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Overview

The GALILEI G6 is a noninvasive, noncontact optical diagnostic system designed for the assessment of the anterior segment of the eye by means of processed images taken with an integrated rotating Dual-Scheimpflug tomography and Placido topography system. The Dual-Scheimpflug system (two opposite cameras instead of one) allows significant reduction in measurement time without losing data coverage and automatic compensation of measurement decentration. Optical A-scans based on time-domain partial-coherence interferometry enables the precise measurement of axial, intraocular distances, thereby adding the information needed to perform IOL power calculation. The precise acquisition of posterior corneal surface data reduces the risk of postoperative surprises. Together with the complete set of biometry data, including lens thickness measurement, the full dataset for making the optimal decision for surgeons and their patients is available.

Hardware

The GALILEI G6 is composed of a measurement head containing Placido disk and Dual-Scheimpflug optics/mechanics/electronics, a main monitor, a PC, an elevation table, and an optical A-scan accessory (Fig. 27.1).

The measurement head includes an optical front end for coupling the light beam from the optical A-scan accessory into the eye, optics for Placido and Dual-Scheimpflug imaging, mechanics to rotate the cameras, as well as electronics for controlling measurement head rotation, light sources, and image acquisition. For data collection, the measurement head is rotated about the central instrument axis by 180°. During the rotation, a series of Scheimpflug, Placido, and Topview images are taken of the cornea, iris, pupil, limbus, anterior chamber, and crystalline lens and transferred to the PC for processing and display. Topography and anterior segment tomography are then calculated from those images. Figures 27.2 and 27.3 show examples of a Dual-Scheimpflug image pair and a Topview/Placido image, respectively.

The scanning process acquires an adjustable number (between 7 and 30, default: 17) of Scheimpflug and Topview images, including two Placido Topview images at 54° apart. On the Scheimpflug images, edges are detected (anterior cornea, posterior cornea, anterior lens, and iris). On the Placido images, the ring edges are

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Fig. 27.1 GALILEI G6
Lens Professional

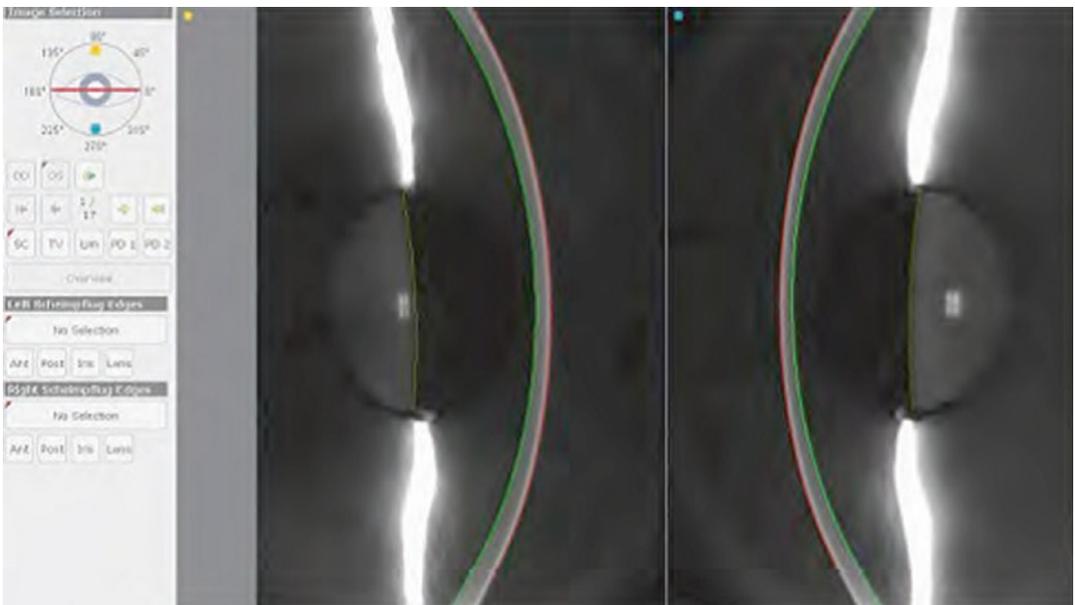
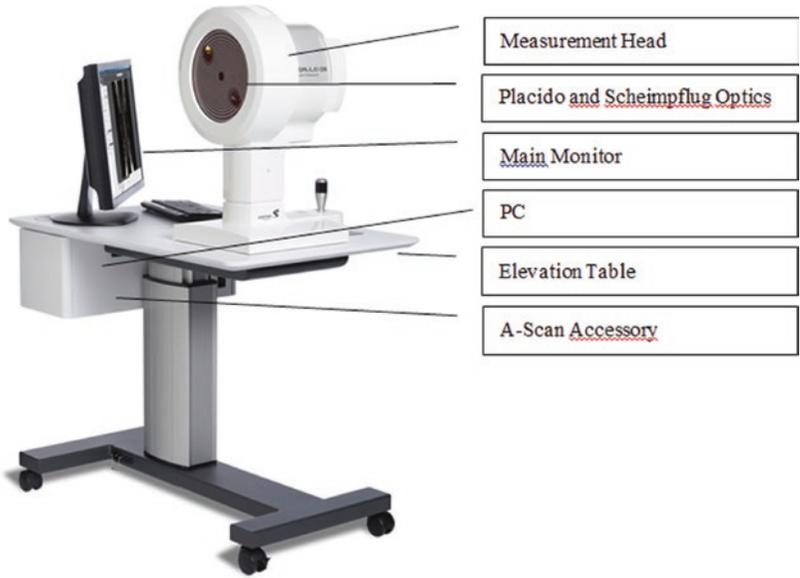


