was performed. This meant a gradual decrease of the descriptor sensitivity to a change in the scale, in the image being analyzed. This allowed the descriptors to be independent from the light intensity. The following step was to detect and select key points.

The scale-invariant feature transform algorithm determined the characteristic points, which were grouped closely together, and analyzed them with regard to "significance" and quality. Then, the selected key points were described as a vector, along with their surroundings. A histogram of change intensity was subsequently created that was the basis for building a topological description of the point, this eliminated the parallax error.[8] While seeking the orientation of the eyeball and eye identification,

INTEGRA compared key points with the reference image. The final stage of image analysis was transformation. This allowed inclusion of the changes in the position and orientation of the eyeball in real time. In this process, the pair of key points of the reference image and analyzed image during the operation was used. The system imposed on the actual image and included the TABO scale, the flat and steep corneal meridians, the implant axis, as well as the location of main incision, side-port incisions, and visual axis.[8]

The algorithms already described were implemented by using an embedded vision system device (EVS-1464RT, National Instruments, Austin, TX) and the LabVIEW package (National Instruments). This is a dedicated vision system, operating under the control of a real-time operating system. A Basler camera scA640-70fc with a resolution of 659 × 490 pixels was used as the vision signal source, providing a color image with a maximum speed of 71 frames/s.[8]

It was possible to eliminate the parallax error, resulting from shifting of the patient's head in relation to the operating microscope, and it also allowed work in the dim light of the operating field. The algorithm used in the INTEGRA system makes it possible to determine the axis of the implant even if the majority of the reference (operated) area is obscured.[8]

The device described here was used in the following procedures:

- phacoemulsification procedures with implantation of toric IOLs;
- implantation of toric phakic lenses.

After performing corneal topography with the OCULUS Keratograph III (OCULUS, Arlington, WA) and anterior segment photography, the system recognized tens of thousands of reference points on the sclera and determined the visual axis. Finally, the TABO scale was applied to the image. The system tracked the eye during surgery, eliminating abnormal readings caused by cyclotorsion of the eyeball or errors resulting from incorrect marking of the reference points on the operated eye (Fig. 3).[8] The system automatically identified the patient, the operated eye, and monitored the course of surgery with extended reality.

Surgeries, in which images were analyzed, took place in 2017 and 2018 at Ophthalmological Center for Children and Adults Optomed, Chorzów, Poland. Before the surgery, the surgeon (PJ) manually marked the implant axis with surgical pen, using a slit lamp. A video recording of the surgery was analyzed using the INTEGRA system. The OMS-800 operating microscope (TOPCON, Tokyo, Japan) was used. The surgeon and one of the researchers independently assessed the location of the designated implant axes using both methods, and next compared them with regard to method used. Images from surgery are presented in Figure 4. The exclusion criteria for further INTEGRA analyses were blurry image, iris and conjunctiva not fully presented in the footage, conjunctival hemorrhage covering more than half of the eye, nontoric intraocular implant, and no patient's consent for further analyses.

The statistical analysis was conducted using the Statistica software (version 7, StatSoft, Inc., Tulsa, OK) and Microsoft Excel (version 16.20, Microsoft, Redmond, WA). To check normal distribution, Shapiro–Wilk normality test was applied and showed no characteristics of normal distribution. The Wilcoxon matched pairs test was used to compare designated axes in control group (manual method) and researcher 1, and control group and researcher 2.

Pursuant to the decision of Bioethics Committee of Medical University of Silesia in Katowice, Poland no. KNW/0022/KB/36/19, the study is of observational character and does not constitute medical experiments. Therefore, they do not require any evaluation given by Bioethical Committee. This study adheres to the tenets of the Declaration of Helsinki. The patients signed their consents for the use of images for further analysis by the INTEGRA system.

3. Results

The median disparities were 0.0 and 0.5 degrees, the standard deviation was 0.61 and 0.81 for researchers 1 and 2, respectively, when comparing the INTEGRA TABO scale view to the manually determined method. Dominant value was 0.0 for both researchers (Fig. 5). Measured data between groups have

