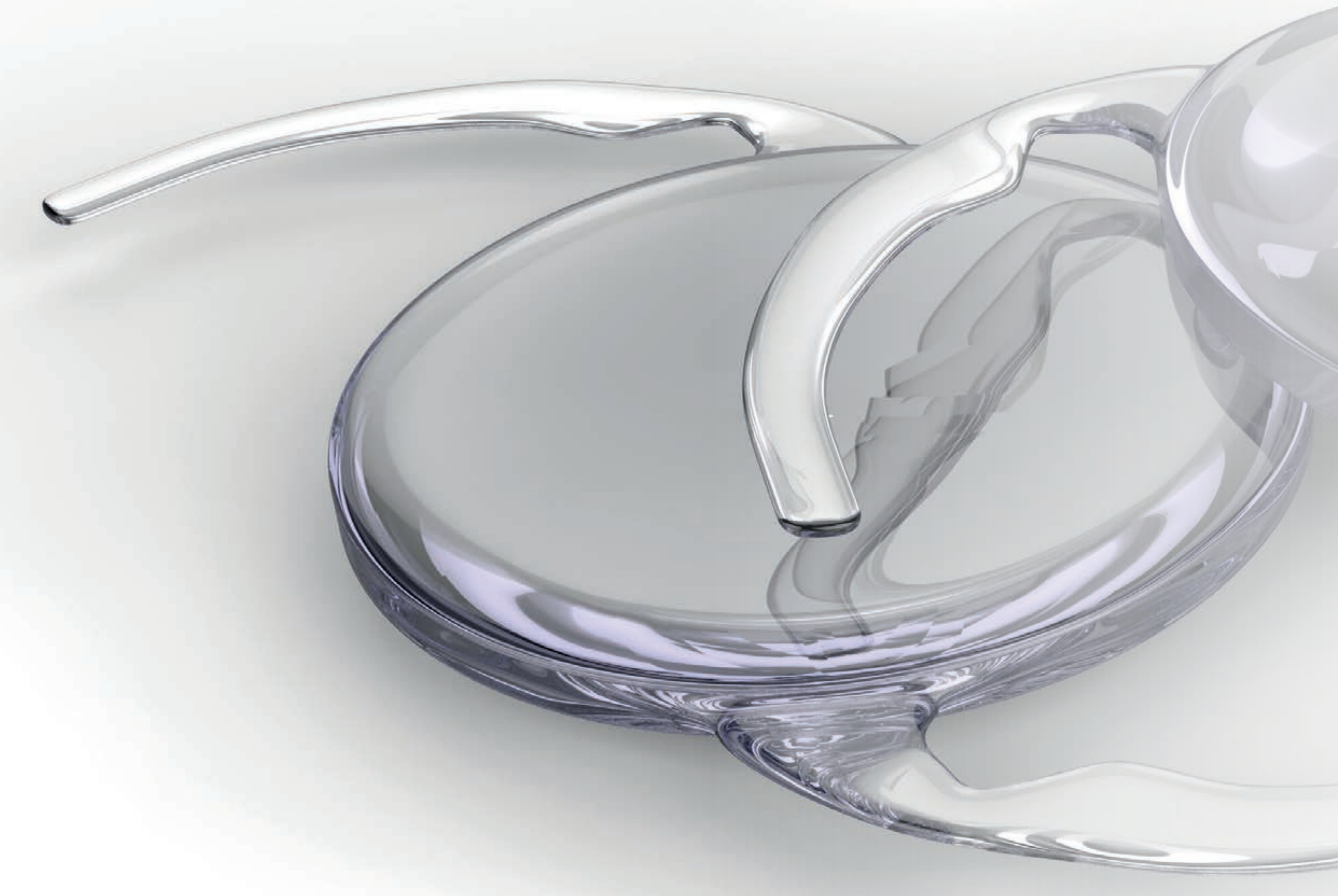


ISO-compliant IOL inspection

Implementing the ISO-compliant Intraocular Lens (IOL) inspection in your production

The demand for IOLs is exponentially rising worldwide. In addition, IOL production technology requirements and patients' expectations of implants are changing. Manufacturers are responding with developing premium lenses, including trifocal toric and extended depth of focus (EDOF) lenses. For all IOL manufacturers, it is therefore becoming more important to have their lens production quickly and comprehensively organized. However, they face the challenge of an ISO 11979-compliant inspection. ISO 11979 precisely describes the measurement parameters, method and conditions under which the IOLs should be tested. These conditions include the use of real model eyes (variant ME 1 and ME 2) with the lenses' in-situ placement. By Samira Bajrovic and Dörte Zimmermann

