Twelve (12) center study proves better than 0.10D accuracy in Autorefractions with the Marco ARK-530A (March-September, 2010)

The following clinicians contributed data for use by Marco in this study. This report was compiled and published by Marco.

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Clinical Study: There is growing awareness that variable pupil size measurement in patient autorefraction can capture valuable data and result in greater accuracy, better patient care and improved clinical efficiency. This awareness has led to the development of a new pupil imaging system from Marco, allowing the autorefractor to read at the largest available pupil size, from 1.98 mm up to 4.0 mm.

This report describes the results of a random, corroborating study of 1146 eyes, conducted from March to September 2010, comparing autorefraction measurements to the subjective manifest refraction of 16 optometrists.

Select Results: The study reveals the following average variances:

- **Sphere: -0.134 Diopters**
- **Cylinder: 0.136 Diopters (measured and refracted in minus cylinder)**
- **Axis: 6.26 degrees**
- **Spherical Equivalence: 0.0664 Diopters**

Summary: The results of this study demonstrate that Marco's new autorefraction technology, supporting variable pupil size measurement, yields greater consistency and accuracy in comparison to the clinician's subjective best corrected manifest refraction. Eye care professionals no longer need settle for "close enough" being good enough.

As clinicians come to accept and rely on this consistency and accuracy, they identify ways to save time and operate their entire practice more efficiently. The adoption of this technology becomes an entry point to the automated refraction system that improves patient care, benefits clinic personnel and delivers on the promise of Electronic Health Records.

Introduction

An idiosyncrasy, if not a frustration of the technology evolution in health care regards the advances in diagnostic technologies exceeding the capabilities, if not the practical realities of existing, related therapies and corrections. Such is the case in eye care with multiple diagnostic entities including glaucoma (optic nerve head measuring capabilities in microns with virtually no corresponding glaucoma “correcting” therapies); retina (diagnosing retinal layer abnormalities with limited medical/surgical options); and foremost in vision care, electronic automated refraction (accurate to 0.1 diopter with limits of 0.25 diopter lens and surgical correcting modalities).

Regarding the later, a recent study just completed by Marco Ophthalmic, demonstrates the increased accuracy of the latest autorefractors, as compared to the traditional manual, manifest refraction. This compelling data, as with most clinical data from automated instrumentation, is repeatable, mostly free of doctor/technician transcription errors, and requires less data-gathering time (more time for patient care and patient education), than the standard subjective and objective refraction methods. But notwithstanding these benefits of automated refraction, without direct application to lens or surgical therapies, can one consider such highly refined, sophisticated refractive information of substantive, practical value? Indeed, as with glaucoma and retinal diagnostic information, maximally accurate refractive information allows advanced clinical interpretations, better professional judgments and more improved decisions about final prescriptions and patients’ general vision care.

Higher order aberration information, especially spherical aberration relative to pupil size is a dramatic example of objective information that allows refinement of a final (lower order) prescription. Consider the typical myope with large pupils where retinoscopy and oftentimes induced “instrument stimulated accommodation” leads to classic over-minusing with subsequent, erroneous validation through the patient’s own subjective responses. Such adjustments could be the difference between patient satisfaction or rejection of a final prescription.

Correcting technologies are ‘catching up’ to diagnostic automated instrumentation and soon, the sophisticated vision information from these instruments will produce a new generation of customized, high definition correcting lenses and surgeries. Currently, state-of-the-art practitioners are better understanding and utilizing this advanced vision information to adjust and refine existing lens and surgical technologies during their transition into the era of electronic health care.

—Lou Catania, O.D., Jacksonville, FL

Changing Practice Standards in Clinical Refractions

Eye care professionals spend much of their time in exam rooms asking patients, “Which is better: 1 or 2?” while flipping lenses in a phoropter, then turning to change slides in the projector, then turning again to record responses on paper. Although this time-honored process results in a prescription that has the complete confidence of these professionals (subjective best corrected manifest refraction), it is slow, ergonomically taxing, and allows for transcription errors.

Whatever the clinical or business motivation may be, doctors can now rely on Marco’s new autorefraction technology to provide objective refractive and keratometric measurements with accuracy and consistency. The benefits of an accurate and reliable starting point are the expedition of the subjective portion of the eye exam, enabling doctors to spend more time focusing on the assessment, treatment and education of their patients and less time gathering data. As this study further demonstrates, the entire process consistently preserves the accuracy of the clinician’s subjective best corrected manifest refraction.

Variable pupil size measurement: key to consistency, repeatability, and accuracy

The trend among optical equipment manufacturers has been to design autorefractors to measure through even smaller pupils (2.2-2.4mm, or even smaller). The main advantage of this standard is that many older patients have smaller pupils and this capability allows the instruments to measure the vast majority of patients. The disadvantage of measuring at a fixed 2.2-2.4mm diameter is in the pin-hole effect it induces. With the introduction of wavefront analysis we now know that most of the refractive errors that affect the quality of vision are present in the 3-5mm optical zone. These errors include, but may not be limited to, irregular and asymmetrical astigmatism, spherical aberrations, and high order aberrations.

