Accuracy of objective refraction from a wavefront sensor as glasses prescription

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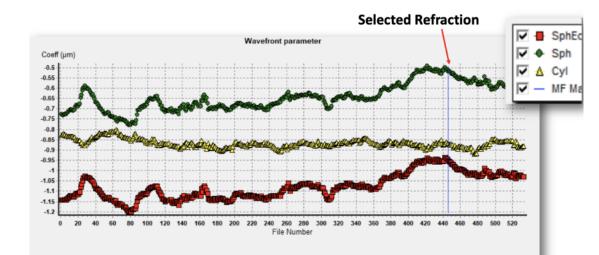


Financial Disclosures

- Dr. Koch is a consultant with Alcon, Carl Zeiss Meditec, Johnson & Johnson Vision, and Perfect Lens
- Dr. Weikert is a consultant with Alcon, Carl Zeiss Meditec, and Epion Therapeutics
- Dr. Wang is a consultant with Alcon and Carl Zeiss Meditec

WaveDyn Wavefront aberrometer

- Obtains objective autorefractions using ultra high-resolution Shack-Hartmann wavefront sensor
- 2870 lenslets
- Captures eye's dynamic optical system over time
- Best objective measurement is selected with algorithm





Methods

- Enrolled patients S/P phacoemulsification with monofocal IOL
- Three consecutive measurements: first one used for comparison to MR
- WaveDyn visual outcomes and objective refractions were compared to:
 - Subjective MR by skilled optometrist based on WaveDyn objective refraction
 - Blinded subjective MR by:
 - Skilled optometrist based on Veracity-predicted postop refraction
 - Technicians based on existing refraction



Results: Repeatability

n = 100 eyes	Mean (range) (D)	Within-Subject SD (D)
Sphere	-0.65 (-3.25 to 1.00)	0.13
Cylinder	0.60 (0.00 to 2.25)	0.13
SE	-0.35 (-2.88 to 1.13)	0.11

Refraction variability is low and remains below minimum measurement increment of 0.25D used in clinical practice

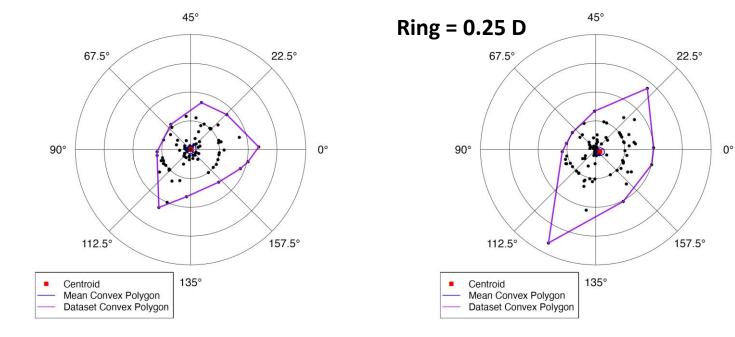


Results: Repeatability

Measurement Difference (1 & 2)

Measurement Difference (1 & 3)

Astigmatism variability remained below 0.25 D in most eyes



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Results: Accuracy (Non-Blinded)— Optometrist's MR based on WaveDyn

n = 100 eyes Measurement	Mean ± SD (D)	95% Limits of Agreement (D)
Sphere	-0.09 ± 0.21 *	-0.49 to 0.31
Cylinder	0.08 ± 0.18 *	-0.26 to 0.43
SE	-0.05 ± 0.18	-0.40 to 0.31

* Statistically significant difference obtained using the Wilcoxon matched-pairs signed-rank test with Bonferroni correction.

Differences in refraction between WaveDyn and optometrist are unlikely to be clinically significant

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Results: Visual Outcomes (Non-Blinded) Wave-Dyn – MR in number of letters

n = 100 eyes Modulation by optometrist	VA Improvement (letters)	95% Confidence Interval (letters)
Sphere	0.6 ± 1.1 (0.0 to 6.0)	-1.6 to 2.8
Sphere + Cylinder	1.0 ± 1.5 (0.0 to 7.0)	-1.9 to 3.9

Optometrist's adjustment of WaveDyn objective refraction led to on average 1.0 Snellen letter improvement in CDVA, but not statistically significant.



Results: Visual Outcomes (Blinded): MR – WaveDyn in number of letters

Comparison	VA Difference (letters) ^a	95% Confidence Interval ^a (letters)
Technicians* (n = 16)	-2.8 ± 3.7 (-11.0 to 2.0)	-10.1 to 4.5
Optometrist* (n = 9)	0.8 ± 2.0 (-1.0 to 6.0)	-3.2 to 4.8

^a Results not significant

Trend of WaveDyn achieving a greater CDVA than did technicians but slightly worse than the same optometrist



Conclusion

- WaveDyn streamlines clinical workflow and offers repeatable objective refractions in monofocal pseudophakic patients
- Differences in refractive measurements between WaveDyn and skilled refractor are minimal
- In a blinded head-to-head comparison, WaveDyn autorefractions may match or exceed CDVA achieved by clinic technicians
 - Study ongoing enrolling more subjects