Fig. 27.2 Pair of Dual-Scheimpflug images

detected. In a separate process, the limbus and pupil are detected from a Topview image. The limbus and pupil do not influence any other calculations performed by the system. From the Scheimpflug edges, height data is determined. The slope data from the Placido images are transformed into conforming height data. Scheimpflug

and Placido data are thereafter merged based on respective quality using a proprietary merging algorithm. The merged data are then used to create surface fits from where indices are calculated and maps are generated. In addition, a color Topview camera permits taking color images of the front view of the eye (Fig. 27.4).



Fig. 27.3 Topview image of Placido ring reflection

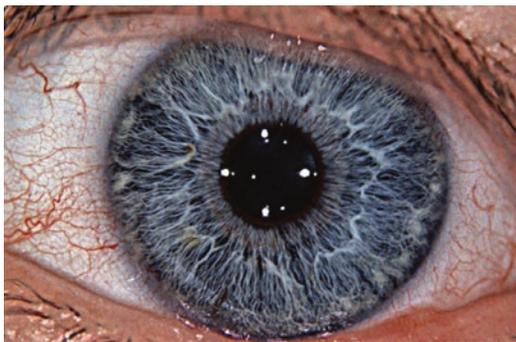
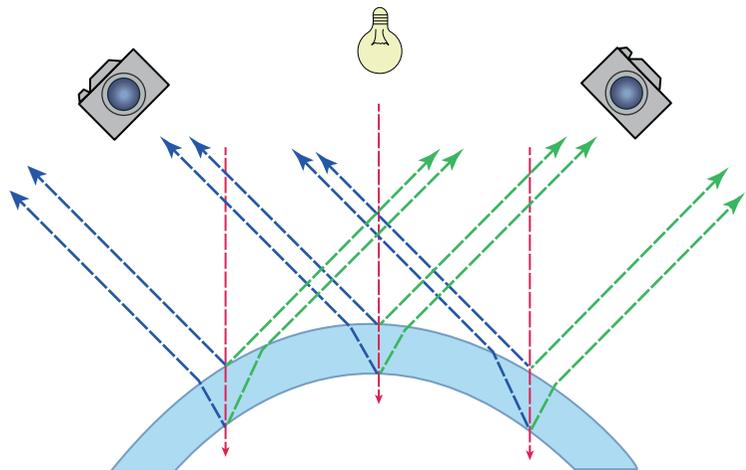


Fig. 27.4 Color Topview image

Dual-Scheimpflug Concept

Figure 27.5 illustrates how decentration and eye motion during a measurement can affect height data of the posterior surface, which directly affects pachymetry, as pachymetry is determined from anterior and posterior height data. When the slit light is well centered on the cornea, the left and right Scheimpflug cameras view the same corneal thickness as outlined by the blue and green lines. In the case of decentration to either side, the two Scheimpflug cameras view different

Fig. 27.5 Decentration affecting the images as viewed by the two Scheimpflug cameras



corneal thicknesses. Note: the difference in separation of the blue and green line pairs depends on the camera angle and the direction of displacement from the center of the cornea.

Combining the two camera views using ZIEMER's patented Dual-Scheimpflug solution, the systematic error in the original captured image is automatically corrected by averaging the two opposed camera images. Averaging the two images corrects the decentration error caused by eye motion or misalignment, making the measurement of the posterior edge independent of eye motion, allowing for accurate pachymetry and elevation data.

Accurate anterior surface calculations technically require only one of the two Scheimpflug images, along with the Placido image. However, for posterior surfaces, both Scheimpflug images are needed to compensate for decentration due to eye motion. Therefore, accurate determination of corneal pachymetry, anterior chamber depth, and posterior corneal surface requires complete Dual-Scheimpflug images. Loss of one of the two means that the corresponding image will be discarded and the Scheimpflug quality percentage will drop accordingly.