Cataract is the leading cause of vision impairment and remains the principal cause of preventable blindness worldwide. Cataract surgery has become the most frequently operation performed worldwide and has exponentially grown in the past decade, affected by demographic changes, increased access to healthcare and healthcare spending ability. The analysis of Market Scope in 2017 estimated more than 26 million surgeries and an increased procedure capacity at a compounded annual growth rate of 3.1 %. A trend of constant growth in the cataract surgical equipment market is expected at a compound annual growth rate (CAGR) of 5.6 % a year, calculating USD 2 billion by 2022. Grand View Research expects the global intraocular lenses (IOLs) market to reach USD 5.54 billion by 2025.

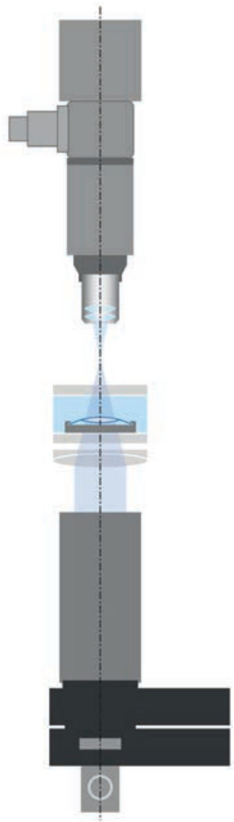
In view of the continuous increase in the cataract market, requirements for IOLs production and technology are advancing. Patients' demands are becoming more challenging by expecting a perfect vision for proximity and distance without glasses or contact lenses after surgery. In order to meet the market needs, manufacturers are developing premium multifocal IOLs, which include trifocal-toric and extended depth of focus (EDOF) lenses, to achieve the best possible refractive result. A trend of increasing adoption and growth rate of premium multifocal lens implants has been observed over the last years. By proving to deliver better visual function, greater spectacle independence and lower levels of astigmatism, premium IOLs are considered more cost-effective and safer in the long run than conventional monofocal IOLs.

Thus, there is a high demand for powerful measurement systems to test the power and quality of both these innovative complex and conventional lenses in accordance with the ISO 11979 requirements.

MEASUREMENT AND SORTING PARAMETERS POWER AND MTF

The effective focal length (EFL) [mm] is defined as the distance between the principal plane of the lens and the imaging plane. By measuring the EFL, the refractive power (sphere, cylinder and add power) is calculated. It displays the IOL's ability to focus into the retina plane. Thus, the power of the intraocular lens is the most important parameter to determine. For evaluation of the optical quality or performance of an IOL, the Modulation Transfer Function (MTF) needs to be assessed. It is defined as the ability of an optical system to transfer the details of an object to the image. The MTF is determined by using the magnitude of the Fourier domain analysis. It can be measured directly via a cross target or point target to obtain the line or point spread function (LSF, PSF), resulting from imaging a thin line or point of light. In addition, the measurement parameters power and MTF also serve to filter out lenses with false power and/or bad quality.

PATIENTS' DEMANDS ARE BECOMING MORE CHALLENGING BY EXPECTING A PERFECT VISION FOR PROXIMITY AND DISTANCE WITHOUT GLASSES OR CONTACT LENSES AFTER SURGERY.



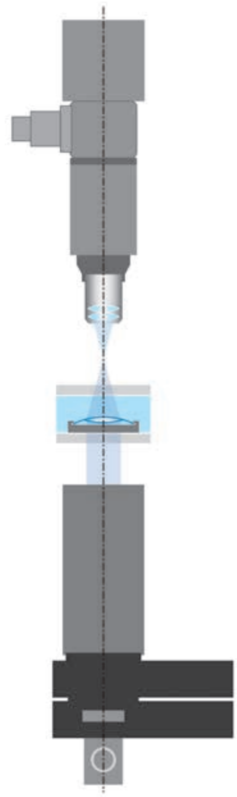


Fig. 1 and Fig. 2: Lens bench design compliant with ISO 11979 as implemented in Trioptics' OptiSpheric IOL Pro 2: Measurement principle with and without model cornea.