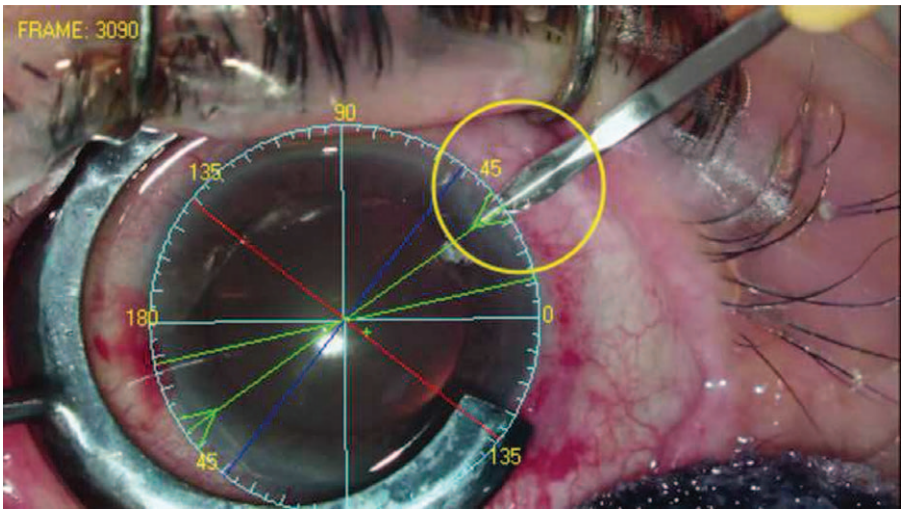

Figure 3. . The INTEGRA system operation view: blue lines and numbers indicate TABO scale. Green cross indicates visual axis. Blue line indicates flatter meridian. Red line indicates steep meridian. Green line with reverse-arrow-ended indicates incision suggestion. Green line indicates intraocular lens implantation axis. Yellow circle indicates place of ongoing incision.