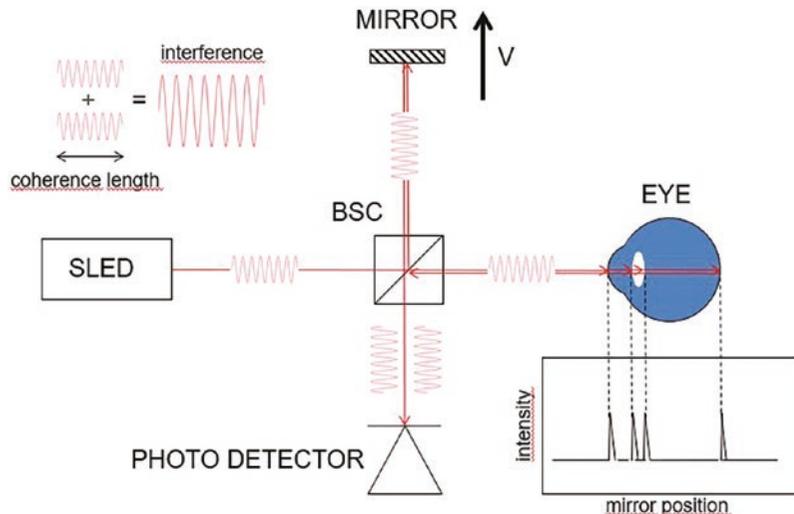
Comparing the GALILEI to a single Scheimpflug device, Aramberri et al. [1] reported that, while repeatability and reproducibility were good with both devices for all parameters and agreement was good with some relevant excep-

tions, the single-camera device was more precise for curvature, astigmatism, and corneal wavefront error measurements, and the dual-camera device was more precise for pachymetry measurements.

Axial Biometry by Optical A-Scan

Within the optical A-scan accessory, a collimated beam of an infrared, super-luminescent light emitting diode (SLED) is split by a beam splitter (BS) into a reference beam and a sample beam that are directed to a reference mirror and the patient's eye along its visual axis, respectively (Fig. 27.2). Whenever the sample beam passes a transition between ocular layers with different refractive indices (e.g., corneal surfaces, crystalline lens surfaces, and retinal surfaces), a portion of the light is reflected back toward the beam splitter. The optical path length of the light reflected from ocular surfaces is compared to the optical path length of light that is reflected from the reference mirror which is adjusted by moving the reference mirror at a constant velocity (V). When these optical lengths match to within the coherence length (CL) of the SLED, an interference signal is generated whose intensity is recorded with a detector and plotted as a function of the mirror position. The sample position is then deduced from the location on the plot's x-axis of the interference peak (Fig. 27.6).

Fig. 27.6 Time-domain, partial coherence interferometry for precisely measuring axial, intraocular distances



Conversion of Optical Distances to Geometrical Distances

Optical biometers, including the GALILEI G6, measure optical distances that represent geometrical (actual) distances multiplied with the measured material's refractive index. Thus, optical distances are converted to geometrical distances through division by the material's refractive index. When converting optical axial length (AL) to geometrical AL, one faces the challenge that the components along the measurement axis (cornea, anterior chamber, crystalline lens, vitreous chamber) have different refractive indices, and that refractive indices are dependent on the wavelength of the measuring light. With some optical biometers, the surfaces of the crystalline lens cannot be determined, such that an average refractive index must be employed for the conversion of optical AL to geometrical AL. This works reasonably well if the measured AL is within a certain range of normal AL. For very long or very short ALs, however, significant measurement errors may result because of altered refractive index contributions of the various axial components to the average refractive index. Such errors can be prevented by dividing the components' optical distances separately by their respective refractive indices and then adding the resulting, separate geometrical distances to obtain geometric AL. The Galilei G6 is capable of determining the surfaces of the crystalline lens, thereby measuring lens thickness, and therefore capable of converting optical distances segment-wise to geometrical distances. Two different AL are calculated and displayed by the GALILEI G6:

1. Total AL (tAL) that is converted segment-wise using component-specific, wavelength-adjusted, group refractive indices. It is defined as the distance from the anterior cornea to the

posterior retina and designed for specific IOL equations that employ optical approaches such as ray tracing.

2. AL that is converted using an average refractive, wavelength-adjusted, group refractive index. It is defined as the distance from the anterior cornea to the anterior retina as is the case with ultrasound AL and matched to AL as measured with the IOLMaster. It is used with standard, empirical IOL equations.

Total Corneal Power (TCP)

Three types of TCP are computed with the GALILEI: TCP1, TCP2, TCP_IOL. They differ from each other in terms of what reference surface (anterior or posterior cornea) is used to determine the total focal length (f') of the cornea, and what refractive index (n ; either that of the cornea or that of the aqueous) is used to convert the total focal length of the cornea to the total power of the cornea ($D = n/f'$).

- TCP1 is calculated using the corneal index of refraction ($n_{\text{cornea}} = 1.376$), and f' is referenced to the anterior corneal surface.
- TCP2 is calculated using the aqueous index of refraction ($n_{\text{aqueous}} = 1.336$), and f' is referenced to the anterior corneal surface, as is the case with TCP1.
- TCP_IOL is calculated using the aqueous index of refraction ($n_{\text{aqueous}} = 1.336$), and f' is referenced to posterior corneal surface.

TCP1 was the original value incorporated in the GALILEI G1 and carried forward in subsequent device iterations. TCP2 was introduced to try to better estimate true corneal power, and finally this too was replaced by TCP_IOL, though all options remain on current devices to allow users to customize individual preferences.

