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ORIGINAL RESEARCH

An evaluation of the accuracy of the ORange® (Gen II) by comparing it to the IOLMaster® in the prediction of postoperative refraction

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Purpose: The aim of this study was to evaluate the accuracy of ORange® Gen II (WaveTec Vision, Aliso Viejo, CA).

Setting: The Surgical Suites, Honolulu, HI.

Methods: The prospective 28 consecutive cataract surgical cases were selected from 85 cataract surgical cases between December 16, 2010 and February 24, 2011. With the same intraocular lens implantation, the predicted spherical equivalent refraction from IOLMaster® (Carl Zeiss AG, Oberkochen, Germany) and ORange Gen II were statistically compared and verified with 1-month postoperative manifest refraction. The data were put into IBM SPSS 19 (SPSS Inc, Chicago, IL) for analysis of variance. Pearson's correlation coefficient was also calculated to evaluate the correlation between the IOLMaster, ORange Gen II, and 1-month postoperative manifest refraction.

Results: There were no statistically significant differences in the mean spherical equivalent refraction from the IOLMaster, ORange Gen II, and 1-month postoperative manifest refraction (IOLMaster –0.40 diopters, $P = 0.07$; ORange Gen II –0.43 diopters, $P = 0.16$; 1-month refraction –0.41 diopters, $P = 0.07$). Pearson's correlation study demonstrated that all three were positively correlated ($P < 0.05$), with the strongest correlation between the ORange Gen II and 1-month postoperative manifest refraction ($r = +0.6$, $P < 0.01$).

Conclusion: The ORange Gen II can be considered as an alternative method for intraocular lens selection for cataract patients.

Keywords: cataract surgery, phacoemulsification, IOL implantation, IOLMaster®, ORange® Gen II, postoperative refraction

Introduction

The intraoperative wavefront aberrometer (ORange®; WaveTec Vision, Aliso Viejo, CA) incorporates a Talbot–Moiré interferometer to enable cataract surgeons to perform refraction during cataract surgery. The Talbot–Moiré interferometer is different from other wavefront technologies, such as Hartmann–Shack, in that it uses optical and mathematical principles to capture and analyze a wavefront. The wavefront passes through a pair of gratings set at a specific distance and angle offset to each other. The diffraction of the wavefront as it passes through the grating pair produces a fringe pattern. Aberrations cause distortions in the fringe pattern and, after being analyzed, are translated into the refractive value.[1] Cataract surgeons can confirm or change the intraocular lens (IOL) based on the output of the ORange intraoperatively. Currently, the IOLMaster® (Carl Zeiss AG, Oberkochen, Germany) is the widely accepted equipment used to select the proper IOL power for patients before cataract surgery

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(data from Carl Zeiss). However, if the cataract is dense or mature, the IOLMaster is unable to perform an accurate selection. In this case, the ORange Gen ll can be used intraoperatively to conduct the selection of the IOL after a dense cataract has been removed.

The ORange Gen I can perform intraoperative refraction after IOL implantation (pseudophakic) while Gen II can perform refraction before IOL implantation (aphakic).[2,3] The issue with ORange Gen I is that the surgeon must exchange the IOL if the refraction output from the ORange Gen I is different from the proposed refraction. The ORange Gen I is the first generation of ORange which is an objective pseudophakic refractor and an intraoperative wavefront aberrometer.

Many limitations apply in using the ORange Gen II, such as small pupil, corneal disease, fovea disease, wound leakage, nystagmus, local block, and use of lidocaine gel. There are also differences in performing the refraction between the ORange Gen II and postoperative manifest refraction, such as patient position, corneal edema, and pupil size.

A search of the peer-reviewed literature to date produced no comparative studies of the ORange Gen II and IOL-Master for the accuracy of IOL power selection. However, there were several studies sponsored by the manufacturer (WaveTec Vision) that demonstrated better refractive outcomes after using the ORange.[2,3] Since the IOLMaster is the widely accepted equipment used to select the proper IOL power for patients, this study compared the prediction of refractive outcomes between the ORange Gen II and the IOLMaster with the same IOL implantation to the manifest refractive outcomes 1 month after uncomplicated cataract surgery.

