

Repeatability of ocular biomechanical data measurements with a Scheimpflug-based noncontact device on normal corneas

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Abstract

Purpose: To analyse the repeatability of a new device measuring ocular biomechanical properties, central corneal thickness (CCT) and intraocular pressure (IOP) and to investigate these parameters and their correlations in healthy eyes.

Patients and methods: Exclusion criteria were any anterior segment disease, >2.0 D spherical or >2.0 D astigmatic refraction error, previous intraocular surgery and contact lens wearing. Three consecutive measurements were carried out using the CorVis ST device on each eye. Ten specific parameters characteristic for CorVis ST, and CCT and IOP were measured. Biometric data were recorded with IOLMaster.

Results: This study comprised 75 eyes of 75 healthy volunteers (age: 61.24 ± 15.72 years). IOP was 15.02 ± 2.90 mmHg, CCT was 556.33 ± 33.13 μm measured with CorVis ST. Intraclass correlation coefficient (ICC) was 0.865 for IOP and 0.970 for CCT, coefficient of variation was 0.069 for IOP and 0.008 for CCT. ICC for maximum amplitude at highest concavity was 0.758, A1 time showed ICC of 0.784, all other parameters have ICC less than 0.6. The device-specific data showed no significant relationship with age and axial length. Flattest and steepest keratometric data and also IOP showed highly significant correlation with the ten specific CorVis ST parameters.

Conclusions: The novel technique measuring ocular biomechanical properties showed high repeatability for only IOP and pachymetric data determined in our study. Single measurements are not reliable in case of the ten device-specific parameters. The equipment allows for conducting clinical examinations, and screenings of surgeries altering ocular biomechanical properties with some form of averaging of multiple measurements.

Keywords: age-related changes, biomechanics, CorVis ST, Ocular Response Analyzer

Introduction

An accurate and reliable measurement of the anterior segment parameters of the eye is of high importance in planning ophthalmological and refractive surgeries and in postoperative monitoring. The diagnostic techniques used presently have the potential to measure only static parameters of the anterior segment. However, the cornea has been identified as a substance with viscoelastic properties.¹ Up until recently, the only device conducting in vivo measurements of the ocular biomechanical properties has been the Ocular Response Analyzer (ORA, Reichert Ophthalmic Instruments, Depew, New York, USA) which became commercially available in 2005.^{2,3}

With the introduction of ORA, an emphasis has been laid on the biomechanical measurements of the cornea in glaucoma diagnosis and in the assessment of the outcomes of refractive surgeries and corneal collagen cross-linking therapies.⁴⁻¹¹ Already the first publication reported differences in the parameters measured with ORA in healthy and keratoconus eyes and in those subsequent to refractive surgeries.^{12,13,14}

Recently, a new device called CorVis ST (Corneal Visualization Scheimpflug Technology, CorVis ST, Oculus Inc., Wetzlar, Germany) has been introduced that uses a high intensity air impulse for biomechanical measurements applying an ultra high-speed Scheimpflug camera.

The equipment has the potential to measure the amplitude of maximal applanation and time taken to reach this applanation. CorVis ST also monitors the speed of the cornea during first and second applanation and the distance of the two apexes at highest concavity time. In addition, the images of the Scheimpflug camera capturing 4330 frames/second are also recorded on a video throughout the whole examination period of 30 milliseconds. For further applications of such a new device, the repeatability and consistency of the obtained

parameters are of a great importance and also a database of normal eyes for further comparisons. Our aim was to define “normal” data in healthy eyes for the parameters obtained by this new device. We were also interested in assessing the repeatability of the equipment.

Our aim was to investigate the specific parameters determined with CorVis ST, to assess repeatability of these data and to analyse correlations between CorVis ST data and other biometrical parameters and also age.

Patients and Methods

Our examinations were conducted in healthy eyes. Exclusion criteria were any anterior segment disease, >2.0 D spherical or >2.0 D astigmatic refraction error or any intraocular surgery in medical history and contact lens wearing.