Technical Specifications (Table 27.1)

Table 27.1 Technical specifications of the GALILEI G6 Lens Professional

Measurement principle tomography/topography	Rotational Dual-Scheimpflug tomography/topography merged with Placido disk topography
Measurement principle biometry	Partial coherence interferometry (optical A-scan)
Measurement time tomography/topography	<1 s
Measurement time biometry	≈ 30–40 s per eye (3 consecutive scans in anterior segment and retina)
Placido disk geometry	20 rings, ranging in diameter from 20 mm to 200 mm
Number of cameras	3 (2 Scheimpflug, 1 Topview)
Number of measurement points	Up to 100,000 (Scheimpflug and Placido)
Displayed map coverage	10 mm maximum
Measurement ranges	Keratometry: 25–75 D (4.5–13.5 mm) Central corneal thickness: 250–800 μm Pupillometry: 0.5–10 mm Corneal Diameter: 6–14 mm Anterior chamber depth: 1.5–6.5 mm Lens thickness: 0.5–6.5 mm Axial length: 14–40 mm (default: 18–35 mm)
Measurement precision (standard deviation of repeated measurements). In brackets: Typical precision in normal eyes	SimK: ≤0.25 D (0.05 D) Angle of flattest meridian: ≤10° for astigmatism >0.5 D (2.9°) CCT: ≤3.00 μm; (1.2 μm) Pupillometry: ≤50 μm (6 μm) CD: ≤50 μm (16 μm) ACD: ≤50 μm (15 μm) LT: ≤100 μm (29 μm) AL: ≤50 μm (17 μm)
Illumination wavelengths	Scheimpflug: 470 nm (UV-free LED) Topview: 810 nm (IR LED) Placido: 810 nm (IR LED) Fixation target: 617 nm (LED) Biometry: 880 nm (SLED)

Study Results

A clinical study in adult subjects was performed to assess repeatability and reproducibility in the parameters indicated in Table 27.2 as measured by the GALILEI G6 Lens Professional (G6) in 20 normal, adult eyes. Measurements were repeated on the same eye and on the same device under the same conditions. To obtain reproducibility values, measurements were taken and compared for different operators using the same device. All parameters showed repeatability with coefficients of variation comparable to those reported with a predicate device, the Pentacam® AXL (PAXL; OCULUS Optikgeraete GmbH, Muenchholzhaeuser Str. 29, 35,582 Wetzlar, Germany), where only normal eyes were assessed.

In the same clinical study, parameters indicated in Table 27.3 measured by the G6 to those obtained by the PAXL. A total of 105 eyes were measured, 49 being right eyes and 56 being left eyes. Only one eye of each subject was measured, and 20 eyes were measured to represent each of the following five eye populations: (1) normal eyes (phakic eyes without cataracts or corneal disease), (2) eyes with varying degrees of cataract, (3) eyes with high myopia, (4) eyes with high hyperopia, and (5) eyes with postkeratorefractive surgery). The additional five eyes analyzed were two eyes with severe keratoconus and three eyes with prior cross-linking treatment. The G6 demonstrated agreement with the PAXL for the assessment of AL, CCT, *R* flat, *R* steep, *R*m, CC, *A* flat, and ACD in eyes with normal eyes, eyes with cataracts, eyes with high myopia

Table 27.2 Repeatability and reproducibility with the GALILEI G6 in 20 normal eyes

Parameter	Nr of eyes	Mean	Repeatability		Reproducibility	
			SD	CV [%]	SD	CV [%]
AL (mm)	20	23.82	0.02	0.08	0.02	0.08
CCT (um)	20	543	1.49	0.27	1.49	0.27
R flat (mm)	20	7.76	0.01	0.18	0.01	0.18
R steep (mm)	20	7.63	0.02	0.22	0.02	0.22
R mean (mm)	20	7.69	0.01	0.16	0.01	0.16
CC (D)	20	0.75	0.12	16.07	0.12	16.07
A flat (deg)	20	163	4.52	2.78	4.52	2.78
ACD (mm)	20	3.63	0.01	0.35	0.01	0.35
CD (mm)	20	12.19	0.02	0.20	0.02	0.20

Table 27.3 Differences between GALILEI G6 and Pentacam AXL (PAXL) in 105 eyes, including eyes with severe keratoconus or prior cross-linking treatment

Parameter	G6 mean (SD)	PAXL mean (SD)	Mean diff (SD)	95% CI for mean diff	Paired <i>t</i> -test <i>p</i> -value
AL (mm)	23.96 (1.74)	23.95 (1.78)	0.05 (0.04)	0.05, 0.06	<0.001
CCT (um)	532.73 (43.82)	536.50 (41.91)	-3.77 (7.71)	-5.26, -2.28	<0.001
R flat (mm)	7.88 (0.44)	7.89 (0.46)	-0.01 (0.07)	-0.03, 0.00	0.07
R steep (mm)	7.66 (0.47)	7.66 (0.50)	-0.00 (0.10)	-0.02, 0.02	0.65
R mean (mm)	7.77 (0.45)	7.78 (0.47)	-0.01 (0.08)	-0.03, 0.01	0.18
CC (D)	1.28 (1.10)	1.36 (1.47)	-0.09 (0.65)	-0.21, 0.04	0.18
A flat (deg)	140.56 (63.26)	142.27 (62.24)	-1.71 (12.43)	-4.12, 0.70	0.16
ACD (mm)	3.54 (0.37)	3.50 (0.38)	0.04 (0.07)	0.03, 0.06	<0.001
CD (mm)	12.16 (0.40)	11.81 (0.39)	0.33 (0.07)	0.32, 0.34	<0.001

