Evaluating the Predictability of Postoperative Target Refraction Using the Prototype of a New Intraoperative Aberrometer

Evaluation des Prototyps eines neuen intraoperativen Aberrometers für die Vorhersage der postoperativen Zielrefraktion

Authors
Tamer Tandogan[1,2], Ramin Khoramnia[3], Chul Young Choi[4], Gerd U. Auffarth[1]

Affiliations
1 Augenklinik, Pallas Kliniken AG, Olten, Schweiz
2 Universitäts-Augenklinik, UniversitätsKlinikum Heidelberg, Deutschland
3 International Vision Correction Research Centre (IVCRC) und David J Apple International Laboratory for Ocular Pathology, Universität Heidelberg, Deutschland
4 Ophthalmology, Sungkyunkwan University School of Medicine at Samsung Medical Center Cancer Center, Gangnam-gu, Republic of Korea

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Georg Thieme Verlag KG, Rüdigerstraße 14,
70469 Stuttgart, Germany

Correspondence
PD Tamer Tandogan, MD
Augenklinik, Pallas Kliniken AG
Louis Giroud-Strasse 20, 4600 Olten, Schweiz
Phone: + 41 7 64 19 62 89
tamer.tandogan@pallas-kliniken.ch

ABSTRACT

Despite all the progress in cataract and refractive lens surgery, refractive surprise is common in clinical practice. A significant postoperative refractive error is particularly annoying – and contributes to the patient's dissatisfaction with the procedure and the surgeon – when a multifocal IOL, an EDOF-IOL or a toric IOL has been implanted. The relatively new technology of intraoperative aberrometry offers the surgeon the option to intraoperatively measure the eye and its refraction, either directly after lens extraction and/or following IOL implantation. Currently, three different systems are available. In a number of studies, the technology has shown a better refractive predictability than preoperative biometry. Besides giving an evaluation of the prototype of a new intraoperative aberrometer, the I-O-W-A system, we also present our results on the influence of the kind of anaesthesia chosen and of two different IOL designs on the predictability of intraoperative aberrometry.

ZUSAMMENFASSUNG

Bei allen Fortschritten der präoperativen Biometrie in der Kataraktchirurgie und der refraktiven Linsenchirurgie sowie den verschiedenen heute gebräuchlichen Kalkulationsformeln gehören „refraktive Überraschungen" nach wie vor zum klinischen Alltag. Besonders nachteilig und enttäuschend ist ein Abweichen von der Zielrefraktion für Patienten, die sich für eine spezielle Linse wie eine Multifokal- oder EDOF-IOL entschieden haben sowie vor allem für Patienten, die eine torische IOL implantiert bekommen, bei der schon leichte Abweichungen von der Zielachse die Sehschärfe nachteilig beeinflussen können. Die intraoperative Aberrometrie ist eine Methode, die es dem Chirurgen ohne zusätzlichen größeren Aufwand erlaubt, die Refraktion des aphaken Auges (nach Entfernung der natürlichen Linse) und kurz darauf des nunmehr pseudophaken Auges zu überprüfen. Die Methode, für die es zurzeit 3 unterschiedliche Geräte gibt, zeigt in den meisten Evaluationen eine deutlich geringere Abweichung von der Zielrefraktion als die präoperative Biometrie. Neben einer Evaluation des Prototyps des I-O-W-A-Systems zur Ausmessung des Auges während der Operation werden eigene Ergebnisse über den Einfluss des Anästhesieverfahrens und des IOL-Typs vorgestellt.

Introduction

Today, cataract surgery is always refractive surgery as a matter of course. Achieving a target refraction that gives the patient partial or – if the patient chooses an advanced intraocular lens (IOL) design such as a multifocal (MIOL) or extended depth of focus (EDOF) IOL – near-total spectacle independence is key to surgical planning and meeting patient expectations. However, this goal is not always achieved: according to a large Swedish statistical study, 72.2% of operated eyes are within ± 0.5 dpt of the target refraction [1] after cataract surgery. Partial coherence interferometry, swept-source optical coherence tomography (SS-OCT), and optical low-coherence reflectometry have become established as standard methods for preoperative biometry [2, 3]. However, depending on the calculation formula, only about ¾ of patients are within ± 0.5 dpt of the target refraction [4]. In such cases, the technology of intraoperative aberrometry could provide additional complementary optimization.