The ability to automatically measure refractive error through pupils 1.98mm up to 4.0mm simultaneously offers the best of both features. It allows a relatively unskilled technician to gather very accurate information from a large majority of patients as well as providing the doctor with refractive information from a larger optical zone.

Even moving the patient from the normal lighting in the pre-test room used for objective autorefraction, to the usually darker exam room used for manifest refraction, can affect pupil size. Larger pupil size, when available, is more representative of how patients see most of the time.

The essence of variable pupil size measurement is the Marco pupil imaging system, which sets the reading zone between 1.98mm and 4.0mm, depending on the patient's largest available pupil size. Objective autorefraction based on variable pupil sizes yields more data from patients with larger pupils. The result is an accurate, repeatable, and consistent starting point for manifest refraction.

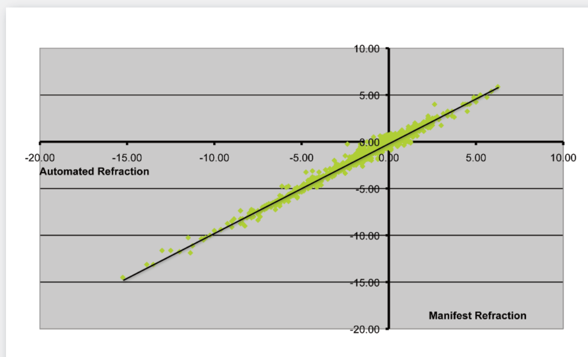
Study results and observations

The results of the 1146 eye study show how closely the autorefraction approximates manifest refraction. The key to interpreting the data lies in average variance figures for each measurement.

- Measurements for sphere varied by an average of -0.134 D. Since the standard of care is to report in increments of 0.25 D, this variance is comparable to the rounding factor of the instrument. While the system measures in 0.01 D it was set to report in 0.25 D. It also suggests that the autorefractor is effectively leaning toward more plus.

- Measurements of cylinder varied by an average of +0.136. Again, this is close to the margin of rounding. The refractions were performed in minus cylinder so +0.136 suggests the system is measuring all the cylinder and the doctor is cutting to the least acceptable cylinder.

Regression Analysis



Points falling on diagonal line indicate exact correlation between autorefraction (x-axis) and manifest refraction (y-axis); i.e., spherical equivalence = 0. Regression analysis demonstrates consistency and repeatability (R^2=0.982). Measurements are from both smaller and larger optical zones simultaneously over a broad range of optical errors. Sample size from 1146 eyes/576 patients. Graph incremented in Diopters.

	Autorefractor Reading				Manifest Refraction				Difference			
	Sphere	Cylinder	Axis	Spherical Equivalent	Sphere	Cylinder	Axis	Spherical Equivalent	Sphere	Cylinder	Axis	Spherical Equivalent
Avg	-1.00	-0.84	92	-1.4239	-1.14	-0.71	72	-1.4903	-0.1342	0.1355	6.2666	0.0664
Max	7.25	0.00	n/a	6.25	7.00	0.00	n/a	5.875	1.75	2.75	90	1.375
Min	-14.50	-5.50	n/a	-15.25	-14.00	-5.25	n/a	-14.5	-1.25	-1.25	0	-2.125
St Dev	2.76	0.83	58	2.7707	2.68	0.83	64	2.6902	0.3915	0.3072	10.0654	0.3836

- The average variance on spherical equivalence is 0.0664 D. This calculation is a way of minimizing the subjective variability among clinicians and this variance is well with in the tolerances set by American National Standards Institute (ANSI) standard Z80.1-2010 (refer to www.opticampus.com/tools/ansi.php)

•American National Standards Institute Z80.1 – 2010 General Tolerances for Single Vision and Multifocal Lenses		
Measurement	**Power Range**	**Tolerance**
Sphere Power	**≥ 0.00 D, ≤ ±6.50 D > ±6.50 D**	**±0.13 D ±2%**
Cylinder Power	**≥ 0.00 D, ≤ 2.00 D > 2.00 D, ≤ 4.50 D > 4.50 D**	**±0.13 D ±0.15 D ±4%**
Cylinder Axis	**> 0.00 D, ≤ 0.25 D > 0.25 D, ≤ 0.50 D > 0.50 D, ≤ 0.75 D > 0.75 D, ≤ 1.50 D > 1.50 D**	**±14° ±7° ±5° ±3° ±2°**

All measurements were taken between March and September 2010 in 12 eye care clinics by 16 total clinicians. Total eyes measured: 1146/576 patients. To simulate the patient base of an actual practice, no restrictions were placed on the age of participants. The study results were gathered using the Marco ARK-530A which features fully automated 3 dimensional tracking, X, Y, and Z alignment, and auto acquire. This feature contributes significantly to the accuracy and consistency of the measurements by eliminating human alignment and acquisition errors.

The accuracy of the data, captured by the autorefractor in a fraction of the time – typically 2 seconds per eye (3 measurements >1 second each), compared to roughly 1 minute per eye required to capture the same data manually with retinoscopy – enabling clinicians to perform better-focused manifest refractions.

