# ARGOS<sup>®</sup> Swept Source OCT Biometer

ARGOS

# Clinical Science Compendium

Summary of peer-reviewed bench and clinical research



Medical Affairs North America

#### INTRODUCTION

At Alcon, our surgical medical device products, such as the ARGOS<sup>®</sup> swept-source optical coherence tomography (SS-OCT) biometer, are designed, manufactured and marketed with a body of science developed through rigorous bench research and clinical studies. As the body of knowledge behind Alcon's products grows, so does the challenge of making our customers aware of its depth. Our medical affairs organization is thus focused on both high-quality data generation and its communication to the clinical community. High-quality scientific publications are essential to convey the clinical community's knowledge and experience with the latest technology. This clinical science compendium provides a consolidated view of peer-reviewed publications for ARGOS<sup>®</sup>, an industry-leading SS-OCT biometer used to measure eye parameters for patients before cataract surgery.

In addition to exploring this compendium, we encourage you to visit Alcon's Medical Affairs website—AlconScience.com—to learn more about how medical science matters to us. Beyond scientific publications relating to Alcon's portfolio, you will find more information on independent medical educational grants, teaching facility equipment placement, and areas of interest for investigator-initiated trials.

# METHODOLOGY

The 16 articles summarized in this compendium were identified using the PubMed and Google Scholar databases incorporating the search terms "ARGOS" and "swept-source optical coherence tomography biometer." Articles were included when they were published between January 1, 2009 and July 31, 2020 and contained research relevant to the ARGOS<sup>®</sup> SS-OCT biometer and its indication for acquiring ocular measurements and performing calculations to determine the appropriate IOL power and type for implantation during IOL placement. Only manuscripts published in peer-reviewed journals and available in English were included in this compendium.

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# Large Coherence Length Swept Source for Axial Length Measurement of the Eye

Chong et al. Appl Opt. 2009;48:D144-D150

Repeatability/Reproducibility

#### **OVERVIEW**



### STUDY DESIGN

Proof of concept study to demonstrate the measurement of AL with a swept source using a quasi-phase continuous tuning (QPCT) technique **STUDY SITE(S)** Single center in Japan



**PATIENTS** Not applicable; bench study



Illustrate the new technology and measurement of AL in a pig's eye

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# BIOMETERS

Experimental SS-OCT biometer with QPCT and multiple beam expanders (Santec, Inc.)



### **KEY ENDPOINT(S)**

Optical performance, AL, repeatability of measurement

# ANALYSIS AND CONCLUSIONS

This study demonstrated a swept source with a large coherence length for IOL measurement with a quasi-phase continuous tuning technique as well as multiple beam expanders.

This experimental SS-OCT system enables the measurement of the AL of a pig's eye with 20 mm length in physical size.

#### **STUDY RESULTS**

#### **TECHNOLOGY PARAMETERS**

 The swept source consists of a fiber ring extended cavity laser with a diffraction grating and a polygon scanner-based tunable filter configuration; the projected beam on the diffraction grating is expanded with a multiple of beam expanders to achieve high finesse of the filter

#### **PERFORMANCE PARAMETERS**

- The source demonstrated an 18 nm swept range at 1060 nm wavelength, 28 mm coherence length, and 6.2 MW peak power at a 2.5 kHz swept rate
- OCT imaging results showed that a coherence length of 28 mm enables the measurement of the AL of a pig's eye with 20 mm length in physical size
- Figure 1 shows a tomographic image of the whole eye over 5 mm width with 200 A-lines in the transverse direction; the contours of the cornea and iris, lens surface, and retina on the far side are all recognized, although the detail of each segment is slightly blurred because lateral resolution is only 0.8 mm
- Figure 2 shows a 1D signal indicating the positions of the different parts; peaks at the cornea, lens, and retina are apparent, and the distances between them are 3.5 mm and 27 mm between the cornea and lens and the lens and retina, respectively

#### REPEATABILITY

 The repeatability of measurement was better than 20 µm, which is superior to the performance of commercial IOL measurement equipment Figure 1. (Color online) Cornea U-2D image of the whole 2pig's eye. Lens Iris 6-8-10-12-14-16-18-(mm) 20-) Depth 22– 24– 26-Retina 28-

Figure 2. 1D signal of one A-line (solid line in Figure 1).



# Biometry Measurements Using a New Large-Coherence-Length Swept-Source Optical Coherence Tomographer

Shammas et al. J Cataract Refract Surg. 2016;42:50-61\*

Axial Length

**Biometric Parameters** 

Repeatability/Reproducibility

#### OVERVIEW



#### STUDY DESIGN

Prospective observational study to evaluate the repeatability and reproducibility of ARGOS<sup>®</sup> measurements and to compare them with IOLMaster<sup>®</sup> 500 and LENSTAR LS 900<sup>®</sup> STUDY SITE(S) Single private practice

in the United States



## PATIENTS

Sixty-six (66) consecutive patients enrolled (41 patients had bilateral cataracts), 107 eyes (54 right eyes) measured by SS-OCT and OLCR and 91 eyes (46 right eyes) measured by PCI

# METHODOLOGY

ARGOS® performance and comparison to IOLMaster® 500 and LENSTAR LS 900® in cataractous eyes (same day); for the comparison part, only the first eye of each patient was used



# BIOMETERS

ARGOS® (SS-OCT, Movu, Inc.), IOLMaster® 500 (PCI, Carl Zeiss Meditec AG), LENSTAR LS 900® (OLCR, Haag-Streit AG)



# **KEY ENDPOINT(S)**

Repeatability and reproducibility of ARGOS® measurements; comparison of AL, ACD, and average anterior corneal radius of curvature (RAV) measurement with results obtained by PCI and OLCR; comparison of CCT, aqueous depth, lens thickness, pupil size, and corneal diameter with results obtained by OLCR

## ANALYSIS AND CONCLUSIONS

# This study found that AL measurements obtained with ARGOS<sup>®</sup> were comparable to those obtained with the IOLMaster<sup>®</sup> 500 and LENSTAR LS 900<sup>®</sup>, with a faster and higher acquisition rate, even in the presence of a dense nuclear or posterior subcapsular cataract.

The authors believe that this is the first study to report the precision of ARGOS<sup>®</sup> in measuring all parameters needed for IOL power calculation in patients having cataract extraction, with good repeatability and reproducibility of measurements. The wide scanning beam and longer wavelength of SS-OCT may contribute to the higher AL acquisition rate.

\* Drs. Ortiz, Kim, and Chong have proprietary interest in the new technology

#### **STUDY RESULTS**

#### **REPEATABILITY/REPRODUCIBILITY (N=104 EYES)**

 Repeatability (intraset) and reproducibility (interset) of ARGOS<sup>®</sup> measurements showed comparable values and a low variation rate; data are shown in Table 1

#### COMPARISON OF BIOMETRIC PARAMETERS (N=56 EYES)

- The patient population in this study included a large number of eyes with advanced cataracts
- ARGOS<sup>®</sup> successfully measured AL in 96% (54/56) of the cases; in comparison, LENSTAR LS 900<sup>®</sup> successfully measured 79% (44/56) of cases (Dense Cataract Measurement mode was not available at the study time) and IOLMaster<sup>®</sup> 500 successfully measured 77% (43/56) of cases. Reasons for unsuccessful AL measurement:
  - ARGOS®: 2 cases with the mature cataracts discarded because of no visibility of the retina
  - IOLMaster<sup>®</sup> 500: 2 mature cataracts, 2 cases with stage 5 nuclear sclerosis with posterior subcapsular changes, and 9 cases of stage 2 to stage 3 nuclear sclerosis with stage 3 posterior subcapsular changes
  - LENSTAR LS 900<sup>®</sup>: 2 mature cataracts, 3 cases with stage 4 cortical changes, and 7 cases with stage 3 posterior subcapsular changes
- Table 2 shows comparisons of all measurements for ARGOS<sup>®</sup> vs IOLMaster<sup>®</sup> 500 and LENSTAR LS 900<sup>®</sup>; Spearman correlation coefficients of the AL were extremely high and relatively high for ACD and R<sub>AV</sub> comparisons, but poor for corneal diameter
- Similarly, Bland-Altman plots showed excellent agreement for AL and good agreement for ACD and for R<sub>AV</sub>

Table 1. Mean, SD, and range of the variation of the 9 images produced by  $\mathsf{ARGOS}^{\circledast}$  in 3 consecutive acquisitions.

Parameter	AL	сст	AD	ACD	LT	PS	CD	RAV
Mean	0.01	0.01	0.01	0.01	0.03	0.10	0.14	0.02
Standard deviation	0.02	0.01	0.01	0.01	0.02	0.06	0.06	0.02
Range	0.00, 0.11	0.00, 0.04	0.00, 0.04	0.00, 0.03	0.01, 0.10	0.02, 0.32	0.05, 0.38	0.00, 0.08

All measurements are in millimeters. AD, aqueous depth; CD, corneal diameter; LT, lens thickness; PS, pupil size; RAV, average anterior corneal radius of curvature

Table 2. A Summary of the comparison of ARGOS®, IOLMaster® 500 and LENSTAR LS 900®. Adapted from Shammas et al. *J Cataract Refract Surg.* 2016;42:50-61.