The first measurements were carried out using the CorVis ST device. CorVis ST is a non-contact tonometer and pachymeter measuring ten specific ocular biomechanical parameters as well. CorVis ST uses an ultra high-speed Scheimpflug camera (4330 frames/second) covering 8.0 mm horizontally. The light source is an UV free blue LED light with a wavelength of 455 nm. In the slow motion video, the deformation response of the cornea to a high intensity air impulse is seen approximately within a range of 30 milliseconds. The air impulse employs a metered, symmetrical and fixed maximal internal pump pressure of 25 kilopascal. The measurement periods of 30 milliseconds were also recorded on a video. The video and the data obtained during measurements can be easily exported from the device for further statistical analysis. Due to the air impulse, the cornea goes through 3 distinct phases (first applanation, highest concavity and second applanation). During these phases a

number of parameters are recorded: maximum deformation amplitude (the highest concavity {HC} of the cornea), time taken to reach it, first and second applanation time, cord length (length of the flattened cornea), maximum corneal velocity in and out, peak distance, which is the distance of the two apex at highest concavity and a radius value which represents the central concave curvature at HC (Table 1 and Figure 1). Central corneal thickness (CCT) and intraocular pressure (IOP) is also determined. Patients were seated with their chin on the chinrest and forehead against the equipment. Using the joystick, the examiner targets at the centre of the cornea, thus enabling the patients to see a red light at which they have to fixate. The adjusting direction we need to be able to centre on the corneal apex is seen on the screen. At accurate setting, the air puff automatically starts and then, subsequent to measurements, the data are exported to a computer. Three measurements were conducted in the right eyes of all our patients using CorVis ST with software version 1.00r24 rev. 772. The measurements were taken by the same investigator and at the same day period. During the time between scans the patient could move their chin from the chinrest. Subsequently, ocular biometric parameters (axial length {AL} with signal noise ratio >10.0 and keratometric data) were recorded with IOLMaster (Carl Zeiss Meditec, Jena, Germany).

Every patient was provided with an explanation of the measurements and the research protocol adhered to the tenets of the Declaration of Helsinki. Statistical analysis was performed with MedCalc 10.0 and Microsoft Excel softwares. Descriptive statistical results were described as mean, standard deviation (SD) and 95% confidence interval (95% CI) for the mean. Multiple regression analyses were performed adjusting CorVis ST data for age, AL, keratometric data and IOP. Spearman's rank correlation test was used to study correlation between age and IOP. P value below 0.05 was considered statistically significant. The coefficient of repeatability ($1.96 \times SD$), the mean coefficient of variation (CV) for all parameters, the intraclass correlation coefficient (ICC) and its 95% CI value and the value of

Cronbach's alfa were also determined. The intraclass correlation coefficient (ICC) is a measure of the reliability of measurements and the obtained data determine the intrasession repeatability. It was suggested that the ICC values should be at least 0.9 in order to ensure a reasonable reliability.¹⁵

Results

Our measurements were conducted in 75 right eyes of 75 healthy volunteers (age: 61.24±15.72 years, 95% CI: 57.62-64.86 years, range: 22.2-87.3 years). Specific parameters were measured with the CorVis ST and values representing repeatability are shown in detail in Table 2 and Table 3. Kolmogorov-Smirnov test reject normality in case of all parameters.

AL was 23.28±1.26 mm (95% CI: 22.98-23.57 mm, range: 21.19-27.7 mm, flattest keratometric data was 43.58±1.58 D (95% CI: 43.22-43.95 D, range: 39.24-47.2 D), steepest keratometric data was 44.43±1.53 D (95% CI: 44.08-44.78 D, range: 40.13-48.01 D) measured by IOLMaster.

Repeatability data

IOP and pachymetry showed the highest repeatability with an ICC of 0.865 and 0.970. Maximum amplitude at the highest concavity (Def. amp. max) and time from starting until the first appplanation (A1 time) showed moderate repeatability with an ICC of 0.758 and 0.784. All other parameters showed poor repeatability (Table 3).