MEASUREMENT PRINCIPLE

The concept of lens power is related to the magnification of a lens. According to ISO 11979, testing instruments are required to use the magnification method in order to determine the refractive power of any IOL types (monofocal, multifocal, toric) with any type of structure (refractive, diffractive, sector) or materials (hydrophobic, hydrophilic). A collimator projects the image of a target to infinity. The parallel beam enters the lens under test and emerges from the IOL as a convergent beam focusing in the focal plane. This target image is collected by the objective lens of the microscope and is focused on the high-resolution CCD camera. The EFL of the lens is calculated using the magnification ratio between the well-known target size and the gained image size as described in ISO 11979. For EFL measurement (power determination), double slits are preferable. The size of the magnified double slit is precisely determined and thus, the EFL and the power of the lens are calculated. High quality instruments should reach a measurement accuracy for the power of 0.1 % to 0.3 %. Powers between -2.5 and +3 diopters are measured with an additional lens. Multifocal lenses have different image planes, in which the magnification of the target is determined individually. In toric lenses, the object is imaged in two focal planes that lay orthogonally to each other. The measurement with cross or square targets allows seeing both focusing directions in one setup.

The target used to measure the MTF should either be a slit, crosshair or a pinhole. Its intensity profile is scanned electronically in both the radial and tangential directions. By using Fourier transformation, the MTF is calculated and displayed on the PC monitor in real time. The pinhole target should be used in association with a high-resolution, low-noise camera in order to display a two-dimensional MTF and have a description of the lens in all azimuths. The MTF is determined in the focus or even defocused position. Following the ISO, the IOL can also be tilted and shifted by predefined values with respect to the optical axis. This simulates the condition after the lens's implantation and thus provides feedback on the lens's realistic performance.

In any case, the instrument must offer traceability to international independent testing institutes (PTB-Germany, NPL-UK, NIST-USA) and must be designed to be compatible with the FDA validation (protection of measurement conditions and instrument calibration, improved saving of data, user warnings).

IN-SITU MEASUREMENT AND MODEL EYE

In order to fulfill the ISO 11979 requirements, testing instruments for quality inspection of IOLs need to perform in-situ measurements in a physical model eye, simulating the real human eye condition. For this purpose, two types of model

Fig. 3: The Trioptics OptiSpheric IOL PRO 2 in-situ production tray for 100 lenses.

ESPECIALLY FOR THE PRODUCTION ENVIRONMENT, A USER-FRIENDLY SOFTWARE SHOULD ALLOW A SIMPLE AND EFFICIENT BATCH MANAGEMENT.

eyes (ME1 ≙ c[4.0] = 0 µm, ME2 ≙ c[4.0] = 0 µm ... 0.28 µm), are to be used as an artificial cornea lens.

The standard model eye for single lens testing consists of a wet cell with two parallel glass plates (BK7) as top and bottom surfaces, which are filled with aqueous humor/saline solution with naq= 1.336 (546.1 nm) at 35 °C (optional heating). A small IOL holder positions the IOL in the model eye where the distances between the optical elements are fully designed in order to fulfil the ISO standards. Different apertures for the IOL plane are available. In case of ME1, an achromatic lens is used as an artificial cornea lens to simulate the real eye cornea. While a model cornea is required for in-situ MTF measurements following the ISO standard, in-air and in-situ power measurements are to be performed without a model cornea.

ORTHOGONALITY AND TORIC AXIS

The measurement of orthogonality describes the angle between the IOL's two principle planes, orthogonal = 90°. Toric intraocular lenses have different powers in orthogonal meridians. The toric marker position is detected by assessing the deviation between marker position to toric axis. First, the test algorithm determines the toric axes, followed by the marker detection through image recognition.

TRANSFERRING THE ISO REQUIREMENTS TO PRODUCTION

All ISO 11979 stipulations result in time-consuming measurements when performed individually and manually. An automated procedure is necessary for an efficient production. Mounting all targets, filters, model corneas, apertures and head lenses needed for a complete IOL analysis on fully automated changers as well as a XY translation table, streamline the production. Other optimizations for serial lens production testing are necessary. A motorized tray system and a fully automated measuring procedure are needed to easily and quickly test complete batches of IOLs in a reasonable short time. For a comprehensive usage, it should be applicable for