The increases in reliability, consistency and accuracy that come from this new autorefraction technology add up to an important factor for doctors seeking to grow their practice: efficiency.

Autorefraction, efficiency and the automated refraction system

The integration of the autorefraction measurements into the exam lane is completed with the addition of the Marco Automated Refraction System. The autorefraction measurement now can be used as a starting point for the subjective refraction, as a confirmation point throughout the refraction and most importantly as an end point reference for final prescription verification.

The efficiencies gained through integration (including the automated transfer of data to the patient's EHR) can save the clinician 5 minutes or more on each complete exam. Greater exam room efficiency for the future will be dictated by how efficient and accurately data can be entered into the patient's computerized medical record and then how quickly it can be viewed by the various people involved in providing care. Data that must be continuously scrutinized for transcription errors will be the most time consuming responsibility of doctors and their staff when data is manually entered.

The autorefraction process takes less than a minute of staff time, requires none of the clinician's time, and expedites the process of manifest refraction. This level of efficiency – combined with greater consistency and accuracy – holds long-term benefits for patient care and practice growth.

The autorefractor is also the logical starting point for an end-to-end, automated refraction system that moves patients and their data smoothly from intake, through refraction and consultation, to optical and billing.

Clinicians, seeing the consistency and high correlation between autorefractions and their own subjective best corrected manifest refractions, will soon become confident in the system's accuracy and rely on it to increase efficiency and patient-flow in their practice.

Objective Measurement and Subjective Refraction

An objective autorefraction measures the whole optical system as a single unit, averaging all the refractive components (tear film, cornea, lens, vitreous fluid, etc.) together. In a subjective refraction we measure the components (Sphere, Cylinder, Axis) individually, then we try to put them back together like a puzzle.

For this reason, it is common for a clinician to refract a patient's Sphere, Cylinder and Axis all to 20/20 individually, then "loose letters" on the 20/20 line after putting the measurements back together and adjusting accordingly. This is caused by higher-order aberrations and the fact that the patient's eye has developed as an entire biological function, blending these differences and interpreting the data through cortical adaptation.

Benefits of Automated Refraction Systems

For patients:

- Split prism test for cylinder and axis lets patients select from side-by-side images without relying on memory
- Instant comparison of old and new prescriptions allows patients to see potential for improved vision
- Greater efficiency means patients spend less time in refraction and more quality time with the doctor

For clinicians:

- Improved consistency and accuracy result in fewer doctor re-do's and lens re-makes
- Time savings per patient add up to more patients per day
- More time for patient consultation
- Additional special testing leads to better overall eye care - benefiting both doctor and patient

Continuing the workflow, the autorefractor and automated refraction system position the practice for a new, significant step: compliance with requirements for electronic health records (EHR).

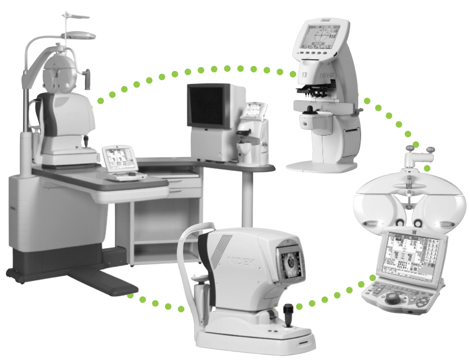
The road to EHR

A combination of government deadlines and Medicare EHR incentives of up to $48,000 over five years will lead many eye care practices to invest in EHR between now and 2016.

Clinicians pondering the opportunities and obstacles posed by EHR face several issues:

- Adapting to changes in process. The automated refraction system supports the changes in the process of providing eye care that come with EHR: preference for electronic charts over paper files, instant retrieval of patient history, standardization of data entry and presentation.
- Capturing data. When technology allows clinicians to refract, perform additional special tests, consult, prescribe and record digital measurements in a continuous patient-flow without jotting notes or entering keystrokes, they have an advantage in the transition to EHR.
- Ensuring the integrity of the data. As software and databases change over time, clinicians need to be certain that new measurements will be mapped correctly before committing them from the refraction system to the EHR system. To validate the consistent high quality of the data transferred into EHR, Marco Ophthalmic, Inc has created "Marco Connect" software and "Marco Certified EHR" partners.
- Integrating with EHR software. Clinicians must consider the effects of EHR compliance on their front-office practice management software. Integration with the automated refraction system enables staff to store and instantly access patient data for optical, patient and third-party billing and reporting.

While a successful EHR effort depends on more than automated refraction equipment, it benefits greatly from the workflow and electronic advantages of the system.



Marco Connect software links automatic refraction technologies.

About Marco

Founded in 1967, Marco of Jacksonville, Florida, is the leader in offering the eye care industry the latest in automated diagnostic products. Visit www.marco.com, and follow Marco on Facebook. Please contact Marco at 800-874-5274 to arrange your free practice consultation and technology demonstration.

Notes: This report refers to products available exclusively from Marco, including the ARK-530A Automatic Refractor/ Keratometer, the LM-600 series of lensmeters, the Marco line of automated refraction systems, and the Marco Connect interface for ensuring data integrity in to EHR.

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