Correlation data

The ten specific CorVis ST data showed no significant relationship with age (adjusted r^2 of coefficient of determination=0.11; $p=0.10$) or AL (adjusted r^2 of coefficient of determination=0.05; $p=0.21$) determined by multiple regression. Flattest (adjusted r^2 of coefficient of determination=0.2; $p=0.008$) and steepest (adjusted r^2 of coefficient of determination=0.24; $p=0.002$) keratometric data showed highly statistically significant, positive correlation with the ten specific CorVis ST parameters. Highly significant, positive correlation can be seen between IOP and CorVis ST data (adjusted r^2 of coefficient of determination=0.96; $p<0.001$). There was no significant correlation between age and IOP measured by CorVis ST ($r^2=0.03$; $p=0.71$)

Discussion

A novel equipment measuring ocular biomechanical properties in vivo has been introduced recently. Using an air impulse, CorVis ST measures central corneal thickness, intraocular pressure and ten specific biomechanical parameters. Our aim was to assess repeatability of this new device and to examine correlations with biometric parameters and also age.

According to literature data, the intraclass correlation coefficient for corneal hysteresis (CH) and IOP is between 0.84 and 0.92 when applying ORA,^{2,3} thus measurements yielded excellent repeatability. Our data obtained with CorVis ST showed excellent repeatability data for only IOP and pachymetric data. Highest concavity data and first applanation time showed

good repeatability, but all other parameters have poor or unacceptable repeatability according to our data, although A2 time, HC time and radius data have low CV values. Possible reasons for the bad repeatability could be due to the technology limitation or some other unknown issues needs for further researching.

Significant correlation was observed between CH, corneal resistance factor (CRF) and CCT, and IOP with ORA.¹⁶ CH and CRF values measured with ORA showed significant correlation with visual acuity and certain corneal parameters, for example they showed negative correlation with the highest keratometric readings,^{17,18} although others did not prove keratometric correlation.¹⁹ Our data obtained with CorVis ST device show that significant correlation was observed between keratometric data and CorVis ST parameters, so corneal curvature has an influence on the measured data.

The age dependency of the biomechanical parameters is also well known from the literature,^{5,20-23} conforming that the elastic properties of the cornea are changing with age.²³ On the contrary, others found that CH and CRF are very independent of age.^{24,25} Toubul et al.²⁴ hypothesized that viscoelasticity still decreasing with age, because the CRF is positively correlated with IOP and because it is known that IOP increases with age, and thus CH and CRF variations are compensated with the IOP elevation. According to our data, CorVis ST was not capable of detecting age-related difference in normal population.

In biomechanical measurements cornea is considered to be a viscoelastic substance. Up until recently, the only known equipment applied in the in vivo measurements of ocular biomechanical properties has been ORA, which releases an accurate and regular air impulse onto the surface of the cornea. It results in the cornea passing from a resting shape into a concave shape and finally due to its flexibility, returning to its natural shape. The parameters of this deformation allow us to understand the biomechanics of the cornea, which is described by two main data measured by ORA. During the 20 milliseconds deformation period it

records two applanation pressure measurements and the difference between the two values are called corneal hysteresis. The equipment also determines a calculated value, the corneal resistance factor, and the latest software provides further information as well. Biomechanical measurements are applied in the diagnosis of keratoconus,^{13,14,26,27} in studies detecting effects of refractive surgeries⁴⁻⁶ and corneal collagen cross-linking (CXL)^{5,9,10} and also in glaucoma diagnosis.^{7,8,11}

The ORA has been reviewed in a recent publication.²⁸ Changes in CH and CRF after LASIK,⁴⁻⁶ epi-LASIK²⁹ and clear corneal phacoemulsification³⁰ are well known. CXL causes no changes in the two main parameters measured with ORA,^{5,10} however, biomechanical differences were observed in corneas after CXL when applying the latest parameters of the latest ORA software.¹⁰ Using a uniaxial tensile test it could be observed, that CXL treatment lasting for 30 minutes increases the stiffness of the porcine corneal tissue, but CXL therapy lasting for 60 minutes reduces it.³¹ A number of publications, in which ORA was used, report on changes in ocular biomechanical properties in keratoconus eyes.^{17,26,27,32,33} Statistically, CH and CRF are significantly lower in keratoconus eyes compared to normal eyes, but both parameters have low sensitivity and specificity for distinguishing between the groups, thus alone are not suitable for establishing the diagnosis.^{32,33}

Although CorVis ST analyses corneal deformations due to air puff applanation as well, parameters obtained by the two equipments cannot be compared.