or hyperopia, eyes with postkeratorefractive surgery, and eyes with prior cross-linking treatment. Demonstration of agreement in eyes with severe keratoconus was limited by inherent difficulties in assessing the above parameters both by the G6 and the PAXL. The difference in CD between G6 and PAXL is due to differences between the devices—as well as between other devices for CD measurement on the market—in the definition of the transition zone between sclera and cornea, the modality used for the measurement, the measurement geometry, the wavelength of the measuring light source, and assumptions in ocular refractive indices.

Comparing the GALILEI G6 to the IOLMaster 700 swept-source optical biometer, Soyeon et al. [2] reported that the two biometers showed high repeatability and relatively good agreement. Supiyaphun et al. [3] compared anterior segment parameters and axial length using the G6 and the Pentacam AXL and found good repeatability of

corneal curvature, ACD, and AL in both devices. Most parameters obtained from the Pentacam AXL were statistically significantly different from those obtained from GALILEI G6, except for steep meridians and ACD. Savini et al. [4] assessed the refractive outcomes of intraocular lens power calculation using different corneal power measurements with the GALILEI G6. They demonstrated that biometric measurements provided by the GALILEI G6 can be used to accurately calculate IOL power. Simulated K and TCP led to similar outcomes after constant optimization. Jung et al. [5] compared biometry and postoperative refraction in cataract patients between GALILEI G6 and IOL Master 500. The study revealed that ocular biometric measurements and prediction of postoperative refraction using GALILEI G6 were as accurate as with IOL Master 500. Jae et al. [6] reported that the GALILEI G6 provided precise ocular biometrics that were well correlated with results from stan-

standard biometers, and in particular, obtained accurate ACD measurements compared to AS-OCT. Furthermore, prediction of postoperative refraction using GALILEI G6 was comparable to the IOL-Master 500. Wang et al. [7] demonstrated that GALILEI G6 Dual-Scheimpflug measurements of corneal power, pachymetry, ACD, and corneal aberrations for Zernike terms in the middle of the Zernike tree showed excellent repeatability.

Software

Axial, intraocular distances, including axial length and lens thickness, are precisely measured with a series of optical A-scans (Fig. 27.7). Peak locations within the interference curve, and hence intraocular distances, are determined with cus-

tomized peak detection algorithms. Automatically detected lens surfaces positions may be manually adjusted to allow for specific individual assessment (red arrows). Optical distances are converted to geometrical distances segment-wise: axial length is determined by dividing optical distances of each segment along the measurement axis by its respective refractive index and then adding the resulting geometrical distances.

For accurate biometry in an eye filled with silicon oil, the option “Silicon” may be selected prior to data collection to account for the difference in refractive indices.

Several IOL power calculation formulas are readily available on the GALILEI G6 to determine the adequate power of a given IOL in a given patient during cataract surgery. These formulas include Haigis, Holladay 1, HofferQ, SRK/T, SRK II, Shammas post-LASIK,



Fig. 27.7 Biometry display with interference curve, detected peak locations, indices, and selectable maps