Wavefront aberrometry has been used for many years, predominantly in the field of laser refractive surgery. Wavefront measurements are used to plan more accurate and more individualized treatment. This technology is also increasingly used in cataract surgery. Implants of premium lenses (i.e., the above-mentioned IOLs with special functions such as EDOF-IOL, MIOL, or toric IOLs) are becoming increasingly common [5]. A major problem, depending on the severity of the cataract, is caused by fluctuating refractive indices of the crystalline lens [6, 7]. The more recent approaches include intraoperative wavefront measurement, which theoretically overcomes some of the sources of error in classic biometry based on axial length measurement, natural lens, and keratometry [8].

Currently available systems for intraoperative aberrometry

In order to be used intraoperatively in cataract surgery, the devices need to meet specific requirements. Their small measuring distance to the eye and their size and heavy weight, up to 15 kg in older systems, prevent them from being mounted on the microscope in the operating room. Therefore, the equipment manufacturers had to innovate and find new solutions.

▶ **Tables 1** and **2** provide an overview of the systems currently available. The ORA system (Alcon, USA) uses a Talbot-Moiré interferometer and converts the image pattern into the frequency domain. In the I–O-W-A wavefront meter (Eyesight&Vision GmbH, Nuremberg, Germany), a laser beam scans the cornea, which corresponds to a sequential Tscherning measurement principle (▶ **Fig. 1**). In the HOLOS IntraOp system (Clarity Medical Systems, USA), a sequential Hartmann-Shack sensor is used through an aperture. All three devices can be affixed to the microscope's biometric mount (▶ **Fig. 2**).

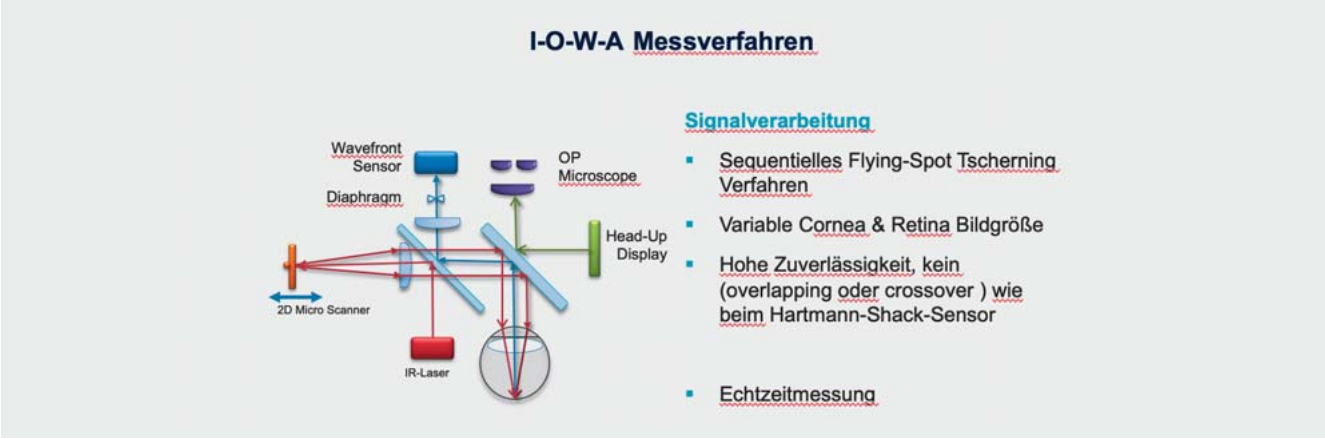
▶ **Table 1** Available intraoperative aberrometers.

Device	Interface	Measurement range (dpt)	Application	Approval
ORA	Panel PC with Internet connection, cable connection to the wavefront sensor	− 5 – + 20	Refraction of aphakic and pseudophakic eye	2010 FDA 2012 CE
I–O-W-A	Contactless control, 3D microscope image, PC connection not required	− 8 – + 25	Cylinder axis marking	2013 CE
HOLOS	Panel PC with cable connection to sensor	− 10 – + 30	Limbal and corneal relaxing incisions (LRI and CRI)	2014 FDA

Source: Manufacturer's information

▶ **Table 2** Product characteristics of intraoperative aberrometer.