Parameter	Devices vs. ARGOS®	Spearman Correlation Coefficient (r <sub>s</sub> )	Mean difference (SD) (mm)	95% confidence interval (mm)
AL, mm	IOLMaster <sup>®</sup> 500 LENSTAR LS 900 <sup>®</sup>	1.00 1.00	-0.01 (0.05) 0.01 (0.06)	-0.10, 0.08 -0.10, 0.12
ACD, mm	IOLMaster <sup>®</sup> 500 LENSTAR LS 900 <sup>®</sup>	0.76 0.88	-0.17 (0.20) 0.08 (0.15)	-0.57, 0.23 -0.21, 0.37
R <sub>AV</sub> , mm	IOLMaster <sup>®</sup> 500 LENSTAR LS 900 <sup>®</sup>	0.98 0.97	-0.01 (0.05) 0.00 (0.05)	-0.10, 0.09 -0.09, 0.09
CCT, mm	LENSTAR LS 900®	0.93	0.00 (0.01)	-0.03, 0.02
AD, mm	LENSTAR LS 900®	0.91	0.07 (0.14)	-0.20, 0.34
LT, mm	LENSTAR LS 900®	0.80	-0.22 (0.20)	-0.62, 0.18
PS, mm	LENSTAR LS 900®	0.87	-0.29 (0.53)	-1.33, 0.76
CD, mm	LENSTAR LS 900®	0.41	-0.34 (0.76)	-1.83, 1.15

AD, aqueous depth; CD, corneal diameter; LT, lens thickness; n, number of eyes studied for the comparison; PS, pupil size; R<sub>AU</sub>, average anterior corneal radius of curvature

# **Changes in the Anterior Segment After** Cycloplegia With a Biometer Using Swept-Source **Optical Coherence Tomography**

Higashiyama et al. PLoS One. 2017;12:e0183378

**Axial Length** 

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**BIOMETERS** 

**Biometric Parameters** 

**Refractive Outcomes** 

#### **OVERVIEW**



### **STUDY DESIGN**

Prospective study to investigate changes in the anterior segment of the eve after cycloplegia as measured by a biometer with SS-OCT

# STUDY SITE(S)

PATIENTS Single center in

Ten (10) eves of 10 pediatric patients with strabismus or amblyopia who underwent cycloplegia; mean age of 7.2 years; range: 4 to 14 years



## **METHODOLOGY**

Biometric and refractive assessment ARGOS<sup>®</sup> (Santec, Inc.) before and after cycloplegia with SS-OCT. Cyclopentolate hydrochloride 1% (Cyplegin 1% ophthalmic solution, Santen Pharmaceutical, Osaka, Japan) was instilled three times at 10-min intervals. The measurements were obtained 60 min after the last instillation



# **KEY ENDPOINT(S)**

AL, CCT, ACD, lens thickness, spherical and cylindrical refraction

# ANALYSIS AND CONCLUSIONS

Japan

This study demonstrated that ARGOS® was useful for accurately detecting changes in the anterior segment of the eye after cycloplegia in pediatric patients.

Measurements with ARGOS® showed that ACD was increased and lens thickness was decreased after cycloplegia, and also that ACD was increased relative to the decrease in lens thickness. No significant differences were detected on AL and CCT.

#### **STUDY RESULTS**

#### **BIOMETRIC PARAMETERS**

- After cycloplegia, mean lens thickness significantly decreased (P<0.001) (Figure 1), and mean ACD significantly increased (P<0.001) (Figure 2). The change in lens thickness was significantly correlated with the change in ACD (r = -0.73, P=0.02)
- Other changes in biometric parameters were not statistically significant (Table 1)

### **REFRACTIVE OUTCOMES**

- For refractive parameters, statistically significant changes were seen for spherical power and for spherical equivalent (P=0.04 for both)
- No change was observed for cylindrical power before and after cycloplegia (P=1.00)
- Mean change in lens thickness was -0.35 ± 0.18 mm, and mean change in spherical equivalent was 0.68 ± 0.83 D; thus, the change in lens thickness was not significantly correlated with that of the spherical equivalent (r = -0.27, P=0.46)

Figure 1. Lens thickness before cycloplegia (left plots) and after cycloplegia (right plots), showing that mean lens thickness had significantly decreased after cycloplegia (P<0.001).

Figure 2. ACD before cycloplegia (left plots) and after cycloplegia (right plots), showing that mean ACD significantly increased after cycloplegia (P<0.001).



Table 1. Anterior segment and refraction before and after cycloplegia.

Davamotor	Mear	P Value	
Parameter	Before After		
AL (mm)	22.75 ± 0.96	22.75 ± 0.95	0.66
CCT (µm)	516 ± 33	519 ± 34	0.17
ACD (mm)	3.40 ± 0.21	3.68 ± 0.16	<0.001
Lens thickness (mm)	3.77 ± 0.26	3.42 ± 0.20	<0.001
Spherical power (D)	0.10 ± 1.62	0.78 ± 1.46	0.04
Cylinder power (D)	-0.68 ± 0.53	-0.68 ± 0.54	1.00
Spherical equivalent (D)	$-0.24 \pm 1.64$	0.44 ± 1.46	0.04

# Comparison of a New Biometer Using Swept-Source Optical Coherence Tomography and a Conventional Biometer Using Partial Coherence Interferometry

Axial Length

Comparative Accuracy

Higashiyama et al. PLoS One. 2018;13:e0196401

#### OVERVIEW



### STUDY DESIGN

Retrospective review of medical records to compare AL using a biometer with SS-OCT versus using a conventional biometer with PCI STUDY SITE(S) Single center in Japan



#### PATIENTS Fifty-five (55) eyes in 55 patients who underwent cataract surgery; mean age of 72.9 years



# METHODOLOGY

Comparison of AL measurements with SS-OCT and PCI, including subgroup analysis in short, intermediate and long-AL groups (<23.27 mm; 23.27-24.03 mm; ≥24.04 mm respectively)



# BIOMETERS

ARGOS<sup>®</sup> (SS-OCT, Santec, Inc.), IOLMaster<sup>®</sup> version 5 (PCI, Carl Zeiss Meditec AG)



# KEY ENDPOINT(S)

AL and AL acquisition rate

### ANALYSIS AND CONCLUSIONS

The success rates for AL measurements in this study were 98.2% with ARGOS<sup>®</sup> and 87.3% with IOLMaster<sup>®</sup>; a strong correlation was observed between AL measurement obtained with two biometers. Statistically significant differences of AL between the two biometers in short and long subgroups were shown; however, the difference might not be clinically significant.

Based on the higher success rate seen with ARGOS<sup>®</sup> in this study, the authors concluded that AL measurements obtained using a biometer with SS-OCT may be more useful than those obtained using a conventional biometer with PCI.

#### **STUDY RESULTS**

#### **AXIAL LENGTH**

- The success rate for AL measurements was 98.2% (54/55 eyes) with ARGOS<sup>®</sup> and 87.3% (48/55 eyes) with IOLMaster<sup>®</sup>; one eye was not measurable by either biometer; 48 eyes that could be measured successfully with both biometers were further analyzed
- The mean AL was 24.14 ± 1.68 mm with ARGOS® and 24.13 ± 1.71 mm with IOLMaster®; there was no significant difference between the measurements (P=0.67), and there was a significant positive correlation between the biometers (r = 0.998, P<0.001) (Figure 1)</li>
- Figure 2 shows the Bland–Altman plot of axial length using ARGOS<sup>®</sup> and IOLMaster<sup>®</sup>

#### SUBGROUP ANALYSES

- The ALs (mm) measured with ARGOS® and IOLMaster® are shown in Table 1. Mean ALs in the short-AL group were longer with ARGOS® than with IOLMaster® (P=0.002), whereas mean ALs in the long-AL group were shorter with ARGOS® that with IOLMaster® (P<0.001)</p>
- ALs measured with ARGOS<sup>®</sup> were longer than IOLMaster<sup>®</sup> in 81.3% of eyes in the short-AL group and were shorter in 87.5% of eyes in the long-AL group
- There was no significant difference between ARGOS<sup>®</sup> and IOLMaster<sup>®</sup> in the intermediate-AL groups (P=0.14)

**Figure 1.** Correlation of AL between ARGOS® and IOLMaster<sup>®</sup>. Significant positive correlations were observed between the biometers (r = 0.998, P<0.001).



**Figure 2.** Bland–Altman plot of AL using ARGOS<sup>®</sup> and IOLMaster<sup>®</sup>. The limits of agreement were set at  $\pm$  1.96 × standard deviation. There was a significant negative correlation between the mean AL of the two biometers and the AL difference (r = -0.63, P<0.001).