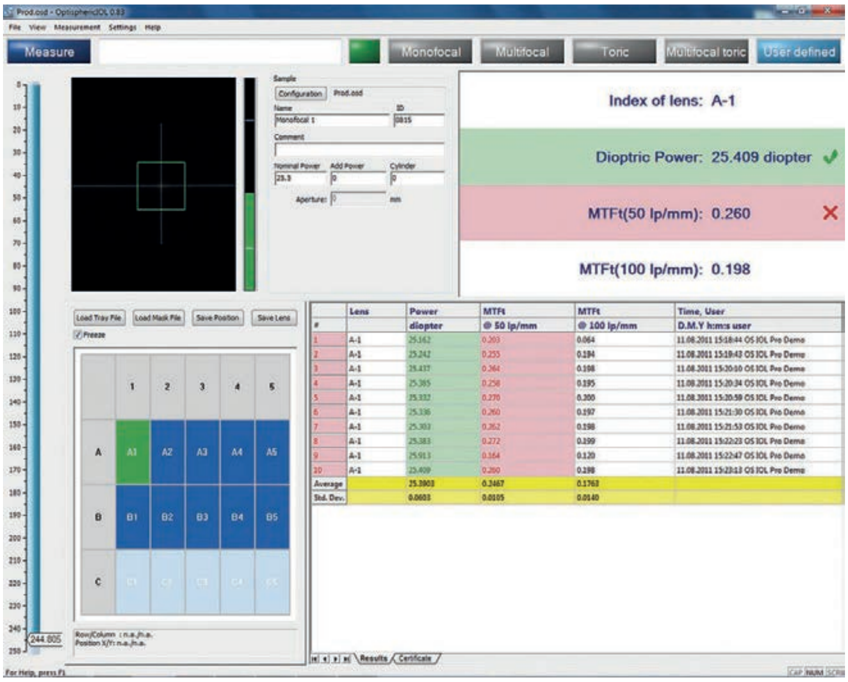


Fig. 4: Software for batch measurement in production with OptiSpheric IOL PRO 2 by TRIOPTICS

different measurement conditions (in-air and in-situ measurements). The in-situ tray should be entirely designed in compliance with ISO 11979 and be equipped with a temperature sensor. To position each lens on the optical axis of the instrument, a transport frame with two translation precision stages is used. A fully automated and software controlled accurate autofocusing should allow a precise calculation of measurement data.

Especially for the production environment, a user-friendly software should allow a simple and efficient batch management. At best, it guides the user through the entire automated measurement and test results management procedure. The software should provide predefined controlled measurement programs with head lenses, filter and cornea changers, depending on the IOL type (monofocal, multifocal, toric) for precise testing of all required measurement parameters in one run. In the event of temperature differences, medium and/or spherical correction, a controlled software-based correction of the refractive power needs to be performed. The software should immediately present and display highly accurate and repeatable measurement data by graphics (MTF, through focus, LSF, PSF) including depiction of the camera image in real time. The analysis of measurement results can additionally be presented with associated diagrams by means of pass/fail analysis. Classification maps allow the lenses to be easily sorted, which optimizes the production testing of IOLs. Measurement conditions should be saved in configuration files for easy access. Different result displays, summarizing tables and raw data need to be available for further processing. The protection of the test result against manipulation must be guaranteed. Thus, parallel saving in protected binary files is recommended.

SUMMARY

Powerful measurement instruments are needed to test the power and quality of premium lenses, by being capable to comply with the quality assurance requirements of the valid ISO 11979 for IOL inspection. Thus, fully automated, ISO-compliant optical systems use the required magnification method for evaluation of all important parameters. They can measure any type of IOL (monofocal, multifocal, toric) with any type of structure (refractive, diffractive, sector) or materials (hydrophobic, hydrophilic). To optimize the IOL production efficiency, test equipment needs to deliver simple and fast batch testing in an ISO-compliant model eye tray. Software-controlled and fully automated, predefined measurement processes promise for highest accuracy in testing of different lens types, including all required measurement parameters.

TRIOPTICS' OptiSpheric® IOL PRO 2 offers a competent and complete solution for all manufacturers who face inspection of IOLs in mass production. Thus, it can be proficiently implemented for quality assurance. ■

Samira Bajrovic works as a freelancer, specialized in medical, technical and marketing writing. She began her career at bioskin GmbH in Hamburg, Germany where she worked in clinical project management and medical writing in dermatology research from 2007 until 2016.
She then joined the U.S. technology company Canfield Scientific Europe B.V. in Utrecht, Netherlands as Clinical Project Lead EMEA.
Samira Bajrovic holds a master's degree in Cosmetic Science from the University of Hamburg, Germany and gained experience in the fields of dermatology, biophysical measurement methods, cosmetic chemistry and biology.

Dörte Zimmermann joined TRIOPTICS based in Hamburg, Germany in 2015 where she worked in R&D IOL Metrology and in March 2018, she moved into her current position in Product Management IOL.
Dörte Zimmermann holds a master's degree in Medical Engineering Science and an undergraduate in General Engineering Science both from the Technical University of Hamburg–Harburg, Germany. She gained experience in the fields of control and medical engineering during that time and completed her master program with the master thesis "Leakage detection and self-testing capabilities of closed-circuit breathing apparatus".