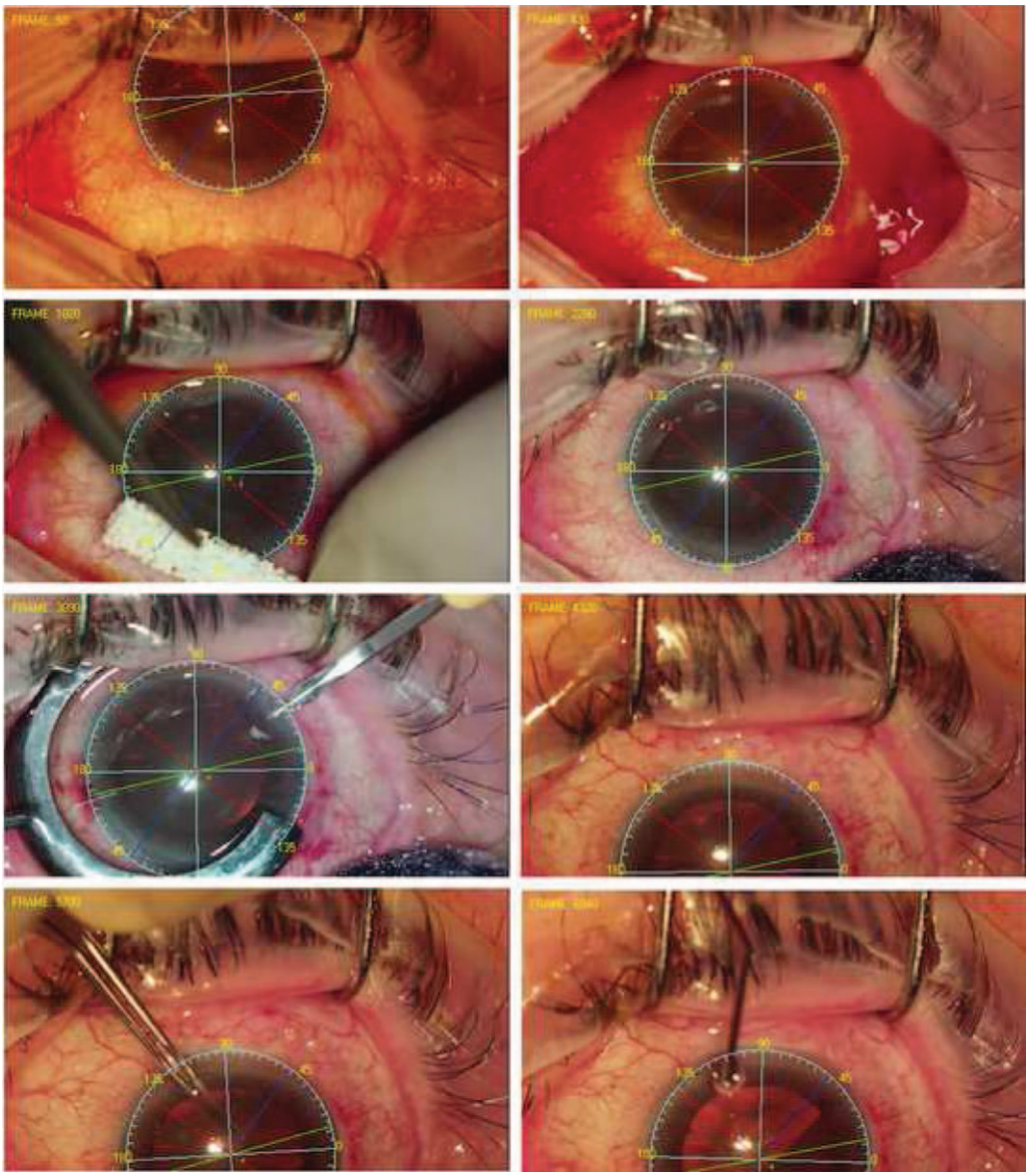

Figure 4. . The INTEGRA system operation view, chosen steps of surgery.

statistically the same distribution (level of significance: $\alpha < 0.01$), manual method to researcher 1 had *P* value of 0.95 and manual to researcher 2 had *P* value of 0.99. Results of the study are presented in Table 1. Researcher 2 had greater disparity from the manual readings than researcher 1 especially in oblique axes of implantation.

4. Discussion

The determination of the axes between INTEGRA and manual marking was statically comparable. In the present study, the median axis disparities did not exceed 1.0 degree. That follows American Society of Cataract and Refractive Surgery survey that incorrect implant axis greater than 10 degrees from that determined preoperatively was unacceptable.[6] Methods of manual marking of axes are effective and precise. However, markers can be dispersed that leads to 10-degree misalignment in axis determination.[1,10,11] Lin et al[12] in 30% cases was unable to determine the axis, because of washed out ink. Additionally, an ink marker may be the source of potential infection. The risk can be dimished by using thermal corneal marking such as ThermoDot (BVI, Waltham, MA).[12] Using INTEGRA system was same statistically accurate as horizontal slit-lamp marking.

Hura and Osher[10] compared 2 methods of intraoperative implant axis determination: the Alcon Verion Image Guided System (Alcon Laboratories, Inc., Fort Worth, TX) and Zeiss Callisto Eye (Carl Zeiss AG, Dublin, CA). In half of the assessed images taken from 16 eyes, the difference in determining axis exceeded 3 degrees.[7,10] It is claimed that objective systems are not fully comparable.[10,11] The disparities recorded with INTEGRA were lower, but a multicenter study comparing all the devices mentioned should be performed to provide better evidence for its reliability. Lin et al believe that the various automated methods, such as Callisto and Verion, used to assist surgeons in determining the TABO scale and incision location during surgery give similar results but with greater

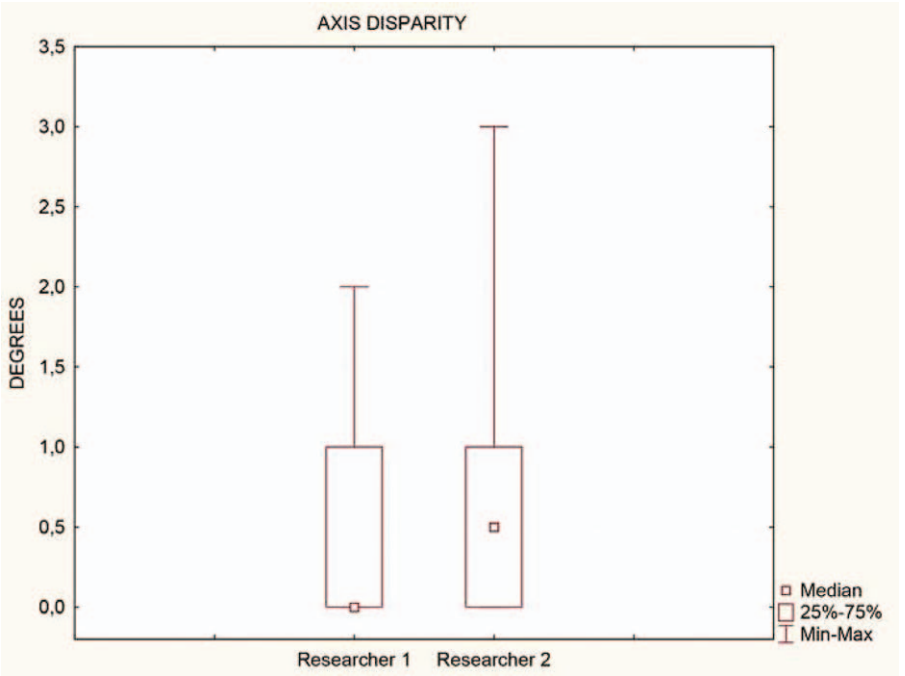

Figure 5. . The axis disparity measured by researchers between manually designated axis and the INTEGRA.