Table 1. Axial length differences, by biometer.

	Mean AL in ARGOS® (mm)	Mean AL in IOLMaster® (mm)	P value	Mean AL difference (ARGOS® – IOLMaster® mm)
Short AL	22.77 ± 0.43	$22.74 \pm 0.44$	0.002	0.03
Intermediate AL	23.63 ± 0.21	23.62 ± 0.21	0.14	0.02
Long AL	26.00 ± 1.61	26.05 ± 1.64	<0.001	-0.05

Comparison of Axial Length Using a New Swept-Source Optical Coherence Tomography-Based Biometer - ARGOS With Partial Coherence Interferometry- Based Biometer -IOLMaster Among School Children

Hussaindeen et al. PLoS One. 2018;13:e0209356

### OVERVIEW



# STUDY DESIGN

Prospective, operator-blinded study to compare AL measurements obtained by an SS-OCT biometer with a PCI biometer in school children



# STUDY SITE(S)

Single center in India (part of a school vision screening program)



#### PATIENTS Three hundred

and seventy-six (376) eyes of 188 children with best corrected vision of 6/9 or better and without any ocular abnormalities; mean (5D) age of 13.88±1.69 years



# METHODOLOGY

Compare biometric measurement from the right eyes with two biometers



# BIOMETERS

**Axial Length** 

**Biometric Parameters** 

ARGOS® (SS-OCT, Santec, Inc.), IOLMaster® (PCI, version 5, Carl Zeiss Meditec AG)



### KEY ENDPOINT(S) AL and corneal

AL and corneal curvature measurements

## ANALYSIS AND CONCLUSIONS

This study demonstrated that AL measurements obtained with ARGOS<sup>®</sup> and IOLMaster<sup>®</sup> were well within the clinically agreeable limits among pediatric population, with comparable measurements for shorter and intermediate AL.

The authors concluded that data from this study can be used as a reference for pediatric AL measurements, and that ARGOS<sup>®</sup> can be recommended for use in a pediatric population due to its speed of acquisition and improved resolution rates.

# **STUDY RESULTS**

#### AXIAL LENGTH/CORNEAL CURVATURE

- The mean (SD) AL was 23.93± 1.02 mm and 23.82 ± 1.05 mm with ARGOS<sup>®</sup> and IOLMaster<sup>®</sup>, respectively
- There was a strong positive correlation between the biometers for both AL (Figure 1) and corneal curvature measurements (Figure 2)
- With respect to agreement between the two biometers, the mean AL difference was -0.11± 0.05 mm with limits of agreement ranging between -0.02 to -0.19, while the mean corneal curvature difference was 0.02 D and the limits of agreement were -0.28 to 0.32





- An additional analysis was conducted in eyes stratified by AL measurements: short (<23.27 mm), intermediate (23.27–24.03 mm) and long (24.04 -26.50 mm). One limitation of this study is no eyes longer than 26.5 mm were included
  - Bland-Altman plots were constructed for each of the AL groups; the mean differences were -0.13 mm, -0.11 mm and -0.08 mm among short, intermediate and long ALs

Figure 2. Correlation of mean corneal curvature between ARGOS® and IOLMaster®.



# Predictive Accuracy of Partial Coherence Interferometry and Swept-Source Optical Coherence Tomography for Intraocular Lens Power Calculation

Axial Length

**Biometric Parameters** 

**Comparative Accuracy** 

Whang et al. Sci Rep. 2018;8:1373

#### OVERVIEW



#### STUDY DESIGN

Retrospective study to compare the predictive accuracy of IOL calculations made with PCI and SS-OCT



Single center in South Korea



# PATIENTS

One hundred and fifty-three (153) eyes of 153 patients who underwent uncomplicated conventional cataract surgery; mean age was 64.84 years (range: 47 to 81 years)

# METHODOLOGY

Use the 3-month postop refractive outcomes and pre-op biometric measurement from two biometers to compare the IOL power prediction error; PCI biometer based lens constants were used



## BIOMETERS

ARGOS® (SS-OCT, Movu, Inc.), IOLMaster® (PCI, version 5, Carl Zeiss Meditec AG)



#### **KEY ENDPOINT(S)**

Biometric measurements; comparison of predictive accuracy for IOL power calculations using the Barret-Universal II, Haigis, Hoffer Q, SRK/T, and T2 formulas

# ANALYSIS AND CONCLUSIONS

In this study, the predictive accuracies of ARGOS<sup>®</sup> and IOLMaster<sup>®</sup> were nearly the same, except in the case of medium-long eyes, for which the predictive accuracy of ARGOS<sup>®</sup> was higher.

The investigators noted that to the best of their knowledge, this was the first study to evaluate the predictive accuracy of ARGOS® in conjunction with the commonly used IOL power calculation formulas (Barret-Universal II, Haigis, Hoffer Q, SRK/T, and T2); personalized IOL constants were used.

### **STUDY RESULTS**

#### AL/CORNEAL CURVATURE/ACD

- AL measurement with ARGOS<sup>®</sup> (24.62 ± 2.29 mm) were significantly shorter than with IOLMaster<sup>®</sup> (24.65 ± 2.35 mm, P<0.001), but agreement and correlation between biometers were good (r = 1.000, P<0.001) (Figure 1)</p>
- There was no significant difference between ARGOS® and IOLMaster® measurements in ACD (P=0.51) or mean corneal power (P = 0.97); both methods were in good agreement and highly correlated (ACD: r = 0.914, P<0.001; mean corneal power: r = 0.981, P<0.001)</p>
- In short eyes, AL and ACD measurements were significantly greater with ARGOS<sup>®</sup> than with IOLMaster<sup>®</sup>. In medium-long and long eyes, AL measurements were significantly smaller than with IOLMaster<sup>®</sup> (Table 1)

#### PREDICTIVE ACCURACY COMPARISON

- With ULIB optimized IOL constants (based on PCI biometry measurement), postoperative myopia would be observed with both biometers; more severe with ARGOS<sup>®</sup> measurements using Haigis (P=0.045) and SRK/T (P = 0.034) formulas
- Following application of personalized IOL constants, mean absolute error (MAE) and the proportion of eyes with prediction error within ± 0.5 D (%) were improved and did not differ significantly between ARGOS<sup>®</sup> and IOLMaster<sup>®</sup> irrespective of the formula used
- In short, medium and long eyes, there were no significant differences in MAE or median absolute error (MedAE) between ARGOS<sup>®</sup> and IOLMaster<sup>®</sup> calculations
- In medium-long eyes, ARGOS<sup>®</sup> calculations had a significantly smaller MAE than IOLMaster<sup>®</sup> calculations, except when the SRK/T formula was used. MedAEs were smaller in medium-long eyes for all formulas examined when ARGOS<sup>®</sup> was used to calculate IOL power

**Figure 1.** Bland-Altman plots for the AL. The limits of agreement were set at  $\pm 1.96 \times$  standard deviation (SD).



Table 1. AL measurements (mm) in subgroups according to average AL values. Adapted from Whang et al. *Sci Rep.* 2018;8:1373.

Axial Length Groups	IOLMaster <sup>®</sup>	ARGOS®	P-value*
Short (n=11)	21.44 ± 0.61	21.51 ± 0.56	0.01
Medium (n=80)	23.32 ± 0.61	23.32 ± 0.60	0.23
Medium-long (n=23)	25.12 ± 0.40	25.05 ± 0.38	<0.001
Long (n=39)	28.02 ± 1.63	27.91 ± 1.57	< 0.001

\*Wilcoxon rank test.

# Accuracy of Swept-Source Optical Coherence Tomography Based Biometry for Intraocular Lens Power Calculation: A Retrospective Cross-Sectional Study

Axial Length

**Biometric Parameters** 

**Comparative Accuracy** 

An et al. BMC Ophthalmol. 2019;19:30

#### OVERVIEW



### STUDY DESIGN

Retrospective observational study to evaluate the accuracy of biometric measurements with SS-OCT for IOL power calculation



**STUDY SITE(S)** Single center and same surgeon for all cataract surgeries in South Korea



#### PATIENTS Four hundred

and thirty-one eyes (431) of 431 patients underwent complicated cataract surgeries; mean age 66.7 years (range of 23 to 87 years)



# METHODOLOGY

Biometric performance from SS-OCT, PCI, and A-scan ultrasonography; prediction error using 2-month post-op manifest refraction spherical equivalent and measurement from 3 biometers using SRK/T formula



# BIOMETERS

ARGOS<sup>®</sup> (SS-OCT, Movu, Inc.), IOLMaster<sup>®</sup> version 5.4 (PCI, Carl Zeiss Meditec AG), Axis Nano<sup>™</sup> (A-scan US, Quantel Medical) in combination with OM-4 (manual keratometry, TOPCON Corp)



#### **KEY ENDPOINT(S)**

Failure rate of AL measurement according to cataract type and severity; comparison of mean absolute error (MAE) and percentage of eyes with a prediction error (PE) of ±0.50 D

# ANALYSIS AND CONCLUSIONS

This study showed that use of biometry with advanced OCT is more effective in obtaining biometric measurements in eyes with posterior subcapsular cataract and predictable refraction results than conventional devices.