In summary, our data allow for the conclusion, that CorVis ST has an excellent repeatability for IOP and pachymetric data only. Maximum amplitude at highest concavity and A1 time showed good repeatability, all other specific parameters had poor repeatability. CorVis ST has the potential for investigating specific ocular biomechanical properties with some form of averaging of multiple measurements. Further studies are needed to evaluate the number of measurements required to attain reasonable repeatability.

Legend of Figure

Figure 1. Normal picture obtained with CorVis ST. After an air impulse, the cornea goes through three phases: first applanation, highest concavity and second applanation phase, while several parameters are recorded: maximum deformation amplitude (the highest concavity {HC} of the cornea), time taken to reach it, first and second applanation time, cord length, maximum corneal velocity in and out, peak distance, which is the distance of the two apex at highest concavity and a radius value which represents the central concave curvature at HC.

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Name of the parameter	Description of specific CorVis ST parameters
Maximum deformation amplitude	maximum deformation amplitude of the cornea at the highest concavity, in millimeter
A1 time	time from air-puff starting until the first applanation, in millisecond
A1 length	length of the flattened cornea at the first applanation, in millimeter
A1 velocity	speed of corneal apex at the first applanation, in meter/second
A2 time	time from starting until the second applanation, in millisecond
A2 length	length of the flattened cornea at the second applanation, in millimeter
A2 velocity	speed of the corneal apex at the second applanation, in meter/second
HC Time	time from air-puff starting until the highest concavity of the cornea is reached, in millisecond
Peak distance	distance of the two apex of the cornea (two "knees") at the time of the highest concavity, in millimeter
Radius	radius of curvature of a circle that fits to corneal concavity at the time of the maximum deformation, in millimeter

Table 1: Description of the ten specific biomechanical parameters measured by CorVis ST.

	mean	95% CI	range
IOP [mmHg]	15.02	14.35-15.68	10.83-26.17
Pachy [μm]	556.33	548.71-563.95	480.67-648.67
Def. amp. max [mm]	1.06	1.04-1.08	0.86-1.25
A1 time [ms]	7.27	7.19-7.34	6.53-8.34
A1 length [mm]	1.75	1.72-1.79	1.32-2.04
A1 velocity [m/s]	0.149	0.14-0.15	0.06-0.19
A2 time [ms]	21.60	21.48-21.71	20.15-24.04
A2 length [mm]	1.91	1.83-1.98	0.77-2.66
A2 velocity [m/s]	-0.34	-0.35- -0.32	-0.49- -0.18
HC Time [ms]	16.84	16.76-16.93	15.63-17.86
Peak dist. [mm]	3.03	2.86 - 3.20	1.19-5.22
Radius [mm]	7.94	7.75 - 8.14	6.02-11.36

Table 2: Data obtained by CorVis ST in a normal population (n=75).

IOP: intraocular pressure, Pachy: central corneal thickness, Def. amp. max: maximum amplitude at the apex (highest concavity), A1 time: time from starting until the first applanation, A1 length: cord length of the first applanation, A1 velocity: speed of the first applanation, A2 time: time from starting until the second applanation, A2 length: cord length of the second applanation, A2 velocity: speed of the second applanation, HC Time: time from starting until highest concavity (HC) is reached, peak dist: distance of the two apex at highest concavity, radius: central concave curvature at HC.

