Date: 17Apr2023

PROTOCOL TITLE: Assessment of Measurement Variability Across Automated Biometry Devices

PROTOCOL # 005

STUDY TREATMENTS: Non-interventional (None)

Background:

Some intraocular surgeries depend on accurate white-to-white (WTW), corneal thickness (CT) and anterior chamber depth measurements (ACD) for optimal outcomes.

Scientific Rationale:

Some intraocular surgeries require accurate WTW, CT, and ACD measurements. Previously, the Orbscan II was used to calculate the positioning characteristics for, and selection of, some phakic intraocular lenses, but newer devices are now available. Variability in the measurements with these newer devices may impact the surgical outcomes for formulas originally based on the Orbscan II. This study aims to determine how the newer devices correlate with measurements obtained with the Orbscan II.

Clinical Hypothesis:

Different biometers/topographers measure WTW, CT, and ACD differently than the Orbscan II.

Study Objectives:

The objective of this study is to determine the correlation of WTW, CT, and ACD measurements from the Orbscan II to a variety of readily available biometric devices.

OVERALL STUDY DESIGN

This is a non-interventional prospective, single center, bilateral, comparative study of WTW, CT, and ACD measurements as taken on the Orbscan II compared to the IOL Master 700 (Zeiss), IOL Master 500 (Zeiss), Atlass 9000 (Zeiss), Lenstar 900 (Haag-Streit), Argos (Alcon), iTrace (Tracey), Pentacam (Oculus), and manual calipers. Additional biometric devices or external photographs may be included as well.

Duration:

3 months or longer to meet required enrollment

Administration:

Patients with healthy eyes who meet the inclusion criteria will be offered the opportunity to participate in the study.

Visit Schedule:

All subjects will undergo 1 visit. At the study visit, after informed consent, the subjects' demographic information will be collected, and the subject will have the following testing:

1) Orbscan II (ACD/WTW/CT)
2) IOL Master 700 (ACD/WTW/CT)
3) IOL Master 500 (ACD/WTW/CT)
4) Atlas 9000 (WTW)
5) Lenstar 900 (ACD/WTW/CT)
6) Pentacam (ACD/WTW/CT)
7) iTrace (WTW/CT)
8) Argos (ACD/WTW/CT)
9) Manual caliper measurement (WTW)
10) Additional biometric devices or external photographs may be included as well

STUDY POPULATION CHARACTERISTICS:

Condition

Myopic patients with a spherical equivalent of at least -1.00D with healthy eyes and no prior eye surgery

Number of Subjects:

Under the assumption that the average WTW on the Orbscan II is 11.65 mm[1] and the average WTW on the IOL Master is 11.76 mm and the Pentacam WTW is 11.61 mm[2], then 168 eyes would be required, for a total of 336 eyes. Other biometers are assumed to have similar averages. The standard deviation for each measurement is 0.36 for the Orbscan II, and a power of 80% and Type I error probability of 0.05 was targeted.[3]

ACD measurements should be statistically similar to WTW measurements.

There are limitations to including both eyes from a single volunteer due to symmetry between eyes. As such, the proposed total number of patients is 200, which allows 400 eyes and 200 different data points assuming relative symmetry between the eyes. To this author's knowledge, this would be the largest comparative study to date of WTW, ACD, and CT measurements.

1. Gharaee H, Abrishami M, Shafiee M, Ehsaei A. White-to-white corneal diameter: normal values in healthy Iranian population obtained with the Orbscan II. Int J Ophthalmol. 2014;7(2):309-312. Published 2014 Apr 18. doi:10.3980/j.issn.2222-3959.2014.02.20
2. Dinc UA, Oncel B, Gorgun E, Yenerel MN, Alimgil L. Assessment and comparison of anterior chamber dimensions using various imaging techniques. Ophthalmic Surg Lasers Imaging. 2010 Jan-Feb;41(1):115-22. doi: 10.3928/15428877-20091230-21. PMID: 20128581.

3. Rosner B. Fundamentals of Biostatistics. 7th ed. Boston, MA: Brooks/Cole; 2011.

Inclusions:

1) Adults ages 18-50 years of age with healthy eyes and no prior ocular surgery.

2) At least -1.00 D of myopia (spherical equivalent).

3) Able to comprehend and willing to sign informed consent and complete all required testing procedures

4) Clear intraocular media

Exclusions:

Subjects will not be permitted to enroll in this study if they meet any of the following exclusion criteria:

1) Any corneal abnormality, other than regular corneal astigmatism (as determined by pre-operative testing) that in the opinion of the investigator would confound the outcome(s) of the study

2) History of or current retinal conditions or predisposition to retinal conditions

3) Amblyopia or strabismus in either eye

4) History of or current anterior or posterior segment inflammation of any etiology

5) Any form of neovascularization on or within the eye

6) Glaucoma (uncontrolled or controlled with medication)

7) Optic nerve atrophy

8) Subjects with diagnosed degenerative eye disorders

9) Subjects who have an acute or chronic disease or illness that would confound the results of this investigation in the opinion of the principal investigator (e.g. connective tissue disease, immunocompromised, clinically significant atopic disease, etc.)

EVALUATION CRITERIA:

The main objective of this study is to determine the standard difference of WTW, ACD, and CT of various biometric devices compared to the Orbscan II.

Primary Clinical Endpoints:

Date: 17Apr2023

The determination of the degree of correlation of WTW, ACD, and CT measurements between various biometric devices.