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The investigators concluded that ARGOS<sup>®</sup> was useful in clinical practice; it was more effective in obtaining AL in eyes with posterior subcapsular cataract and provided accurate measurements for IOL power calculation regardless of cataract type and severity.

# STUDY RESULTS

#### **AXIAL LENGTH MEASUREMENT**

- Among 431 eyes the AL measurement failure rate was 0.00% (0 eyes) for Axis Nano<sup>™</sup>, 2.32% (10 eyes) for ARGOS<sup>®</sup>, and 15.31% (66 eyes) for IOLMaster<sup>®</sup>
- Among 164 eyes implanted with the same IOL (Precizon Monofocal 560), 128 eyes were able to be measured with all three devices (ARGOS<sup>®</sup>, IOLMaster<sup>®</sup>, and Axis Nano<sup>™</sup>) (Group A), while 36 eyes could not be measured with IOLMaster<sup>®</sup> (Group B)
- There was no significant difference in AL or corneal power among the 3 devices in Group A. In Group B, there was a significant difference (P<0.001) in AL between ARGOS<sup>®</sup> and Axis Nano<sup>™</sup>
- The posterior subcapsular opacity score was significantly higher in Group B (3.72 ± 1.06) than in Group A (0.52 ± 1.03) (P<0.001) while no statistically significant differences observed on nuclear opalescence (NO), nuclear color (NC) and cortical (C)

 Table 1. Comparison of refractive outcomes of IOL power calculation using the three devices with the SRK/T formula in Group A and Group B.

		Group A (n = 128	Group E	3 (n = 36)	
Parameter	<b>ARGOS</b> ®	IOLMaster®	Axis Nano™	<b>ARGOS</b> ®	Axis Nano™
Optimized constant	118.02	118.04	117.90	118.02	117.90
PE (D)	$0.00 \pm 0.44$	$0.00 \pm 0.46$	-0.02±0.61	$0.00 \pm 0.47$	-0.01 ± 0.66
MAE (D)	$0.36\pm0.27^{\dagger}$	$0.39\pm0.30^{\dagger}$	$0.47 \pm 0.39$	$0.36 \pm 0.31$	$0.64 \pm 0.36$
P-value	0.027*			<0.001*	
MedAE (D)	0.31	0.32	0.40	0.32	0.60
Eye within (%) ≤ ±0.25 D ≤ ±0.50 D < ±1.00 D	41.44 71.09	42.97 67.19 95.31	36.72 60.16	47.22 72.22	22.22 47.22 83.33

Values are presented as mean ± standard deviation. PE, prediction error; MAE, mean absolute error; MedAE, median absolute error. \*P-value is for Kruskal–Wallis test. †Same letters indicate no statistical significance based on Bonferroni's method. ‡P-value is for Wilcoxon signed rank test

## PREDICTION ACCURACY (MAE AND PE)

- There was no difference in MAE between ARGOS<sup>®</sup> and IOLMaster<sup>®</sup>, but both showed significantly lower MAE compared with Axis Nano<sup>™</sup> in Group A (P<0.05), and ARGOS<sup>®</sup> showed significantly lower MAE compared with Axis Nano<sup>™</sup> in Group B (P<0.001) (Table 1)</p>
- The MAE of ARGOS® was not significantly different between Group A and Group B; the percentage of eyes with a PE of ±0.50 D or less was 71.09% and 72.22% in Group A and Group B, respectively (Table 1, Figure 1)
- The MAE of Axis Nano<sup>™</sup> was significantly different between Group A and Group B (P=0.007), and the percentage of eyes with a PE of ±0.50 D or less was 60.16% and 47.22% in Group A and Group B, respectively (Table 1, Figure 1)

Figure 1. The distribution of absolute prediction error using the three devices with the SRK/T formula in Group A and Group B.



NS = not significant \*P-value is for Mann-Whitney U test.

# A Comparison of Two Methods to Calculate Axial Length

Cooke et al. J Cataract Refract Surg. 2019;45:284-292

Comparative Accuracy

#### OVERVIEW



#### STUDY DESIGN

Case series to compare prediction accuracy with the AL calculation method of the LENSTAR® biometer (traditional AL) and that of the ARGOS® biometer (sum-ofsegments AL) STUDY SITE(S) Single center in the

United States



e One thousand four hundred and fortytwo (1442) eyes (54 short eyes and 67 long eyes) of 1070 patients who underwent small incision

phacoemulsification

cataract surgery



# METHODOLOGY

Predictions developed for 9 formulas, grouped into those derived with ultrasound (SRK/T, Holladay 1 and 2, Hoffer Q, Haigis) and those derived with optical biometry (Barrett, OKULIX, Olsen from PhacoOptics®, and Olsen from LENSTAR®)



# BIOMETERS

LENSTAR LS 900® (Haag-Streit AG); sum-ofsegments AL method used by ARGOS® was employed with measurement from LESNSTAR®, no actual measurements with the ARGOS®



#### **KEY ENDPOINT(S)**

Mean absolute error (MAE); formulas ranked by MAE in short eyes (traditional AL <22.0 mm), long eyes (traditional AL >26.0 mm), and all eyes

# ANALYSIS AND CONCLUSIONS

This study found that using sum-of-segments AL instead of traditional AL improved predictions for formulas designed on ultrasound data (SRK/T, Holladay 1, Holladay 2, Hoffer Q, and Haigis), although it worsened the Barrett and Olsen formulas; OKULIX ranked first based on MAE.

Limitation of the study: only one optical biometer, ARGOS®, uses sum of segments AL. However, this study did not use ARGOS® for actual measurements.

## **STUDY RESULTS**

#### **PREDICTION ACCURACY**

- For PE calculations, optimized lens constants, which remained the same for Holladay
   1, Holladay 2, Barrett, and both Olsen formulas, were used for each formula
- Compared with using traditional AL, the sum-of segments AL methods improved the predictive accuracy of US-derived formulas, especially in short and long eyes (Figure 1)
- Similar comparison showed that the sumof segments AL method decreased the predictive accuracy of optical biometryderived formulas, especially in short and long eyes (Figure 2)
- In all eyes, the best formulas, in general, were those designed using optical biometry, as long as traditional AL was used
- When using sum-of-segments AL instead of traditional AL, Holladay 2 improved the most and Olsen PhacoOptics<sup>®</sup> worsened the most
- Overall, the top two formulas, when ranked by MAE, were as follows:
- Short eyes: OKULIX (sum-of-segments AL), then Olsen PhacoOptics<sup>®</sup> (traditional AL)
- Long eyes: Haigis (sum-of-segments AL), then Olsen LENSTAR<sup>®</sup> (traditional AL)
- All eyes: OKULIX (sum-of-segments AL), then OKULIX (traditional AL)

Figure 1. Ultra-sound derived formulas using (A) traditional and (B) sum-of-segments AL.



Figure 2. Optical-biometry-derived formulas using (A) traditional and (B) sum-of-segments AL.



The 1442 eyes are divided into 12 AL bins. Each bin has data from at least 45 eyes, except for the bin with the shortest eyes, which has data from only 9 eyes and the longest bin, which has data from only 36 eyes.

# Comprehensive Comparison of Axial Length Measurement With Three Swept-Source OCT-Based Biometers and Partial Coherence Interferometry

Huang et al. J Refract Surg. 2019;35:115-120

#### OVERVIEW



#### STUDY DESIGN

Study to compare axial length measurements (and failure rate) of three SS-OCT-based biometers to those provided by a PCIbased optical biometer **STUDY SITE(S)** Single center in China



#### PATIENTS One hundred seventy-one (171) eyes of 119 patients scheduled for cataract surgery; mean age of 68.87 years (range: 38 to 88 years)



#### METHODOLOGY AL measured with four

biometers (SS-OCT and PCI) in a random order; determination of success rates, intraobserver repeatability and agreement assessment



**Axial Length** 

# **BIOMETERS**<sup>#</sup>

ARGOS® (SS-OCT, Movu, Inc.), IOLMaster® 700 (SS-OCT, Carl Zeiss Meditec AG), OA-2000 (SS-OCT, Tomey Corp.), IOLMaster® version 5.4 (PCI, Carl Zeiss Meditec AG)



# **KEY ENDPOINT(S)**

AL measurements and failure rates; intraobserver repeatability (withinsubject standard deviation [S, ], test-retest repeatability [TRT], coefficient of variation [CoV], intraclass correlation coefficients [ICCS]); agreement assessment (Bland-Altman plots)

# ANALYSIS AND CONCLUSIONS

In this study, the SS-OCT-based biometers (ARGOS<sup>®</sup>, IOLMaster<sup>®</sup> 700) demonstrated superiority in terms of the acquisition rate of AL measurements in comparison to the PCI-based biometer IOLMaster<sup>®</sup> version 5.4.