Methods

The prospective 28 consecutive cataract surgical cases were randomly selected from 85 cataract surgical cases between December 16, 2010 and February 24, 2011 at The Surgical Suites, Honolulu, HI. Subjects received a sequentially numbered sealed envelope containing the randomization assignment to be in the ORange Gen II study. Sixteen males and twelve females were selected into the study with an age range of 56–80 years old. One surgeon performed all the cases. All patients' eyes were under topical anesthesia. There were no complications in any of the 28 cases and no case withdrawals. Patients who were cooperative for the measurements without squeezing the eyes were included. During the measurement, the speculum was carefully checked to make sure it was not tight on the eyelid. Exclusion criteria included subjects with a small pupil, corneal disease, fovea disease, leaking wound, and nystagmus, which may prevent their eyes from being measured by the equipment. The IOLMaster was used to select the appropriate power of IOL for implantation by the surgeon. The predicted postoperative spherical equivalent (SE) refractions from the IOLMaster were recorded. Since only the SE was used in the IOLMaster as the refractive data, the vector of cylinder power was not compared. After phacoemulsification, the ORange Gen II was used by the surgeon. There were several IOLs of different power with different predicted postoperative refraction shown on the ORange panel after the output reading. The IOLs

Table 1 Summary of statistics

	Master	Orange	Refraction
Mean spherical equivalent refraction (diopters)	–0.40	–0.43	–0.41
N	28	28	28
Standard deviation	0.30	0.34	0.39

Abbreviations: Master, IOLMaster®; Orange, ORange® Gen II; Refraction, 1-month postoperative manifest refraction.

Table 2 Test of homogeneity of the variance for the validity of analysis of variance

	Levene's test statistic	df1	df2	*P*
Master	2.067	7	17	0.105
Orange	3.351	7	17	0.020

Note: *P* value is not significant ($P > 0.05$) implying that the groups are homogeneous/have equal variance. Therefore, the analysis of variance is valid.
Abbreviations: df, degrees of freedom; Master, IOLMaster®; Orange, ORange® Gen II.

Table 3 Analysis of variance of mean spherical equivalent refractions

	Sum of squares	df	Mean square	F	*P*
Master					
Between groups	1.592	12	0.133	2.248	0.070
Within groups	0.885	15	0.059		
Total	2.478	27			
Orange					
Between groups	1.834	12	0.153	1.721	0.159
Within groups	1.332	15	0.089		
Total	3.167	27			
Refraction					
Between groups	2.632	12	0.219	2.257	0.069
Within groups	1.458	15	0.097		
Total	4.090	27			

Note: All *P* values were greater than 0.05, which shows that all three mean refractions had no statistically significant differences at the 5% level.
Abbreviations: df, degrees of freedom; F, one way analysis of variance; Master, IOLMaster®; Orange, ORange® Gen II; Refraction, 1-month postoperative manifest refraction.

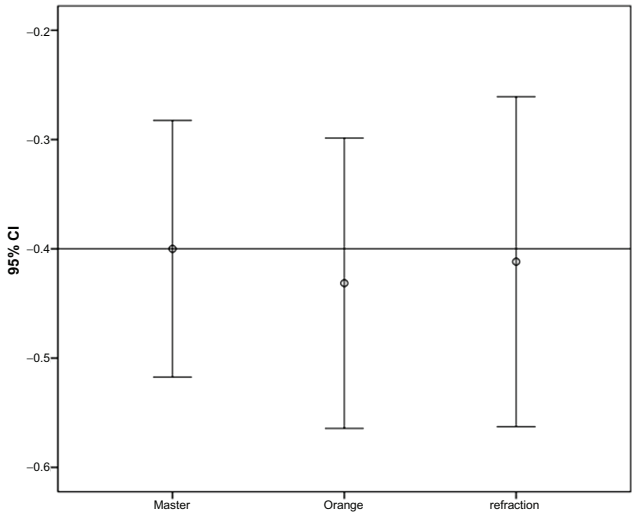

Figure 1 Plot of means.
Note: The error bars (corresponding to 95% confidence intervals for the means) with a reference line for the overall group mean (–0.4) show that all three mean refractions were similar.
Abbreviations: CI, confidence interval; master, IOLMaster®; Orange, ORange® Gen II; refraction, 1-month postoperative manifest refraction.

with the same power that the IOLMaster selected were used and the predicted postoperative SE refraction was recorded. One month later, the patients were examined for a manifest refraction by the technician and the SE refraction data were recorded. The technician was masked (blinded) by being given a numbered form (excluding record of the subject's name, IOL type, and other information) to record the refraction. The data were then entered into IBM SPSS version 19.0.1 (SPSS Inc, Chicago, IL) for analysis of variance comparing the mean predicted SE refraction from the IOLMaster, ORange Gen II, and 1-month manifest refraction.