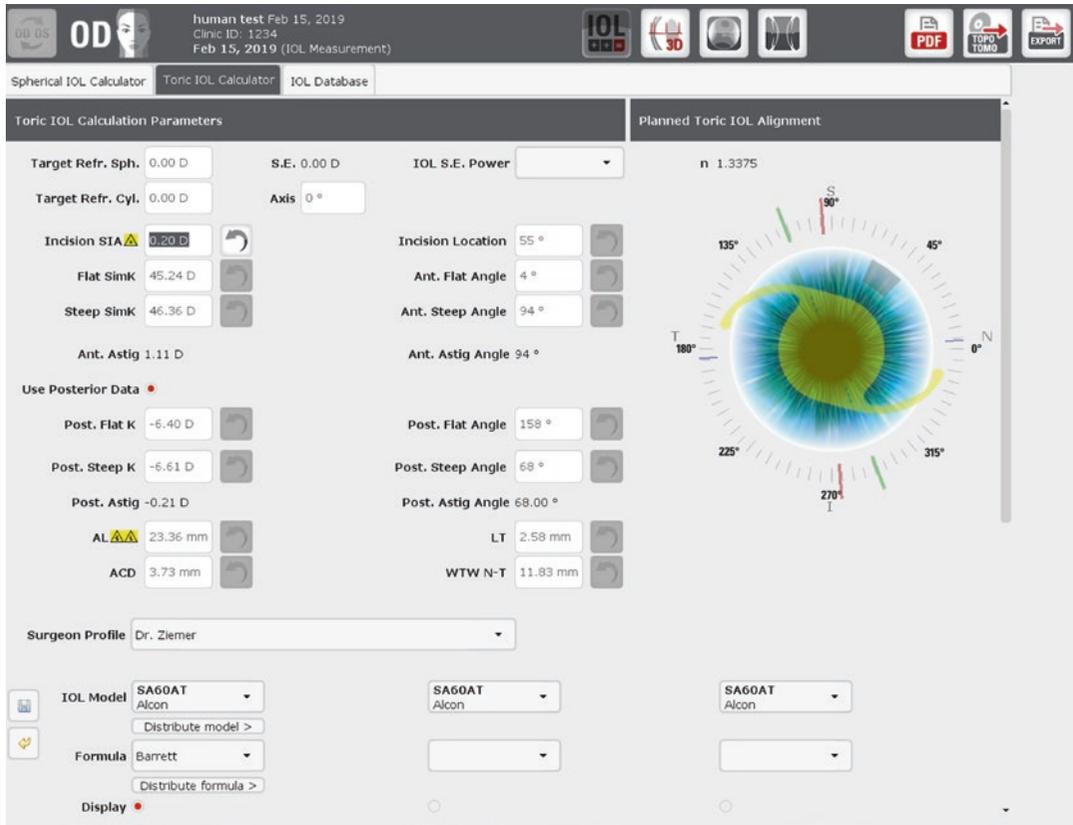


Fig. 27.8 Barrett Toric Calculator (top of display)

Barrett Universal II, and Barrett Toric (Figs. 27.8 and 27.9). A data export to the Holladay IOL Consultant Software and Panacea IOL & Toric Calculator Application will soon be released.

Through direct export and computation on the GALILEI G6, the ray-tracing IOL calculator OKULIX is optionally available. The ray-tracing IOL calculator PhacoOptics is being fine-tuned for the GALILEI G6 and will be released shortly.

An essential display for decision-making in cataract surgery planning is the Advanced IOL Display (Fig. 27.10). The anterior and posterior curvature data minimize the risk of postoperative surprises. The coma map allows a quick assessment of aberrations due to coma, which is an indicator whether premium IOLs are suitable in a given eye.

Other displays containing specific maps and indices may be used for cataract and refractive

surgery planning and the detection of ocular diseases that have the potential to negatively affect the outcome of such surgeries. Various displays are available with the GALILEI G6 for that purpose by switching to the Topo/Tomo software (link via logo at top right):

- The expanded Cone Location and Magnitude Index (CLMI.X) Display searches for asymmetries that are typically related to keratoconus and computes an overall index that represents a clinically established keratoconus detection probability in a given eye (Fig. 27.11).
- The Comparison Display allows point-by-point subtraction of two maps and the creation of the resulting difference map for the assessment of changes over time or differences between fellow eyes (Fig. 27.12).

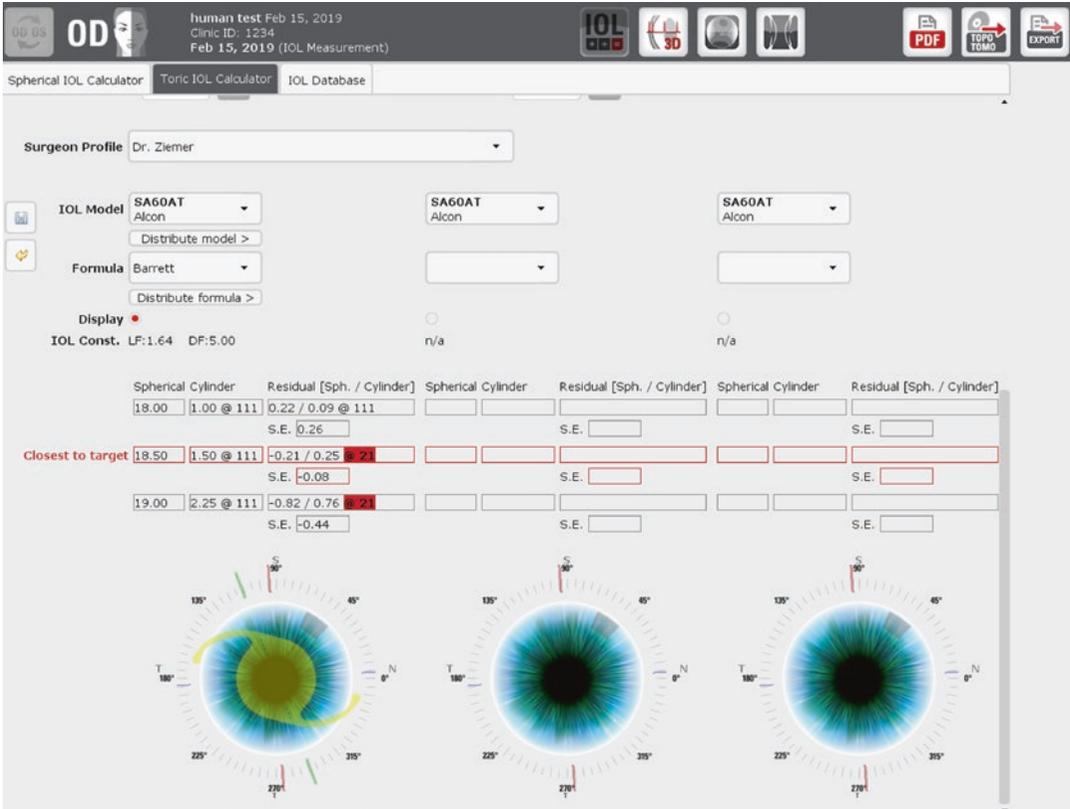


Fig. 27.9 Barrett Toric Calculator (bottom of display)