95% CI: 95% confidence interval for the mean

	ICC	95% CI for ICC	Cronbach's alfa	95% lower CI for Cronbach's alfa	CV	average SD	coefficient of repeatability
IOP [mmHg]	0.865	0.811-0.907	0.951	0.932	0.069	1.02	5.693
Pachy [μm]	0.970	0.956-0.979	0.990	0.986	0.008	4.51	64.939
Def. amp. max [mm]	0.758	0.670-0.829	0.904	0.868	0.043	0.04	0.181
A1 time [ms]	0.784	0.704-0.848	0.916	0.884	0.017	0.12	0.624
A1 length [mm]	0.062	0.170-0.072	0.287	0.020	0.133	0.23	0.283
A1 velocity [m/s]	0.354	0.212-0.496	0.622	0.480	0.148	0.02	0.049
A2 time [ms]	0.305	0.161-0.453	0.568	0.404	0.023	0.26	0.965
A2 length [mm]	0.240	0.099-0.390	0.486	0.294	0.196	0.36	0.623
A2 velocity [m/s]	0.547	0.416-0.665	0.783	0.701	-0.114	0.03	0.118
HC Time [ms]	0.261	0.119-0.409	0.514	0.332	0.021	0.34	0.709
Peak dist. [mm]	0.216	0.077-0.366	0.453	0.248	0.230	0.72	1.437
Radius [mm]	0.560	0.433-0.674	0.792	0.715	0.068	0.54	1.626

Table 3: Repeatability data obtained by CorVis ST in a normal population (n=75).

IOP: intraocular pressure, Pachy: central corneal thickness, Def. amp. max: maximum amplitude at the apex (highest concavity), A1 time: time from starting until the first appplanation, A1 length: cord length of the first appplanation, A1 velocity: speed of the first appplanation, A2 time: time from starting until the second appplanation, A2 length: cord length of the second appplanation, A2 velocity: speed of the second appplanation, HC Time: time from starting until highest concavity (HC) is reached, peak dist: distance of the two apex at highest concavity, radius: central concave curvature at HC.

average SD: the average the standard deviations of the single cases obtained for each parameter, representing repeatability.

95% CI: 95% confidence interval for the mean

ICC: intraclass correlation coefficient, CV: coefficient of variation

Coefficient of repeatability: $1,96 * SD$

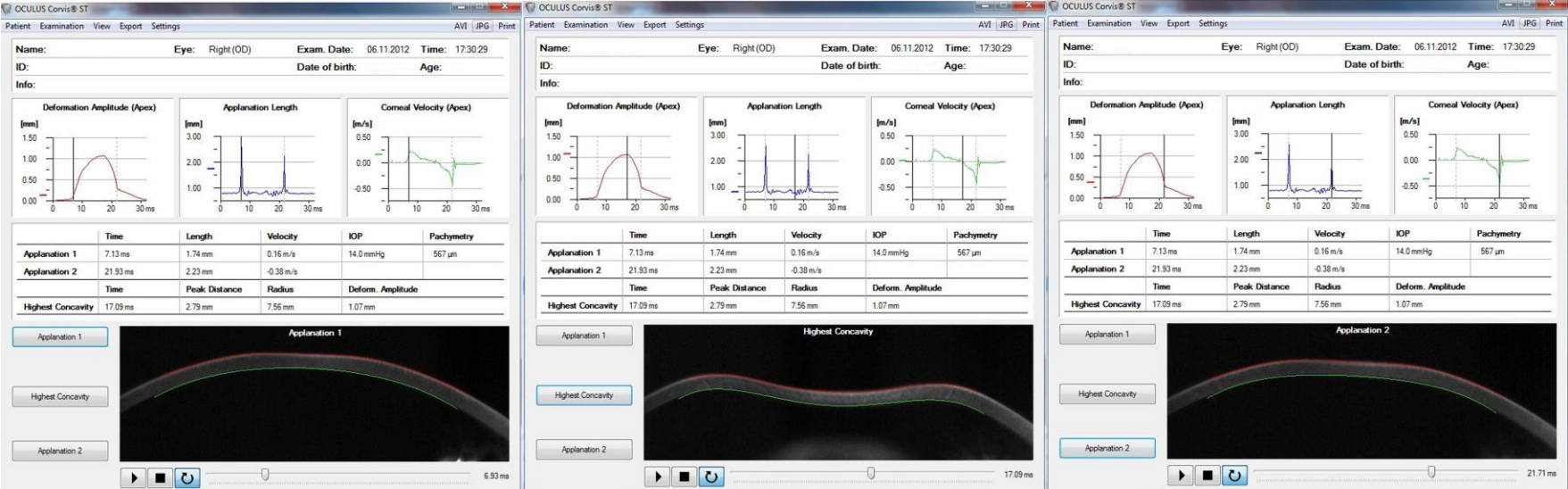


Figure 1.