Results

There were no statistically significant differences ($P > 0.05$) in the mean SE refraction from the IOLMaster, ORange Gen II, and 1-month postoperative manifest refraction (IOLMaster –0.40 diopters [D], $P = 0.07$; ORange Gen II –0.43 D, $P = 0.16$; 1-month postoperative manifest refraction –0.41 D, $P = 0.07$) (Tables 1–3, Figure 1). The surgeon preferred postoperative target refraction around –0.50 D instead of plano. Pearson's correlation study demonstrated that all three were positively correlated in the prediction of postoperative refraction ($P < 0.05$), with the strongest correlation between the ORange Gen II and 1-month postoperative refraction (r = +0.6, $P < 0.01$). The second strongest correlation was between the IOLMaster and ORange Gen II (r = +0.5, $P < 0.01$) and the weakest correlation was between the IOL Master and 1-month postoperative manifest refraction (r = +0.44, $P < 0.05$) (Tables 4–6, Figures 2–4).

Table 4 Correlation between the predicted refraction from IOLMaster® and ORange® Gen II

	Master	Orange
Pearson's correlation	1	0.481*
Significance (two-tailed)		0.010
N	28	28

Note: *Correlation is significant at the 0.01 level (two-tailed), r = +0.5.
Abbreviations: Master, IOLMaster®; Orange, ORange® Gen II; Refraction, 1-month postoperative manifest refraction.

Table 5 Correlation between the predicted refraction from IOLMaster® and 1-month postoperative manifest refraction

	Master	Refraction
Pearson's correlation	1	0.444*
Significance (two-tailed)		0.018
N	28	28

Note: *Correlation is significant at the 0.05 level (two-tailed) r = +0.44.
Abbreviations: Master, IOLMaster®; Refraction, 1-month postoperative manifest refraction.

Discussion

The present work is a subsequent study of the accuracy and reliability of the intraoperative wavefront aberrometer, ORange Gen II. The ORange Gen I can measure the real-time refraction after IOL implantation (pseudophakic), while Gen II can perform refraction before IOL implantation (aphakic)[1,2] and verify the power of the intended IOL before implantation to avoid IOL exchange. The first study evaluated ORange Gen I and found that it can be a good reference intraoperatively for difficult cases such as outliers from previous refractive surgery or cornea abnormality.[3]

This is the first study to evaluate ORange Gen II in predicting postcataract surgery refraction by comparing it with IOLMaster prediction and 1-month postoperative manifested refraction. In this study, the involvement of a single surgeon, a single surgical center, a single technician, and

Table 6 Correlation between the predicted refraction from ORange® Gen II and 1-month postoperative manifest refraction

	Refraction	Orange
Pearson's correlation	1	0.586*
Significance (two-tailed)		0.001
N	28	28

Note: *Correlation is significant at the 0.01 level (two-tailed) r = +0.6.
Abbreviations: Orange, ORange® Gen II; Refraction, 1-month postoperative manifest refraction.

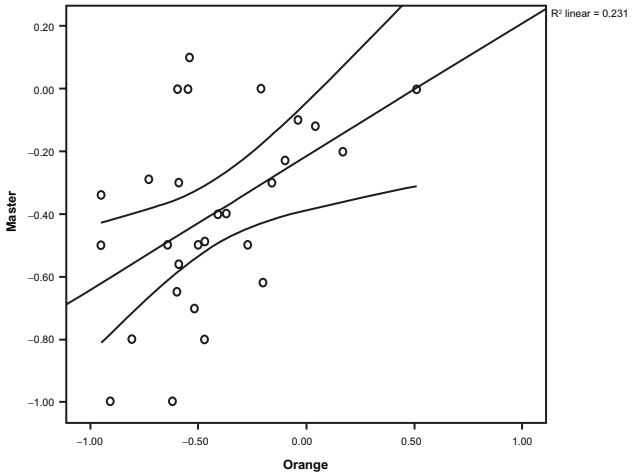

Figure 2 Scatter plot of ORange® Gen II and IOLMaster® predicted refraction in spherical equivalent.
Note: 95% confidence interval range is inside the two curved lines.
Abbreviations: Master, IOLMaster®; Orange, ORange® Gen II.