The Bland-Altman 95% limits of agreement were as narrow as 0.09 mm, indicating excellent agreement among the SS-OCT biometers and the PCI biometer.

### **STUDY RESULTS**

#### **AXIAL LENGTH**

- Out of 171 eyes, AL measurements were successfully measured in 166 eyes (97.08%) with IOLMaster® 700, 170 eyes (99.42%) with ARGOS®, and 138 eyes (80.70%) with IOLMaster® version 5.4
- Chi-square analysis indicated a significant difference in AL measurement success rates between the SS-OCT-based biometers and the PCI-based biometer (P<0.001), but no significant differences were observed among the individual SS-OCT-based biometers

#### **REPEATABILITY AND AGREEMENT**

- Intraobserver repeatability for the IOLMaster<sup>®</sup> 700, and ARGOS<sup>®</sup> showed excellent repeatability with low TRT (0.03 and 0.05 mm, respectively), low CoV (0.04% and 0.07%, respectively), and high ICC (1.000 and 1.000, respectively) (Table 1)
- Excluding the failed measurements, 138 eyes were successfully measured by all biometers; the IOLMaster<sup>®</sup> 700 and ARGOS<sup>®</sup> showed similar excellent repeatability
- The Bland-Altman 95% limits of agreement were as narrow as 0.09 mm, indicating excellent agreement among the SS-OCT biometers and the PCI biometer (Figure 1, Table 2)

#### Table 1. Intraobserver repeatability outcomes for AL measurements.

Device	Eyes (n)	Mean ± SD (mm)	S <sub>w</sub>	TRT	COV (%)	ICC (95% CI)
IOLMaster® 700	166	23.24 ± 1.02	0.01	0.03	0.04	1.000 (1.000 to 1.000)
ARGOS <sup>®</sup>	170	23.22 ± 0.99	0.02	0.05	0.07	1.000 (1.000 to 1.000)

SD, standard deviation;  $S_w$ , within-subject standard deviation; TRT, test-retest repeatability (2.77  $S_w$ ); COV, within-subject coefficient of variation; ICC, intraclass correlation coefficient

#### **Table 2.** AL differences between devices.

Device pairing	Mean ± SD (mm)	P-value	95% LoA
IOLMaster® 700 vs ARGOS®	$0.00 \pm 0.04$	1.000	-0.08 to 0.09
IOLMaster <sup>®</sup> 700 vs IOLMaster <sup>®</sup> v5.4	0.00 ± 0.03	1.000	-0.05 to 0.06
ARGOS <sup>®</sup> vs IOLMaster <sup>®</sup> v5.4	$0.00 \pm 0.04$	1.000	-0.09 to 0.09

SD, standard deviation; LoA, limits of agreement.

**Figure 1**. Bland–Altman plots of agreement in AL measurement between the IOLMaster® 700 and ARGOS®, showing mean results of all patients successfully measured. The solid line indicates the mean difference (bias). The upper and lower lines represent the 95% limits of agreement, the mean results of all patients successfully measured.



\*OA-2000 is not FDA approved; data on non-FDA approved devices are not shown in results.

# Ocular Measurements of a Swept-Source Biometer: Repeatability Data and Comparison With an Optical Low-Coherence Interferometry Biometer

#### Biometric Parameters

#### epeatability/Reproducibility

Nemeth et al. J Cataract Refract Surg. 2019;45:789-797

#### **OVERVIEW**



#### STUDY DESIGN

Evaluation of diagnostic technique to assess the repeatability of a sweptsource biometer in phakic and pseudophakic patients, and to compare measurement data with those obtained by an optical low-coherence interferometry (OLCI) method



Single center in Hungary



## PATIENTS

Ninety-six (96) eyes (50 phakic and 46 pseudophakic) of 96 patients (mean age of 69.22 years and 71.14 years, respectively)

# METHODOLOGY

One eye of each patient was examined with SS-OCT and OLCI biometers; assessment of biometric parameters, cross-cylinder power vector components of astigmatism, repeatability and agreement



#### BIOMETERS

ARGOS<sup>®</sup> (SS-OCT, Movu, Inc.), ALADDIN (OLCI, Topcon Medical Systems Inc.)



#### **KEY ENDPOINT(S)**

Biometric parameters and cross-cylinder power vector components of astigmatism; intrasession repeatability (within-subject standard deviation, intraclass correlation coefficients [ICCs]); agreement assessment (Bland-Altman plots)

#### ANALYSIS AND CONCLUSIONS

This study showed that the repeatability assessment regarding the ARGOS<sup>®</sup> biometer was excellent for all parameters except astigmatism in both the phakic and pseudophakic groups and ACD in the pseudophakic group.

Only limited agreement was observed between ARGOS<sup>®</sup> and ALADDIN in both phakic and pseudophakic patients, except for AL and ACD in the phakic group and AL in the pseudophakic group; therefore, the devices are not interchangeable in clinical practice.

### **STUDY RESULTS**

#### **MEASURED PARAMETERS AND AGREEMENT**

- In the phakic group, the two devices showed a significant difference regarding astigmatism (measured larger by ARGOS<sup>®</sup>, P=0.03) and corneal diameter (CD) (measured larger by ARGOS<sup>®</sup>, P<0.01). The Bland-Altman plots showed excellent agreement for AL and ACD, whereas agreement was not clinically acceptable for CCT, CD, astigmatism, J0 and J45
- In the pseudophakic group, only the CD data were significantly different between ARGOS<sup>®</sup> and ALADDIN (measured larger by ARGOS<sup>®</sup>, P=0.02). The Bland-Altman plots showed excellent agreement for AL, whereas agreement was not clinically acceptable for the remaining parameters

#### **REPEATABILITY (ARGOS® ONLY)**

- In the phakic group, an excellent ICC was reported on the ARGOS<sup>®</sup> device in the case of all measured parameters (AL, CCT, ACD, LT, CD, PS, K1, K2) except for the diopter values of astigmatism and the J0 and J45 vector values of the astigmatism in the phakic group (Table 1)
- In the pseudophakic group, the ICC was moderate in the case of ACD and good in the case of PS, astigmatism and J0 and J45 data (Table 1)
- A subgroup analysis in patients with more than 0.5 D of astigmatism showed that astigmatism and J0 and J45 all showed slightly better ICC values in both the phakic and pseudophakic subgroup compared with the whole patient group

Table 1. ICC in the phakic and pseudophakic groups for the measured parameters derived from  $ARGOS^{\oplus}$  based on three consecutive measurements.

	Phakic group				Pseudophakic group	)
All patients	ісс	95% Cl of the ICC	CoV (%)	ю	95% Cl of the ICC	CoV (%)
AL (mm)	0.993	0.989, 0.995	0.09	0.998	0.996, 0.998	0.09
CCT (µm)	0.921	0.878, 0.951	1.59	0.960	0.936, 0.976	1.20
ACD (mm)	0.934	0.898, 0.959	1.35	0.668	0.524, 0.785	2.23
LT (mm)	0.932	0.895, 0.958	0.79	-	-	-
CD (mm)	0.923	0.881, 0.952	0.95	0.906	0.853, 0.943	0.78
PS (mm)	0.990	0.985, 0.994	2.16	0.871	0.801, 0.921	3.44
K1 (D)	0.981	0.970, 0.989	0.34	0.975	0.958, 0.985	0.47
K2 (D)	0.989	0.983, 0.993	0.32	0.963	0.940, 0.978	0.55
Astig (D)	0.678	0.543, 0.789	-	0.774	0.664, 0.859	-
JO (D)	0.815	0.724, 0.882	-	0.872	0.803, 0.922	-
J45 (D)	0.858	0.784, 0.911	-	0.863	0.845, 0.940	-

Astig, astigmatism; CD, corneal diameter; Cl, confidence interval; CoV, coefficient of variation; ICC, intraclass correlation coefficients; J0, Jackson cross-cylinder, axes at 180 degrees and 90 degrees; J45, Jackson cross-cylinder, axes at 45 degrees and 135 degrees; K1, keratometric value at the flattest meridian; K2, keratometric value at the steepest meridian; L1, lens thickness; PS, pupillary size.