	ORA	I–O-W-A	HOLOS
Real time			
▪ Refraction	+	+	+
▪ IOL calculation	From 40 images (4 s)	+	+
Optical zone diameter	No data	Adjustable 3–6 mm	No data
Working distance	150–200 mm	150–175 mm	150–200 mm
Touchpad operation	+	+	+
Touch control/foot pedal	–	+	–



▶ **Fig. 1** Measurement principle of the I–O-W-A system.

ORA System (Alcon, USA)

This intraoperative wavefront aberrometer was originally developed to support astigmatism correction during cataract surgery, as well as refractive corneal surgery such as arcuate corneal incisions or limbal relaxing incisions (LRI). Although the measurements are taken in real time, they must be sent to the server via a secure Internet connection. There they are compared to the preoperatively transmitted biometric data, as well as the calculated effective lens position (ELP). By using a server-side IOL database, it is possible to calculate the refractive power of the optimal IOL [9].

HOLOS IntraOp (Clarity Medical Systems, Pleasanton, CA, USA)

In the HOLOS system, the measurement is similar to that of the original Hartmann-Shack sensor. However, individual areas of the wavefront are analyzed sequentially. The position of a 2D microscanning mirror controls which part of the wavefront is imaged through an aperture onto a position sensitive detector (PSD). The amount of displacement of the light spot on the PSD is a measure of the eye's local refractive error. These refraction values are converted to sphere, cylinder and cylinder axis in real time [10].

I-O-W-A-System (Eyesight&Vision GmbH, Nuremberg)

In the I–O-W-A wavefront meter, a 2-dimensional microscanning mirror scans the entire surface of the eye with a thin laser beam in about 40 ms. A pixel on the retina leaves the apex of the eye as a reflected beam and is imaged onto a PSD. The information on the wavefront obtained this way (i.e., the refraction measurement in the form of sphere, cylinder, and axis) is presented to the surgeon via a display mounted on the microscope.

This allows real-time reading of the spherical value and alignment of a toric IOL. Refraction values are updated every second. One advantage of this system is that the data is not passed to a central server; this ensures data protection.

All three devices meet the requirements for intraoperative use during cataract surgery. Unlike the ORA system, the I–O-W-A and HOLOS instruments are capable of measuring the wavefront for optical zones of different sizes. I–O-W-A and HOLOS would also be able to calculate higher-order aberrations using their measurement principle. By converting the image pattern to the frequency domain, the ORA system can indeed detect that higher-order aberrations are distorting the dot pattern. However, higher-order aberrations can only be determined by comparing them to reference samples from various calibration targets (according to the manufacturer's statement).

▶ **Fig. 2** I–O-W-A mounting on the operating microscope.

In addition to presenting this technology, the aim of this study was to evaluate the use and functionality of this new aberrometry device in routine surgical practice.

Materials and Methods

The I–O-W-A intraoperative aberrometry device was used consecutively in a double-pass procedure in all patients during routine surgery at two centers. We then evaluated the use of the prototype in the standard surgical setting. Single eyes of consecutive patients at the respective surgical facility were included in the

study. The stop-and-chop technique was used for phacoemulsification, and a bimanual irrigation-aspiration technique was used for removal of the cortex. The main corneal incision was made as a posterior limbal self-sealing tunnel incision 2.5 mm in diameter. Furthermore, two paracenteses were performed, each one 90° from the main incision. The validation of measurement results in comparison to existing preoperative measurement methods and calculation formulas was then analyzed. Potential influences on measurement accuracy and reproducibility as well as on the prediction accuracy of the target refraction were investigated. The results of the intraoperative measurements were compared to the subjective refraction values six weeks after surgery.

In this study, particular emphasis was placed on determining the percentage of eyes in which the measurement was feasible, how long the measurement took, and whether the measurements were reproducible. Furthermore, we investigated the handling of the device and the learning curve required to use it in routine surgical practice, and whether any complications were observed.