repeatability.[1,12] However, other researchers have found a similar repeatability using manual methods.[7,12–16] Lin et al[12] compared the effectiveness of different methods of marking the axis of the implant, in which the Verion system was considered the reference method. The results showed that the method using image tracking has similar credibility to horizontal slit beam marking. Using axis marking by bevel knife tip to perform subjective direct visual marking on the table is inaccurate.[12] In other publications, which compared methods of manual and automated implant axis determination, the results remain inconsistent.[12,13] The current study presents that the axis determination using INTEGRA is enough accurate to daily practice as alternative technique. The dominant value was 0.0; thus, in most of the cases, the system showed the same axis as reference manual.

The cyclotorsion is a state that determines using reliable method of marking, which can be performed horizontally. Vertical methods are inaccurate. Digital methods and slit-lamp marking provide enough precise marking, but digital methods are resistant to mark fading.[12]

The advantage of automated methods is that markers cannot fade and provide extra intraoperative information like the TABO scale, meridians, visual axis, and incision markers. It may help the operator to plan the surgery. The same surgeons used 2 manual methods to limit the misalignment risk, but it was time consuming and cumbersome.[7] The preoperative axis designation with surgical pen assisted with slit-lamp was chosen as reference method, because it has the least vertical misalignment among other manual methods.[7]

In the past, eyeball tracking using iris pattern recognition was shown to be an imprecise method. This was due to pupil dilatation during surgery, resulting in a reduced area of iris. A scleral vessel-tracking system when used intraoperatively is more effective.[4] The authors suggest that the use of adrenaline solution during the procedure additionally contracts the vessels, which can have an effect on the accuracy of tracking. However, the tracking system was not interrupted in this case. Used algorithm in the INTEGRA system showed accuracy and tracking stability.

The reason for the greater disparity in determining oblique axes by researcher 2 may be that he did not receive the patient's

Table 1

Outcomes of measured axes between manually designated axis and INTEGRA.

No.	Operator Axis	Researcher 1 Axis	Researcher 1 Difference	Researcher 2 Axis	Researcher 2 Difference
1	150°	151°	1°	150°	1°
2	140°	140°	0°	140°	0°
3	135°	135°	0°	134°	1°
4	30°	31°	1°	30°	1°
5	55°	56°	1°	57°	1°
6	90°	88°	2°	90°	2°
7	16°	15°	1°	15°	0°
8	33°	32°	1°	35°	3°
9	45°	45°	0°	45°	0°
10	21°	20°	1°	20°	0°
11	11°	10°	1°	10°	0°
12	23°	23°	0°	24°	1°
13	44°	44°	0°	45°	1°
14	160°	160°	0°	160°	0°
15	90°	90°	0°	90°	0°
16	180°	180°	0°	180°	0°
17	155°	155°	0°	155°	0°
18	5°	5°	0°	5°	0°
19	12°	11°	1°	10°	1°
20	148°	148°	0°	149°	1°

history and analyzing the axis from the video alone might have required greater experience as the more eyes he analyzed the lower was the disparity. This observation must be closely watched in larger studies in the future to make sure that adequate training is in place.

5. Limitations

The effectiveness of determining the axis and subsequent surgical results, using this type of device, enables a similar outcome to that achieved with manual methods without the need for manual marking and the caveats associated with this approach. Nevertheless, the results must be confirmed on a larger group, and the procedures performed by a larger number of surgeons and not only the intraoperative implantation axis should be monitored, but postoperatively in a sitting position and recumbent.

6. Conclusions

INTEGRA is a fading-free, contactless method of axis designation. Using intraoperative devices assisting surgeons in determining the implantation axis, based on the scleral vessel image tracking is statistically precise and repeatable as manual slit-lamp technique.

Author contributions

Conceptualization: Dorota Wyględowska-Promieńska, Piotr Jaworski.
Data curation: Marcin Jaworski.
Formal analysis: Marcin Jaworski.
Investigation: Dorota Wyględowska-Promieńska, Piotr Jaworski, Marcin Jaworski.
Methodology: Piotr Jaworski.
Project administration: Dorota Wyględowska-Promieńska.
Resources: Krzysztof Jaskot, Robert Bieda.
Software: Krzysztof Jaskot, Robert Bieda.
Writing – original draft: Marcin Jaworski.
Writing – review & editing: Dorota Wyględowska-Promieńska, Richard Packard.
Marcin Jaworski orcid: 0000-0003-2153-3343.

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