# **Ocular Biometry and Refractive Outcomes** Using Two Swept-Source Optical Coherence **Tomography-Based Biometers With Segmental or Equivalent Refractive Indices**

**Refractive Outcomes** 

Omoto et al. Sci Rep. 2019;9:6557

#### **OVERVIEW**



#### **STUDY DESIGN**

Retrospective chart review to compare measurement data and the postoperative refractive outcomes using two SS-OCT biometers

STUDY SITE(S) Single center in Japan



#### PATIENTS One hundred and six (106) eyes (80 right eves) of 106 patients with cataracts: mean age of 67.0 years; range: 43 to 91 years



#### METHODOLOGY Comparison of biometric

measurements from two SS-OCT biometers and refractive prediction error using 4 IOL formulas; lens constants for IOL optimized for ZCB00 with IOLMaster® measurements



# BIOMETERS

ARGOS<sup>®</sup> (segmental indices, Movu, Inc.), IOLMaster® 700 (equivalent refractive indices, Carl Zeiss Meditec AG)



#### **KEY ENDPOINT(S)**

Biometric measurements and postoperative refractive outcomes: subgroup analysis for eves with medium (22.00 ≤ AL < 26.00 mm, n=76 eyes) and long ALs (AL ≥ 26.00 mm, n=30 eyes)

# ANALYSIS AND CONCLUSIONS

This study demonstrated that the measured parameters obtained from ARGOS® and IOLMaster® 700 differed statistically significantly with overall good agreement, while the refractive outcomes were comparable between devices and clinically acceptable.

The refractive outcomes using segmental refractive indices (i.e. ARGOS®) showed a significant hyperopic trend and less arithmetic prediction errors compared with those using equivalent refractive index (i.e. IOLMaster® 700), especially in eyes with long axial lengths.

### **STUDY RESULTS**

#### **MEASURED PARAMETERS**

- The mean AL, CCT, ACD, and Rm, but not LT, differed significantly (P<0.001) with the IOLMaster® 700 compared with ARGOS<sup>®</sup> (Table 1)
  - Significant differences were seen for the same measured parameters when eyes were stratified by medium (n=76) and long axial lengths (n=30)
- Excellent agreement between the two biometers (Bland-Altman plot) was observed for AL, good agreement for ACD and RM, and only moderate agreement for CCT

## **REFRACTIVE OUTCOMES**

- The percentages of eyes within ±0.50 and ±1.00 diopter of the predicted error (PE) did not differ significantly (P>0.05) with IOLMaster<sup>®</sup> 700 (71.1 and 68.4) compared with ARGOS<sup>®</sup> (67.1 and 61.8)
  - For medium ALs, two formulas (Haigis and SRK/T) provided higher percentages of eyes with arithmetic PE of ±0.50 D or less when the calculations were derived from IOLMaster® 700 compared with ARGOS®
  - For long ALs, all formulas provided higher percentages of eyes with arithmetic PE of ±0.50 D or less when the calculations were derived from ARGOS® vs IOLMaster® 700 (Barrett; 70.0 vs 63.3, Haigis; 73.3 vs 63.3, Hoffer Q; 36.7 vs 30.0, SRK/T; 66.7 vs 46.7)
- The overall median arithmetic PE were closer to zero with the ARGOS<sup>®</sup> than with the IOLMaster<sup>®</sup> 700 for all four formulas (P<0.001) (Figure 1)
  - For medium ALs, the median arithmetic PE were closer to zero with the ARGOS<sup>®</sup> using the Barrett Universal II formula (P<0.001), and for long ALs PE were closer to zero with the ARGOS® using all four formulas (P<0.001)

Table 1. Comparison of biometric measurements using two optical biometers (n=106 eyes). Adapted from Omoto et al. Sci Rep. 2019;9:6557.

Parameter	ARGOS <sup>®</sup> Mean±SD	IOLMaster® 700 Mean ± SD	P-value
AL (mm)	$25.14 \pm 1.90$	25.22±1.95	<0.001
CCT (µm)	533±32	559 ± 32	<0.001
ACD (mm)	$3.33 \pm 0.42$	$3.23 \pm 0.42$	<0.001
LT (mm)	$4.47 \pm 0.44$	$4.46 \pm 0.43$	0.515
Rm (mm)	7.66 ± 0.28	$7.69 \pm 0.28$	<0.001

CCT, central corneal thickness; LT, lens thickness; Rm, mean anterior corneal radius of curvature.



Figure 1. Distribution of the arithmetic PE in refraction with the four IOL power

# Comparative Analysis of 2 Swept-Source Optical Coherence Tomography Biometers

Sabatino et al. J Cataract Refract Surg. 2019;45:1124-1129

#### Axial Length

#### **Biometric Parameters**

Repeatability/Reproducibility

Comparative Accuracy

#### OVERVIEW



#### STUDY DESIGN

Retrospective case series to report the level of agreement, repeatability, and correlation of biometric measurements of two SS-OCT biometers



Single center in the United Kingdom



#### PATIENTS Two hundred

and eighteen (218) eyes of 112 patients from a cataract clinic; median age of 67.9 years; range: 29 to 87 years



# METHODOLOGY

Inter-instrument comparative analysis; each patient assessed using both SS-OCT biometers; subgroup analysis of right and left eyes was conducted



## BIOMETERS

ARGOS<sup>®</sup> (segmental indices, Movu, Inc.), IOLMaster<sup>®</sup> 700 (equivalent refractive indices, Carl Zeiss Meditec AG)



## **KEY ENDPOINT(S)**

Biometric parameters; astigmatism power vectorial analysis (J0 and J45); intraoperator repeatability (intraclass correlation coefficient [ICC]); agreement assessment (Bland-Altman plots)

## ANALYSIS AND CONCLUSIONS

This study found a statistically significant difference between ARGOS<sup>®</sup> and IOLMaster<sup>®</sup> 700 in all measurements except axial length, ARGOS<sup>®</sup> provided good agreement and repeatability compared to IOLMaster<sup>®</sup> 700.

Differences in mean keratometry and lens thickness were found to be statistically significant, but the authors noted that these differences probably did not have a significant impact on IOL power calculation.

# STUDY RESULTS

#### **BIOMETRIC PARAMETERS**

- AL as successfully acquired in 213 of 218 eyes (97.7%), with neither biometer able to acquire AL measurement in 2 eyes (0.92%); no information on the stage of cataract
- There was a statistically significant difference between ARGOS<sup>®</sup> and IOLMaster<sup>®</sup> 700 for all biometric parameters (P<0.05) except AL (Table 1)</li>
  - IOLMaster<sup>®</sup> 700 provided slightly flatter mean K values compared with ARGOS<sup>®</sup>, but this is probably not clinically relevant
  - ARGOS<sup>®</sup> measured higher values for ACD, suggesting the two biometers are not interchangeable for this parameter
  - The difference in lens thickness with the 2 biometers was 0.06 mm; this may not have a significant impact on IOL power calculation with Holladay 2 or Olsen formulas
  - Significant differences were also seen for CCT (crucial for glaucoma screening and preoperative assessment for refractive surgery) and corneal diameter (crucial in planning anterior chamber or phakic IOL implantation to avoid vaulting-related issues)

# CORRELATION AND REPEATABILITY

- The ICC and internal consistency were excellent with both ARGOS<sup>®</sup> and IOLMaster<sup>®</sup> 700
- A very high positive correlation and high agreement (Table 2) between ARGOS<sup>®</sup> and IOLMaster<sup>®</sup> 700 were found for AL, mean K, ACD, lens thickness, and CCT measurements (>0.90), but only low correlation was observed for corneal diameter
- For vector components of astigmatism, mean differences between IOLMaster<sup>®</sup> 700 and ARGOS<sup>®</sup> were 0.01 D for J0 and 0.05 D for J45; differences were not statistically significant

 Table 1. Biometric variables and statistical differences between data acquired with the 2 biometers.

	Both eyes		Right eye	2	Left eye	
Parameter	Mean ± SD/ Median (IQR)	P-value	Mean ± SD/ Median (IQR)	P-value	Mean ± SD/ Median (IQR)	P-value
AL (mm) IOLMaster®700 ARGOS®	23.79 (1.30)* 23.78 (1.26)*	0.07 <sup>s</sup>	23.79 (1.27)* 23.78 (1.22)*	0.543 <sup>s</sup>	23.80 (1.34)* 23.78 (1.30)*	0.04 <sup>s</sup>
Mean K (D) IOLMaster®700 ARGOS®	43.71 (1.70) <sup>†</sup> 43.76 (1.77) <sup>†</sup>	0.00‡	43.67 (1.69)† 43.71 (1.86)†	0.00 <sup>‡</sup>	43.74 (1.67)† 43.85 (1.61)†	0.00 <sup>‡</sup>
CCT (µm) IOLMaster®700 ARGOS®	535.11 (40.83)* 530.53 (39.18)*	0.00 <sup>s</sup>	537.00 (51.00) <sup>†</sup> 531.00 (49.00) <sup>†</sup>	0.00 <sup>s</sup>	535.00 (50.00)† 532.00 (49.00)†	0.00 <sup>s</sup>
ACD (mm) IOLMaster®700 ARGOS®	3.19 (0.44)* 3.31 (0.43)*	0.005	3.18 (0.54)* 3.30 (0.43)*	0.00 <sup>s</sup>	3.19 (0.45)* 3.32 (0.55)*	0.00 <sup>s</sup>
LT (mm) IOLMaster®700 ARGOS®	4.38 (0.70) <sup>†</sup> 4.46 (0.70) <sup>†</sup>	0.00 <sup>‡</sup>	4.40 (0.69) <sup>†</sup> 4.46 (0.71) <sup>†</sup>	0.00 <sup>‡</sup>	4.37 (0.70) <sup>†</sup> 4.45 (0.69) <sup>†</sup>	0.00 <sup>‡</sup>
CD (mm) IOLMaster®700 ARGOS®	12.00 (0.80) <sup>†</sup> 12.45 (1.04) <sup>†</sup>	0.00 <sup>±</sup>	12.00 (0.90) <sup>†</sup> 12.37 (1.02) <sup>†</sup>	0.00 <sup>‡</sup>	12.00 (0.80) <sup>†</sup> 12.49 (1.10) <sup>†</sup>	0.00 <sup>‡</sup>

CD, corneal diameter; LT, lens thickness. \*Mean (SD), †Median (IQR), ‡Wilcoxon signed-rank test, §Student t test for paired samples

Table 2. Level of agreement between ARGOS® and IOLMaster® 700 (both eyes).