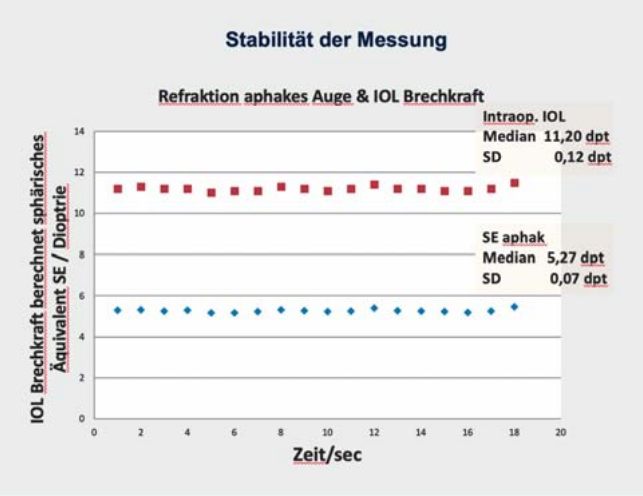
In addition, we identified factors that influenced measurement and were relevant to the prediction accuracy of the postoperative target refraction. We also studied the validity of the measurements, and the predictability of the target refraction. Finally, we compared measurements taken with this new device to established preoperative measurement methods in combination with IOL calculation formulas.

We performed intraoperative aberrometry with the I-O-W-A system in 87 eyes, in which we investigated prediction accuracy under drip anesthesia. In another cohort, we investigated achievement of the target refraction as a function of IOL refractive power. This involved analyzing whether a systematic deviation could be identified. For this purpose, the refractive power of the IOL to be implanted was determined biometrically using the NIDEK-AL-Scan or the IOLMaster in a total of 42 patients prior to surgery. An Alcon SN60AT was used in 15 eyes, and a 1stQ Basis Z hydrophilic IOL was used in 27 eyes. Immediately after IOL implantation, the refraction of the pseudophakic eye was measured intraoperatively using the I–O-W-A aberrometer. These intraoperative refraction values were compared to the subjective follow-up results obtained more than 6 weeks after surgery, and were then used to determine correction factors.

Results

In all patients, a measurement with IOWA could be performed under the usual conditions of cataract surgery and a measurement result could be obtained. The handling of the device proved to be straightforward. No complications arising from the use of the device were observed.

A steep learning curve was involved in operating the device. In the first 10 patients, the measurement took up to 1 minute per eye. During the examination of the subsequent eyes, intraoperative measurement with the aberrometer took no more than 30 seconds. In the initial phase, contact between the surgeon and the measuring device occurred several times; this was due to the slightly reduced working distance. By covering the device in a sterile manner with a protective film, this problem was resolved.



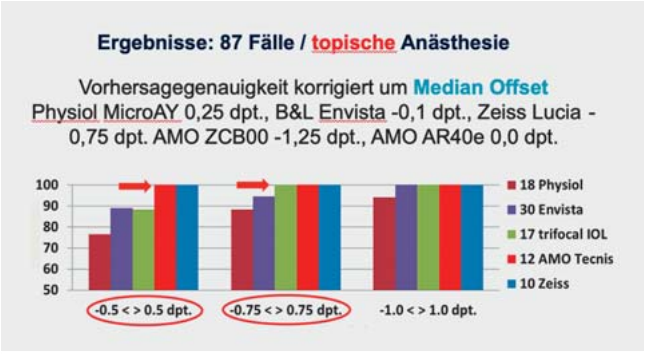
▶ **Fig. 3** Repeated measurements show the stability of the measurement results with the I–O-W-A system.

Furthermore, it proved important to prevent any deformation of the bulb. The pressure of the eyelid retractor on the bulb repeatedly led to deviations in the measured values. Good lubrication of the ocular surface as well as good alignment of the eye were also identified as relevant factors for obtaining reliable and reproducible measurements.

The values obtained intraoperatively demonstrated a high degree of stability in the measurement; in repeated measurements over a period of up to 20 seconds, the values of the spherical equivalent were effectively the same (▶ **Fig. 3**). Our evaluation of the influence of the chosen method of anesthesia showed a clear tendency toward more accurate measurement results with topical anesthesia compared to retrobulbar or peribulbar anesthesia. In some IOL designs, 100% of the operated eyes were within half a diopter of the target refraction under this form of analgesia. With peribulbar anesthesia, the prediction accuracy was lower because of the associated, albeit minimal, bulbar deformation. The results of the measurements under drip anesthesia are shown in ▶ **Fig. 4**.

IOL-specific correction factors turned out to be another important factor in improving prediction accuracy. Both the IOL design and the optical properties of the artificial lens influence the accuracy of intraoperative aberrometry. These showed a clear dependence on the type of implanted IOL and on the biometry of the eye measured preoperatively using the IOLMaster 500. Thus, the 1stQ lens had a median deviation of – 1.1 dpt, and the Alcon IOL had a median deviation of – 0.2 dpt. The results of these measurements are shown in ▶ **Fig. 5** and **Fig. 6**.