- The Wavefront Display (Fig. 27.13) illustrates corneal aberration of lower and higher orders, up to the eighth order, in terms of Zernike coefficients, equivalent diopters, and total RMS. Centration is selectable between Purkinje I, pupil center, limbus center or custom (entry of x and y in mm), and assessment zone diameter is selectable between 3 mm and

10 mm. The dominating type of aberration can easily be identified with the help of a pie chart and is another source of information for preoperative planning. The computation and display of anterior asphericity Q as assessed over a corneal area of 8 mm in diameter allow improving cataract planning involving premium IOLs as well as refractive surgery planning.

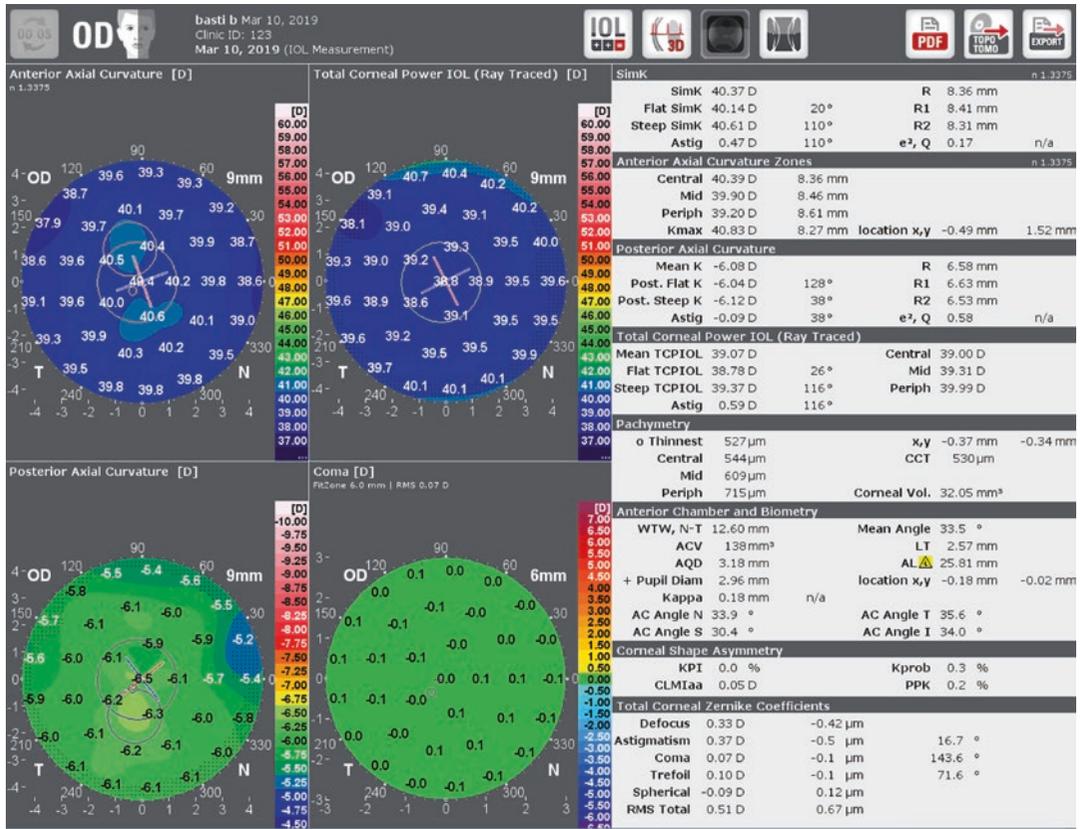


Fig. 27.10 Advanced IOL Display with selectable maps and indices

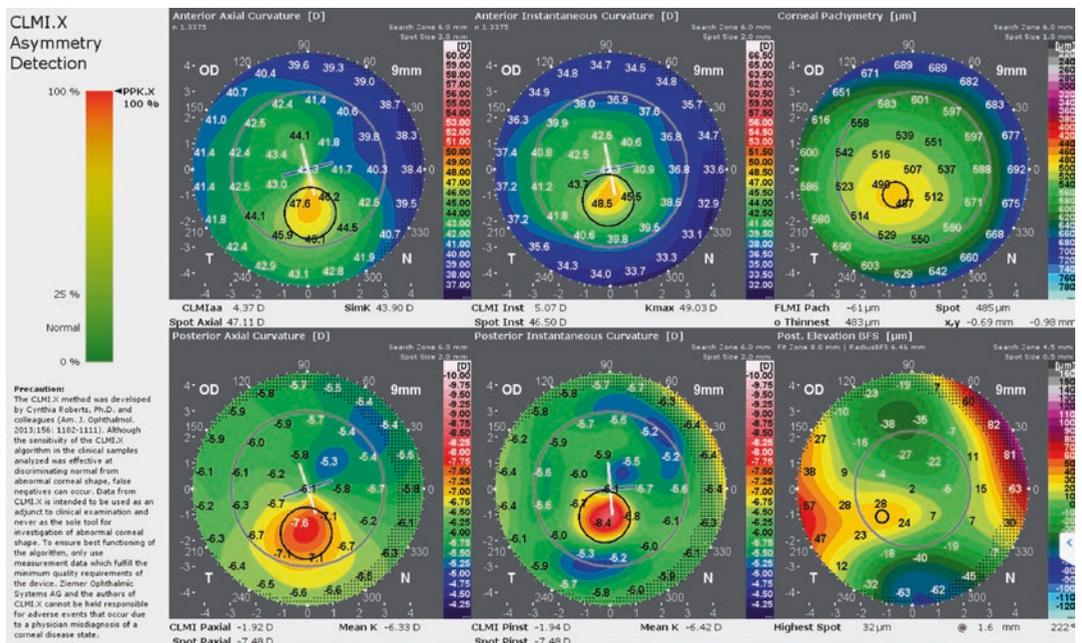


Fig. 27.11 Expanded Cone Location and Magnitude Index (CLMI.X) Display indicating keratoconus detection probability

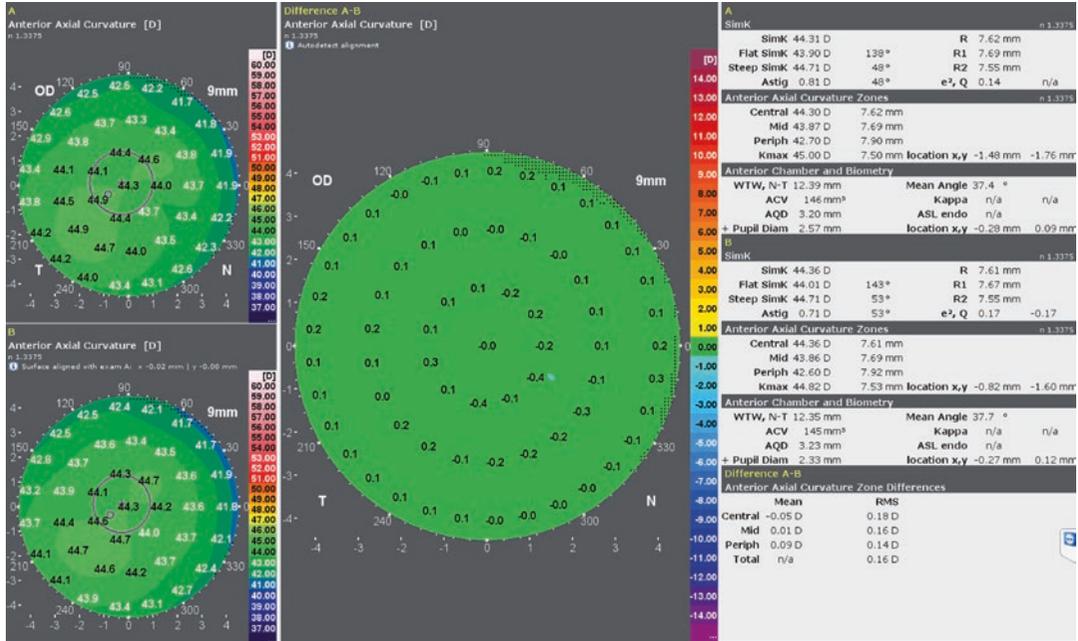


Fig. 27.12 Comparison Display allowing the assessment of differences or changes between two maps by means of point-by-point subtraction



Fig. 27.13 Wavefront Display illustrating corneal aberrations of lower and higher orders

Summary

The combination of Dual-Scheimpflug tomography with high-resolution Placido topography and precise, optical A-scan biometry enables the following features of the GALILEI G6 Lens Professional:

- Short topography/tomography measurement time of less than 1 s, as with the Dual-Scheimpflug system only a half-full-circle measurement head rotation is needed to cover all meridians without losing data coverage.
- Insensitivity to measurement head decentration and eye motion because data of two opposite Scheimpflug cameras is averaged, thereby eliminating decentration and eye motion errors.
- High precision and high resolution in keratometry at both central and peripheral areas due to Placido–Scheimpflug combination.
- Accurate and precise axial length and lens thickness measurement by optical A-scan regardless of eye size due to segment-wise conversion from optical to geometrical distances.
- Improved IOL power calculation and reduction in refractive error due to the availability of posterior cornea data and its inclusion in the IOL power calculation.
- Direct printing capability of every display and IOL calculation report directly from the GALILEI G6 device.

- Availability of additional information and explanation from the E-Learning Center.

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