Parameter	Difference	LoA
AL (mm)	0.01*	-0.11, 0.13
Mean K (D)	-0.09*	-0.54, 0.36
CCT (µm)	4.58*	-12.71, 21.87
ACD (mm)	-0.12*	-0.34, 0.10
LT (mm)	-0.06*	-0.71, 0.59
CD (mm)	-0.31†	-1.52, 0.93

CD, corneal diameter; LoA. limits of agreement; LT, lens thickness. \*Mean. †Median

# Clinical Evaluation of a New Swept-Source Optical Coherence Biometer That Uses Individual Refractive Indices to Measure Axial Length in Cataract Patients

Tamaoki et al. *Ophthalmic Res.* 2019;62:11-23

### OVERVIEW



## STUDY DESIGN

Retrospective study to compare the ARGOS® biometer, which uses individual refractive indices to measure AL, with the IOLMaster® 700 and OA-2000 biometers, which use an equivalent refractive index

# STUDY SITE(S)

lapan



# PATIENTS

Six hundred and twenty-two (622) eyes of 622 patients who had undergone biometry with the three biometers before cataract surgery; mean age of 71.95 years



# METHODOLOGY

Biometric assessment with SS-OCT; postoperative refractive error evaluated using the Haigis formula with lens constants optimized for IOLMaster® 500 (n=158 eyes)

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# **BIOMETERS**<sup>#</sup>

ARGOS<sup>®</sup> (Santec, Inc.), IOLMaster<sup>®</sup> 700 (Carl Zeiss Meditec AG), OA-2000 (Tomey)



# **KEY ENDPOINT(S)**

AL acquisition rate; comparison of biometry measurement values; refractive outcomes; analyses in subgroups of short, medium, and long AL

# ANALYSIS AND CONCLUSIONS

The AL acquisition rate was significantly higher for ARGOS<sup>®</sup> than for IOLMaster<sup>®</sup> 700. In eyes with long axial length, refractive prediction error was slightly more myopic when using ARGOS<sup>®</sup> compared to IOLMASTER<sup>®</sup> 700.

The authors suggest this occurred because the lens constants in the Haigis formula were optimized using measurements of axial length based on the equivalent refractive index.

### **STUDY RESULTS**

#### **AXIAL LENGTH**

- AL acquisition rate was significantly higher for ARGOS<sup>®</sup> (P<0.0001) than for IOLMaster<sup>®</sup> 700; the rate was also significantly higher for ARGOS<sup>®</sup> (P<0.0001) than for IOLMaster<sup>®</sup> 700 in patients with Grade IV or higher cataract (Figure 1)
- The primary reasons for measurement failure for all devices was mature or white cataract, followed by vitreous hemorrhage
- In the comparison of AL by Bland-Altman plot, differences between ARGOS<sup>®</sup> and IOLMaster<sup>®</sup> 700 showed a significant negative correlation with AL, indicating that eyes with longer AL yielded a greater difference between the two devices (Figure 2)
- Statistically significant differences were observed among the devices for mean K, ACD, crystalline lens thickness, and CCT (P<0.0001), but the differences were not considered clinically significant

#### **REFRACTIVE OUTCOMES**

- The median absolute error in refractive prediction error did not differ significantly among the biometers (n=158; 0.29 D with ARGOS<sup>®</sup>, 0.28 D with IOLMaster<sup>®</sup> 700)
- The percentage of eyes correctly predicted within ± 0.5 D was 80.4% with ARGOS<sup>®</sup> and 82.9% with IOLMaster<sup>®</sup> 700; these differences were not statistically significant
- ARGOS<sup>®</sup> showed significantly greater myopic error than IOLMaster<sup>®</sup> 700 in the long AL group (n= 16, post hoc test P=0.0003)

\*OA-2000 is not FDA approved; data on non-FDA approved devices are not shown in results.

Figure 1. Comparison of AL acquisition rate. In all patients (A) and in those with Grade IV or higher cataract (B), the AL acquisition rate was compared between biometers.



Figure 2. Comparison of AL measurement values using Bland-Altman plot in all patients and ARGOS® vs. IOLMaster® 700. Large dashed lines show 95% limits of agreement. Small dotted lines show bias.



All cases: n = 571	ARGOS® vs IOLMaster®700			
Bias, mm	-0.07*			
SD of bias, mm	0.08			
95% limits of agreement, mm	-0.23 - 0.10			
95% confidence interval, mm	-0.070.06			

\* p < 0.0001.

# Axial Length

Refractive Outcomes

**Comparative Accuracy** 

# Comparison of Two Swept-Source Optical Coherence Tomography Biometers and a Partial Coherence Interferometer

Yang et al. PLoS One. 2019;14:e0223114

Axial Length

**Biometric Parameters** 

**Refractive Outcomes** 

**Comparative Accuracy** 

#### OVERVIEW



## STUDY DESIGN

Retrospective study to compare three biometers on ocular biometry, success rate of AL measurement, and prediction of postoperative refractive outcomes STUDY SITE(S) Single center in South

Korea



# PATIENTS

One hundred forty-six (146) eyes of 83 patients who underwent ocular biometric measurements in preparation for cataract surgery; mean age of 64.23 years



Biometric assessments with 3 biometers in a random order; comparing prediction error using Haigis formula in eyes implanted with Alcon SN60WF IOL (106 eyes)



### **BIOMETERS**

ARGOS® (Movu, Inc.), IOLMaster® 700 (Carl Zeiss Meditec AG), PCI : IOLMaster® version 5.4 (Carl Zeiss Meditec AG)



#### **KEY ENDPOINT(S)**

Biometric parameters (AL, ACD, whiteto-white distance); refractive outcomes; agreement assessment (Bland-Altman plots); predictive errors (PE) one month after surgery

# ANALYSIS AND CONCLUSIONS

AL measured by ARGOS<sup>®</sup> showed a significant difference compared with the two IOLMaster<sup>®</sup> biometers, and both SS-OCT devices (ARGOS<sup>®</sup> and IOLMaster<sup>®</sup> 700) were superior in successfully performing measurements compared with PCI device (IOLMaster<sup>®</sup> version 5.4).

The authors emphasized two benefits of SS-OCT: it has a high success rate of AL measurement (making it useful in cases where AL has not been measured with PCI), and it has a low refractive PE (making it useful for accurate refractive correction).

# STUDY RESULTS

#### **AXIAL LENGTH**

- The success rate of AL measurements for IOLMaster® version 5.4 was 88.4% (129/146 eyes); the success rate with the two SS-OCT devices (IOLMaster® 700 and ARGOS®) was 97.9% (143/146 eyes)
- The Pearson correlation coefficients of AL were high (IOLMaster<sup>®</sup> version 5.4 vs. IOLMaster<sup>®</sup> 700: r = 0.999; IOLMaster<sup>®</sup> version 5.4 vs. ARGOS<sup>®</sup>: r = 0.999; IOLMaster<sup>®</sup> 700 vs. ARGOS<sup>®</sup>: r = 0.9996)
- The AL measurements of IOLMaster<sup>®</sup> version 5.4 and IOLMaster<sup>®</sup> 700 were not statistically different (P=0.162), whereas ARGOS<sup>®</sup> showed a statistically significant difference compared with the other two devices (P<0.001, respectively)</li>
- AL as measured by ARGOS<sup>®</sup> showed a tendency to be shorter in long eyes with axial length >26.0 mm (P<0.001) and to be longer in short eyes with axial length <22.5 mm (P=0.005) (Figure 1)</li>

### **OTHER BIOMETRIC PARAMETERS**

- ACD measured by IOLMaster<sup>®</sup> version 5.4 was longer than that measured by IOLMaster<sup>®</sup> 700 (P=0.003) or ARGOS<sup>®</sup> (P=0.006)
- White-to-white diameter measured using ARGOS<sup>®</sup> was significantly different compared with either IOLMaster<sup>®</sup> device (P<0.001)</li>

## **REFRACTIVE OUTCOMES**

- The mean absolute postoperative PEs are shown in Table 1
- ARGOS<sup>®</sup> showed a significant difference in mean absolute error compared with the two IOLMaster<sup>®</sup> devices (IOLMaster<sup>®</sup> version 5.4 vs. ARGOS<sup>®</sup>: P=0.043; IOLMaster<sup>®</sup> 700 vs. ARGOS<sup>®</sup>: P=0.001)

**Figure 1.** Bland-Altman plot of axial length measurements for each device. The mean difference is indicated by the dashed lines, and 95% LoA is indicated by the solid line. Comparison of IOLMaster® version 5.4 and IOLMaster® 700 (A); IOLMaster® version 5.4 and ARGOS® (B); and IOLMaster® 700 and ARGOS® (C).