We determined a correction factor of $y = 0.0266 x + 0.5843$ for the 1stQ lens, and $y = -0.0667 x + 1.4799$ for the Alcon IOL. With the help of these correction factors, it will be possible to improve the prediction accuracy of the target refraction in the future. This cohort also showed higher refractive accuracy in the 15 eyes operated on under topical anesthesia. All eyes achieved a refraction value that was no more than 0.75 dpt away from the target refraction. Using the I–O-W-A system, we were able to show a good correlation – with a Pearson correlation of $r = 0.96$ – between the pre-



▶ **Fig. 4** Under topical anesthesia, a prediction accuracy of up to 100 % could be achieved for some IOL types.

operatively calculated refraction and the intraoperative measurement in the aphakic eye (▶ **Fig. 7**).

Discussion

The new technologies for intraoperative wavefront measurement have the potential to increase the percentage of patients who achieve the specified target refraction after lens surgery.

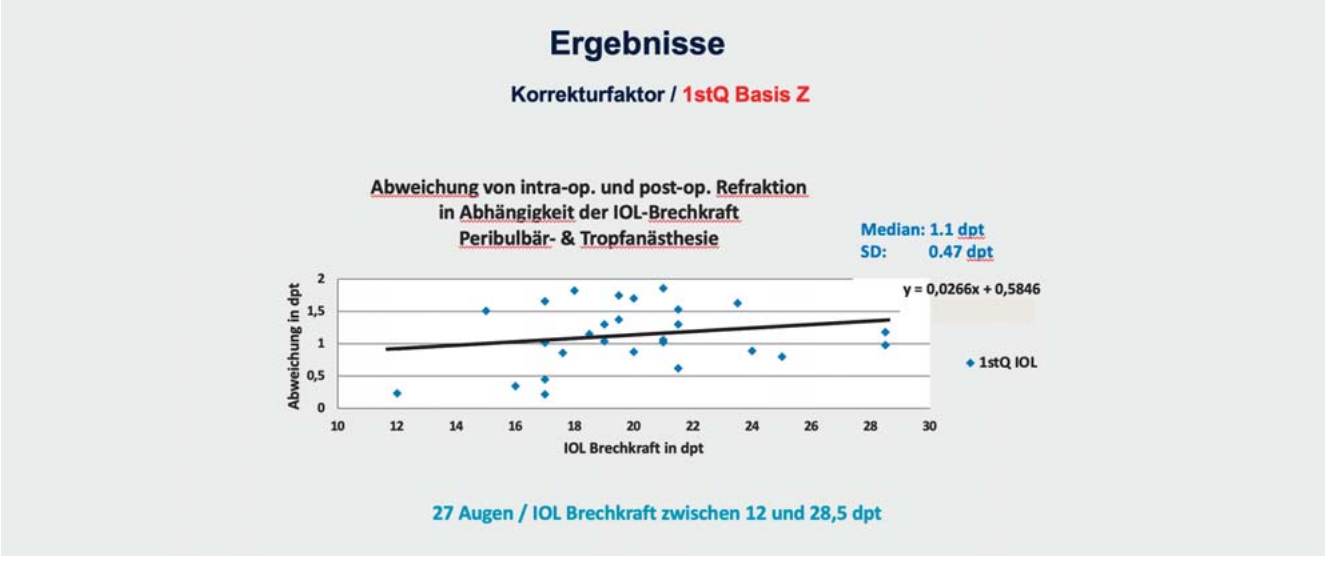
Like most methods for measuring the monochromatic aberrations of the human eye, wavefront measurement is based on ray tracing. A distinction is made between the "single-pass" and the "double-pass" procedure. In Tscherning's single-pass procedure, the incoming light passes through the eye only once and the patient describes his or her own ocular aberrations. Modern objective measurement methods used in laser refractive surgery since 1999 are exclusively "double-pass" methods. In this case, the light reflected from the retina is measured outside the eye by a sensor. Because in this process the measuring beam passes the eye in the optical system a second time, the aberrations can increase. To prevent this, either the entrance or exit pupil must be limited in size [11].