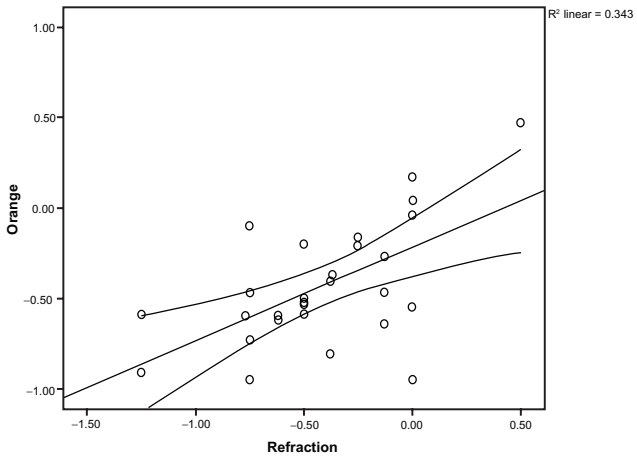

Figure 4 Correlation between ORange® Gen II predicted refraction and 1-month postoperative manifest refraction.
Note: 95% confidence interval range is inside the two curved lines.
Abbreviations: Orange, ORange® Gen II; Refraction, 1-month postoperative manifest refraction.

single equipment was used to avoid interrater disagreement. Analysis of variance is valid for this data and is a valid procedure to use since the *P* value was not significant ($P > 0.05$), implying that the groups are homogeneous, ie, have equal variance. There were no statistically significant differences in the prediction of mean refraction from the IOLMaster, ORange Gen II, and 1-month postoperative manifest refraction. However, because the power calculation indicated insufficient subjects for this study, Pearson's correlation coefficient was calculated for comparison. The strongest correlation was between the predicted refraction by ORange and 1-month postoperative manifest refraction.

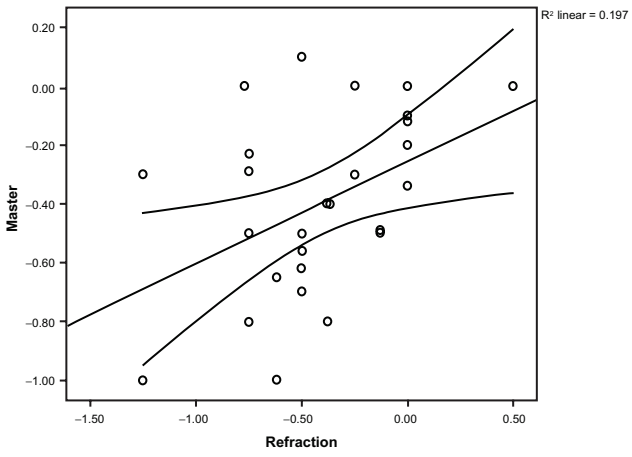

Figure 3 Correlation between IOLMaster® predicted refraction and 1-month postoperative manifest refraction.
Note: 95% confidence interval range is inside the two curved lines.
Abbreviations: Master, IOLMaster®; Refraction, 1-month postoperative manifest refraction.

Despite there being no statistically significant differences in the mean SE, correlation between the three predicted refractive outcomes was not excellent. This may be due to many different situations intraoperatively that can affect the measurement, such as intraocular pressure, IOL position, and IOL power. Clinically, the IOLMaster may not be able to obtain a reading from mature cataracts; the ORange Gen II can be used after the mature cataract is removed to obtain a reading.

Conclusion

The ORange Gen II predicted equivalent and slightly better refractive outcomes compared to the IOLMaster in patients undergoing routine cataract surgery. The ORange Gen II can be considered as an alternative method for determining IOL selection for these patients.

Acknowledgments

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Disclosures

The author reports no conflicts of interest in this work. This study has been approved by the Institutional Review Board of University of Hawaii for ethical issues and "Declaration of Helsinki."

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