Table 1. Comparison of postoperative refractive errors between IOLMaster<sup>®</sup> version 5.4, IOLMaster<sup>®</sup> 700, and ARGOS<sup>®</sup>.

					P-value	
Parameter	IOLMaster® version 5.4	IOLMaster <sup>®</sup> 700	<b>ARGOS®</b>	1 vs 2	1 vs 3	2 vs 3
Mean absolute PE (D)	0.41 ± 0.31	0.42 ± 0.33	0.35 ± 0.30	0.866ª	0.049 <sup>b</sup>	0.001ª
Median absolute PE (D)	0.36	0.35	0.29	-	-	-
Eyes within $\pm$ 0.5 D (%)	68.54	73.03	73.03	0.510 <sup>c</sup>	0.510 <sup>c</sup>	0.999°

°Wilcoxon signed ranks test. Paired t-test. Chi-square test

# Effects on IOL Power Calculation and Expected Clinical Outcomes of Axial Length Measurements Based on Multiple vs Single Refractive Indices

Axial Length

**Refractive Outcomes** 

Shammas et al. Clin Ophthalmol. 2020;14:1511-1519\*



# This study found that differences were found between ALs calculated using a single refractive index and multiple refractive indices, mainly in short and long eyes.

These differences had some effect on IOL power calculation, and the investigators concluded that such effects may become increasingly important as the precision of formulas increases.

\*This study was financially supported by Alcon.

## **STUDY RESULTS**

#### **AXIAL LENGTH**

- Differences between the AL determined in the single and multiple groups ranged from +0.28 mm to -0.14 mm, with a significant correlation between the difference in AL and average AL (r<sup>2</sup> = 0.73, P<0.001) (Figure 1)</li>
- As expected from the methodology, there was no statistically significant difference in the AL measured by group for all eyes
- There were statistically significant differences in the AL between the multiple and single groups in both the short and long eyes, with the single group having slightly shorter AL in the short eyes (P<0.001) and slightly longer AL in the long eyes (P<0.001)</li>

#### PREDICTION ERRORS

- In nearly all cases, the average MAE and median absolute prediction error (MedAE) in the multiple group was lower than that for the single group across all ALs and formulas
- When larger differences in MAE were present, the multiple group results were more often lower (better)
- Within the group of long eyes, 17 eyes exceeded 26 mm; in this smaller group, MAE and MedAE were substantially lower in the multiple group versus the single group
- AE was lower for the multiple group in 53.8% to 62.2% of cases (Table 1)
- In those eyes where the average difference of AEs between the two groups exceeded 0.50 D (an arbitrary cutoff), the AE in the multiple group was lower in 63.3% to 76.6% of cases (Table 1)

Figure 1. Bland-Altman plot of difference in AL (multiple – single) by average AL.



Table 1. Absolute error categorization.

Formula	n	Single Better	Multiple Better	% Multiple Better	P-value
All Eyes					
Barrett	595	275	320	53.8%	0.07
Holladay 1	595	252	343	57.6%	<0.001
Haigis	595	225	370	62.2%	<0.001
Hoffer Q	595	247	348	58.5%	<0.001
SRK/T	595	233	362	60.8%	<0.001
When differer	nce in avera	ge absolute erro	or was > 0.50 D		
Barrett	128	47	81	63.3%	0.003
Holladay 1	145	51	94	64.8%	<0.001
Haigis	141	33	108	76.6%	<0.001
Hoffer Q	153	44	109	71.2%	<0.001
SRK/T	155	48	107	69.0%	< 0.001

# Agreement Between Two Optical Biometers Based on Large Coherence Length SS-OCT and Scheimpflug Imaging/Partial Coherence Interferometry

Tu et al. J Refract Surg. 2020;36:459-465

#### Axial Length

**Biometric Parameters** 

#### **OVERVIEW**



### **STUDY DESIGN**

Prospective study to evaluate the agreement between measurements obtained with two biometers



Single center in China



#### PATIENTS One hundred forty-five (145) eyes of 145 patients: mean age of 37.55 vears



# METHODOLOGY

Measurements with the two biometers (ARGOS® and Pentacam<sup>®</sup> AXL) were conducted in triplicate per instrument in a random order by the same examiner



## BIOMETERS

ARGOS® (SS-OCT, Movu, Inc.), Pentacam® AXL (a rotating Scheimpflug camera combined with a PCI, Oculus Optikgeräte GmbH)



### **KEY ENDPOINT(S)**

AL. CCT. ACD. mean K,  $J_0$  and  $J_{45}$  vectors, and corneal diameter; agreement assessed with Bland-Altman method

# ANALYSIS AND CONCLUSIONS

This study found excellent agreement between the measurements provided by the ARGOS® biometer based on SS-OCT and the optical biometer using Scheimpflug imaging and PCI, except for corneal diameter.

The authors noted that more investigations are to be undertaken to elucidate the agreement between the two optical methods in their application in the diagnosis of a wide range of ocular diseases.

### **STUDY RESULTS**

### **BIOMETRIC PARAMETERS**

- The differences between the Pentacam<sup>®</sup> AXL Scheimpflug imaging biometer and the ARGOS® biometer were as follows: -0.02 ± 0.05 mm for AL,  $1.15 \pm 5.79 \,\mu m$  for CCT,  $-0.04 \pm 0.04 \,mm$  for ACD,  $-0.28 \pm 0.16$  D for mean K, 0.01  $\pm 0.11$  D for J<sub>0</sub>, -0.02  $\pm$  0.10 D for J<sub>15</sub>, and -1.03  $\pm$  0.62 mm for corneal diameter (Table 1)
- A statistically significant difference (P< 0.001) was</p> observed in all measurements, except for AL

#### AGREEMENT

- Bland-Altman plots showed narrow ranges in AL (Figure 1), CCT, ACD, mean K, and  $J_0$  and  $J_{45}$ , which implied excellent agreement between the two biometers
- On the contrary, a systematic overestimation of corneal diameter measurements by ARGOS® with respect to Pentacam® AXL was found (statistically and clinically significant) and confirmed by Bland-Altman plots, which revealed poor agreement
- Similarly, all measurements had acceptable agreement with an ICC of greater than 0.85 except the corneal diameter (95% limits of agreement ranging from -2.25 to 0.19 mm; ICC = 0.21) (Table 1)

Table 1. Mean difference, paired t test, and 95% LOA for differences between Pentacam® AXL and ARGOS®.

Parameter	Mean ± SD	P-value	95% LoA	ICC
AL (mm)	$-0.02 \pm 0.05$	0.125	-0.11 to 0.07	0.999
CCT (µm)	1.15 ± 5.79	<0.001	-10.19 to 12.50	0.981
ACD (mm)	$-0.04 \pm 0.04$	<0.001	-0.12 to 0.03	0.991
Km (2.5 mm) (D)	-0.28 ± 0.16	<0.001	-0.58 to 0.03	0.974
J <sub>0</sub> (D)	0.01 ± 0.11	<0.001	-0.20 to 0.21	0.972
J <sub>45</sub> (D)	-0.02 ± 0.10	<0.001	-0.23 to 0.18	0.858
CD (mm)	-1.03 ± 0.62	<0.001	-2.25 to 0.19	0.21

LoA, limits of agreement; SD, standard deviation; ICC, intraclass correlation coefficient; Km, mean keratometry; CD, corneal diameter

Figure 1. Bland-Altman plots of agreement for the AL between Pentacam<sup>®</sup> AXL and ARGOS<sup>®</sup>. The mean difference is indicated by a solid line, and the 95% limits of agreement is indicated by the dashed lines. SD = standard deviation; D = diopters



# **Abbreviations**

ACD, anterior chamber depth

AD, aqueous depth

AL, axial length

- **CCT**, central corneal thickness
- ICC, intraclass correlation coefficients
- IOL, intraocular lens
- K, keratometry
- LT, lens thickness
- LOA, limits of agreement
- MAE, mean absolute error

ME, mean error

- MedAE, median absolute error
- **OLCI**, optical low-coherence interferometry
- **OLCR**, optical low-coherence reflectometry
- PCI, partial-coherence interferometry
- **PE**, prediction error
- PS, pupil size
- RAV, average anterior corneal radius of curvature
- **SS-OCT**, swept-source optical coherence tomography

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Notes	

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