In this article we aim to present the new method of intraoperative aberrometry on the basis of our own initial clinical experience. The objectives of the study were to determine the accuracy of this technology compared to preoperative biometry, and to identify the potential influence of anesthetic procedures and the use of the eyelid retractor.

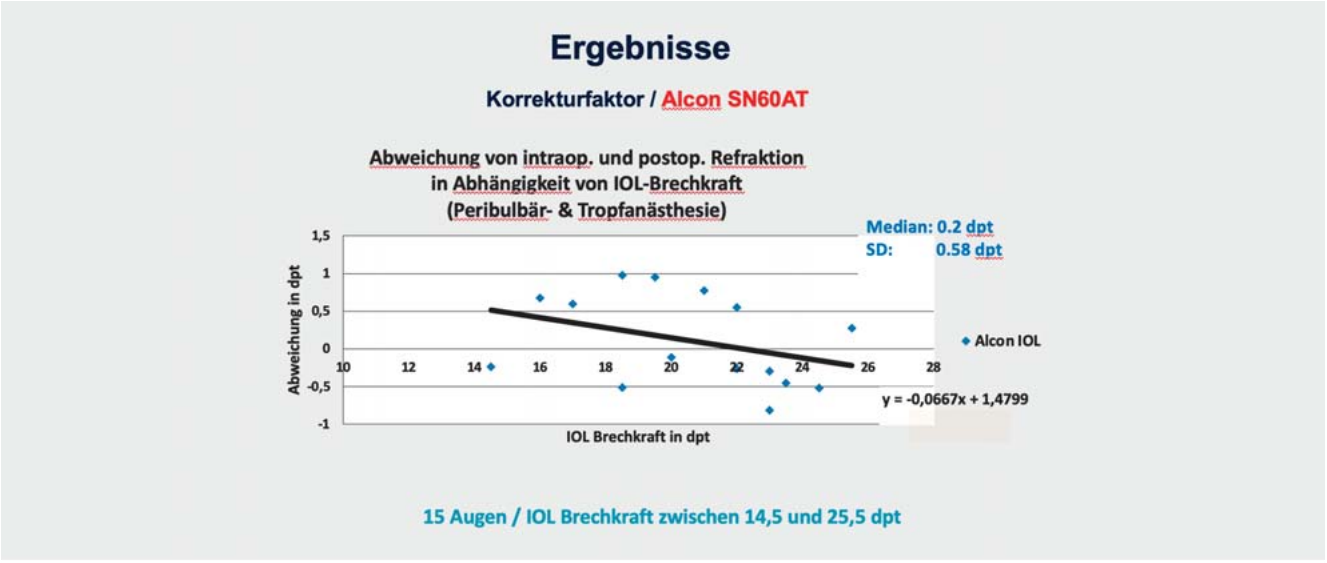
Intraoperative aberrometry: its potential for clinical application

In clinical practice, intraoperative aberrometry offers many benefits:

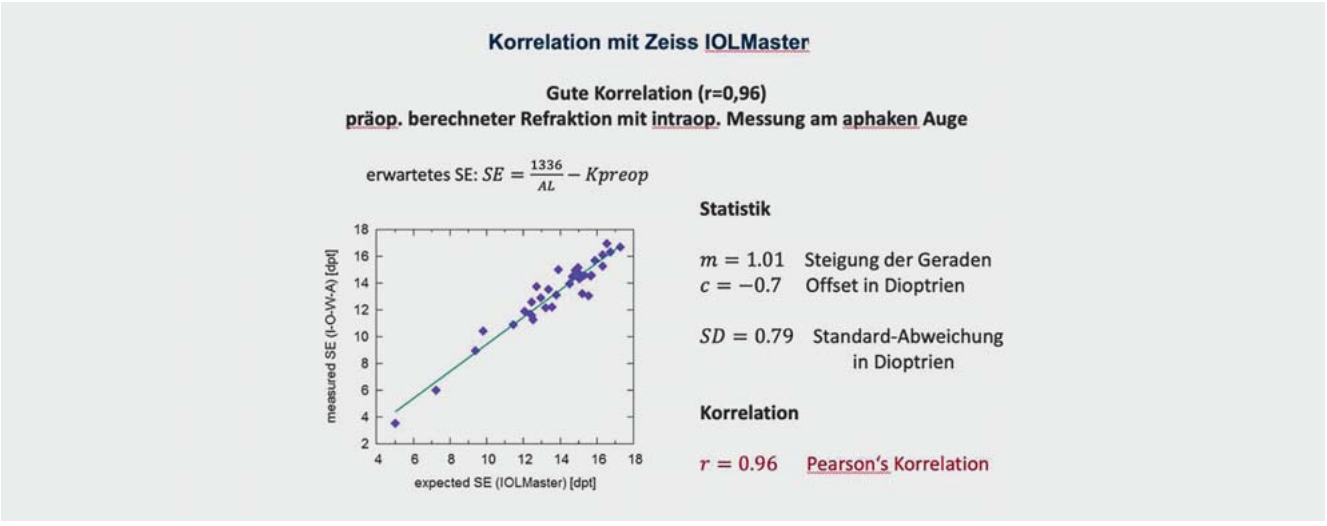
- The method can be used to validate preoperatively collected biometric data during the operation.
- The anterior and posterior sides of the cornea are measured in combination.
- Surgically induced changes in corneal refractive power can be detected or verified immediately.
- This approach can also be used for clinical findings that often defy accurate preoperative measurement, such as mature cataracts, cases of keratoconus, and eyes after LASIK, keratoplasty, and other procedures.
- There are many formulas, such as Haigis, Hoffer and Holladay, that enable IOL calculation based on intraoperative data.
- The cylinder axis is marked intraoperatively.
- If necessary, the refraction check performed towards the end of the surgical procedure on the now pseudophakic eye allows for a final correction, such as rotating a toric IOL, or (in the worst case) replacing the IOL.



▶ **Fig. 5** Deviation of intraoperative and postoperative refraction and correction factor for 1stQ Basis Z.



▶ **Fig. 6** Deviation of intraoperative and postoperative refraction and correction factor for Alcon SN60AT.

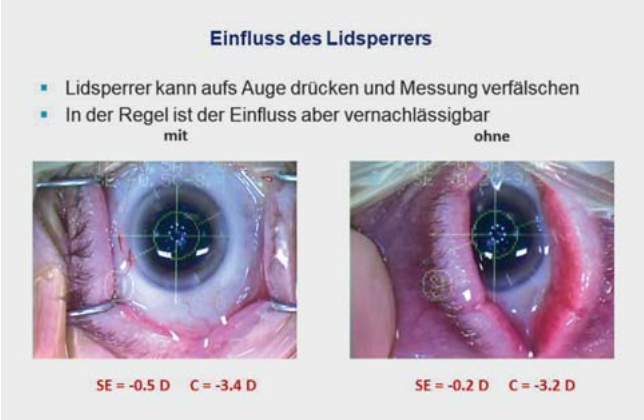


▶ **Fig. 7** Good correlation between intraoperatively determined values and values measured preoperatively (using the IOLMaster).

The development of new technologies for reliable intraoperative measurement of the eye's total refractive power may help to reduce deviation from the postoperative target refraction after cataract surgery and in refractive lens surgery. Intraoperative aberrometry can be considered as a surgical refractometer that allows the surgeon to determine refraction during surgery and after removal of the natural lens, and to verify the preoperative biometrically determined refractive power of the IOL to be implanted – and, if necessary, to implant another artificial lens in the case of major deviation [12]. After the implantation procedure, a new measurement can be performed on the now pseudophakic eye to detect any residual refractive deficit.

In what is probably the largest study to date on this technology which is still very new and under development, a study involving more than 30,000 eyes, a significantly lower absolute prediction error was documented for intraoperative aberrometry compared to preoperative planning [13]. However, some other authors have not found such clear differences [14, 15]. These studies had much smaller cohorts, however.

In eyes fitted with a toric IOL due to astigmatism, the optimal alignment of the axis can be checked at this stage. The excellent predictability of toric IOLs in particular was demonstrated by Blaylock et al. in a publication on 151 eyes of 106 patients. In this study cohort, 89.4% of eyes had a spherical refractive deficit of 0.5 dpt using intraoperative aberrometry and only 85.4% based on preoperative planning. An uncorrected distance visual acuity of 0.10 logMAR or better was recorded in 124 eyes (82.1%) postoperatively, and 0.00 logMAR or better in 90 eyes (59.6%) [12].



▶ **Fig. 8** The pressure exerted by the eyelid retractor on the bulb can influence the measurement results of intraoperative aberrometry.

▶ **Fig. 9** The Purkinje images are used to control the optimal alignment in the visual axis.

Real-time measurement of the total refraction of the eye while the surgery is still in progress may allow immediate correction during the same session, thereby helping to reduce both cost and risk. Intraoperative measurement and adjustment of cylinder power, as well as more accurate positioning of a toric intraocular lens, allows independence from bulbar cyclorotation. Furthermore, this technology could allow a significant improvement of refractive outcomes in complicated situations such as mature cataract, vitreous hemorrhage, or status post corneal refractive surgery.

However, there are still some potential limitations to measurement accuracy that must be considered: an important point is that the refractive power of the eye can vary greatly during surgery. Bulbar deformation caused by the eyelid retractor (▶ **Fig. 8**), lubrication of the corneal surface, and possible bulbar hypotony caused by the surgery all play a role in this [16]. Furthermore, corneal epithelial edema as well as stromal swelling (diffuse or segmental) can cause a significant change in refraction, even if they are so minor that they cannot be detected by the surgeon using the microscope.

Influence of the Anesthesia Method and IOL Design

In our own study, we were specifically interested in investigating the accuracy of aberrometry under different types of anesthesia and as a function of two different IOL designs. We found that the greatest accuracy was achieved with topical anesthesia. In our view, this is due to bulbar deformation caused by the peribulbar injection of a local anesthetic; while this effect may be clinically subtle, it has a significant effect on the measurement accuracy.

Furthermore, we found that different IOL models require different correction factors to achieve the best possible prediction accuracy for the target refraction. Given an expected increase in the use of intraoperative aberrometry, these data will also be determined for other types of IOLs; a separate study on this topic is due for submission shortly. Theoretically, and apparently also in clinical practice, various parameters have an influence on the measurement result and thus on a possible correction factor to be applied. These include asphericity of the IOL, chromatic aberrations, and the unfolding process of the IOL.

In principle, correct centering on the optical axis must be ensured for all measurements in intraoperative aberrometry, otherwise significant deviations may occur. Accordingly, good cooperation from the patient under drip anesthesia or careful control by the surgeon in case of intubation anesthesia or peribulbar anesthesia play an important role in reliable measurement. Thus, the I–O-W-A system allows verification of the patient's fixation by means of Purkinje images (▶ **Fig. 9**), which must appear concentrically arranged in the surgical microscope. Of course, in order to perform this check, the ocular surface must be adequately lubricated (e.g., with BSS), since the Purkinje images may be blurred in dry corneas, resulting in too low a measurement of the spherical equivalent in aberrometry.

This technology can be integrated into surgical microscopes and also partially into phacoemulsification devices by modifying and scaling down the prototype. This can prevent the aberrometer from reducing the working distance, which could be distracting during surgery. Intraoperative measurement of total refraction and aberration of the eye offer new possibilities that could increase achievement of target refraction in modern lens surgery. Currently, these technologies are not yet able to fully replace preoperative biometry and IOL calculation methods. However, it is a new technology whose full potential is far from being exploited and which holds great promise for surgeons and patients in cataract and refractive lens surgery.

This evaluation of initial experience with the technology has some limitations, of course: our case numbers are very small, and there was a training cohort but no validation cohort. The correction factors we have identified need to be validated in a larger prospective cohort in future studies.

CONCLUSION BOX

Already known:

- Real-time refraction measurement during surgery offers a significant advantage in optimizing results.
- Intraoperative aberrometry, for which two different devices are currently available, shows a much smaller deviation from the target refraction than preoperative biometry in most evaluations.

Newly described:

- In this article we aim to present the new method of intraoperative aberrometry on the basis of our own initial clinical experience. To this purpose we investigated improvements in achieving target refraction, and we identified factors that have an influence on this measurement method.
- Among the common anesthetic methods, topical local anesthesia is preferable to peribulbar injection for intraoperative aberrometry because it achieves higher refractive accuracy according to our study results.
- Additional IOL-specific correction factors can increase prediction accuracy.

Conflict of Interest

The authors received no fee for this study, but the following statements are applicable to the laboratory in general: The IVCRC/and David J Apple Laboratory (David J Apple Center for Vision Research.) is supported by these companies: Alcon, Johnson&Johnson, Hoya, Physiol, Rayner, personal fees, and non-financial support from Kowa, Ophtec, Oculentis/Teleon, Santen, and Acufocus, outside the submitted work.

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