Optimizing Visual Performance with Wavefront Refractions

A study of the use of modern technology to improve patient satisfaction.

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The clinical methods for measurement of the manifest refraction of patients have remained unchanged for more than 100 years. At the same time, we have learned that the measurements vary between practitioners and, more importantly, the variation is higher for individual patients.[1] Zadnik concluded that the repeatability of subjective refractions was worse than that of autorefractions, and found to be + 0.63 diopter.[2]

The coefficient of variation between measurements may be based on the subjective nature of the test and the common use of 0.25-diopter steps in sphere and cylinder measurements. The use of the Jackson Cross Cylinder has been questioned for its variable effectiveness as a function of the axis being measured.[3] In addition, we have concerns about the clinical limitation of conducting a subjective refraction under a single light level and pupil size.

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We have experienced patients reporting that they see well with our prescription lenses during the day and less well when driving at night or attempting tasks in reduced illumination. The understanding that the spherical and cylindrical refractive error varies with pupil size has been expanded by the ability to measure the refractive error objectively with autorefractors and wavefront aberrometers using a range of aperture sizes.[4]

As clinicians having a practice philosophy of providing the highest quality of care possible and striving for the highest level of patient satisfaction and enthusiasm, we wondered if we could improve our standard method for determining a final lens prescription. The principles of evidence-based health care and our desire to be ahead of the curve presented a need for discovery. To close this gap, we decided to investigate a new technology that presented the potential to provide a prescription that would optimize visual performance under the full continuum of lighting conditions.

The instrument we investigated is the i.Profiler$^{plus®}$ (by ZEISS) and the resultant lenses with i.Scription technology (Figures 1 and 2). The technology uses an algorithm that blends our manifest refraction with the wavefront data. The manifest refraction is entered into the i.Scription Software, which then calculates the i.Scription prescription up to a pupil size of 5.5mm.[5] The resultant i.Scription is ordered to the one hundredth of a diopter (0.01D) as opposed to the traditional increments of one quarter of a diopter (0.25D). i.Scription uses sphere and cylindrical equivalents for the pupil range of the respective eye and the higher-order aberrations.

We wanted to concentrate on pre-presbyopic patients who were expected to have the largest range of pupil reactivity when measured under mesopic and photopic illumination. The decision to study pre-presbyopic patients also allowed for testing single vision lenses rather than multifocal lenses. This eliminated the variables of style of progressive addition lenses, precision fitting of the PALs and individual adaptation variability.

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OUR STUDY DESIGN

We have served as clinical investigators on scores of contact lens and pharmaceutical studies and knew we could execute a study to determine if new technology was right for our practice. We wished to avoid the pitfall of very small experiences, and we wanted to see if there was an indication that we could do a better job. We used a design similar to contact lens studies we had conducted. A randomized, single-masked, cross-over clinical study comparing the efficacy of customized ZEISS Individual® Single Vision (SV) lenses with i.Scription technology to customized ZEISS Individual® SV lenses without i.Scription technology was selected for our practice, Carmel Mountain Vision Care in San Diego. A direct comparison of the visual quality of 37 subjects was made between the two single vision lenses, under mesopic and photopic conditions.

Each subject was measured with the i.Profiler^{plus} and received a comprehensive eye examination, including our customary subjective manifest refraction. Objective measurements were taken of the wavefront aberrations of the eye with the i.Profiler^{plus} and combined with our subjective manifest refractions by use of the proprietary Zeiss VoluMetric merit function algorithm to create customized ZEISS Individual® SV lenses with i.Scription technology (Figure 3). A second pair of customized ZEISS Individual SV lenses without i.Scription, using only the conventional subjective refraction, were manufactured as the control lenses.

The control and test lenses were fitted into two identical frames, with the same position of wear, measured with the i.Terminal® by ZEISS. A refractive index of 1.6 was used, as the lens material and lenses were manufactured according to the standard customization parameters of ZEISS Individual SV lenses. The study spectacles were randomized for wearing order and labeled to mask the type. The subjects were compensated at their final visit with the study pair that they felt gave them the best overall visual quality and comfort.

SUBJECT SELECTION

Our eligibility criteria for subjects required normal, healthy eyes; patient age between 18-40 years; best corrected monocular distance visual acuity (logMAR) of 0.10 (20/25) or better; and subjects who were full-time eyeglass wearers for all distances.

Subjects were classified according to three different prescription power categories. The classification was made according to the eye with the highest Manifest Refraction Spherical Equivalent (MRSE). Subjects with an MRSE greater than or equal to -4.00D were classified as *Subjects with High Myopia*; between -3.75D and -0.25D inclusive, as *Subjects with Mid-Myopia* and more plus or equal to plano, as *Subjects with Hyperopia*. The study concluded with 11 subjects with high myopia; 21 subjects with mid-myopia and five subjects with hyperopia.

PATIENTS SHARE THEIR IMPRESSIONS

"1st pair (i.Scription) seemed clearer and overall more comfortable for my eyes."

"It (i.Scription) is more comfortable than the other, less strain. They also gave me sharper view of things and brightened my surroundings."

"I prefer the 2nd pair (i.Scription) because my eyes didn't feel any straining, everything seemed clearer."

"The 1st pair (i.Scription) is sharper and clearer and I feel more confident with them."

"Both pairs were very close, but the 1st pair (i.Scription) was a lot better at night."

"Slightly better vision: on computer; viewing screen during presentations; sharpness of lights at night."

"Better night time conditions, overall slightly better."

CLINICAL MEASUREMENTS

Clinical measurements were conducted under mesopic (30 lux) and photopic (300 lux) conditions. The i.Profiler^{plus} measurement, Subjective Refraction and Point-Spread-Function (PSF) test were performed under mesopic conditions. The PSF test was designed with a single green LED light source, the same size as a -0.1 LogMAR letter, that was mounted against a matte black background and placed at the same distance from the patient as the visual acuity chart.

Monocular and binocular high (100%) and low (10%) contrast distance visual acuities were measured in a straight-ahead gaze position with the M&S Smart System II 20/20^{TM} 2010. Monocular and binocular high-contrast near visual acuities were measured in a straight ahead gaze position, with ZEISS near VA chart. Independent mesopic and photopic pupil sizes were measured with a Colvard Pupilometer.

Control and Test eyeglasses were worn independently for a 10-day period each, followed by a one-week direct comparison period. Clinical measurement evaluations and patient-reported outcomes were performed on days 10, 20 and 27, respectively. Results were analysed using the following methods: Percentage Analysis; Descriptive Statistical Analysis; P-Test Analysis; Bland-Altman Plots and ANOVA calculations. A Visual Analog Scale response valuation was used in all questionnaires (Figure 4).

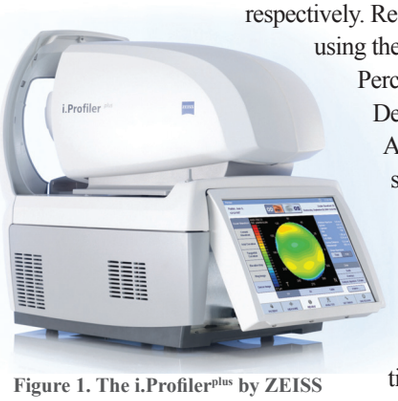

Figure 1. The i.Profiler^{plus} by ZEISS

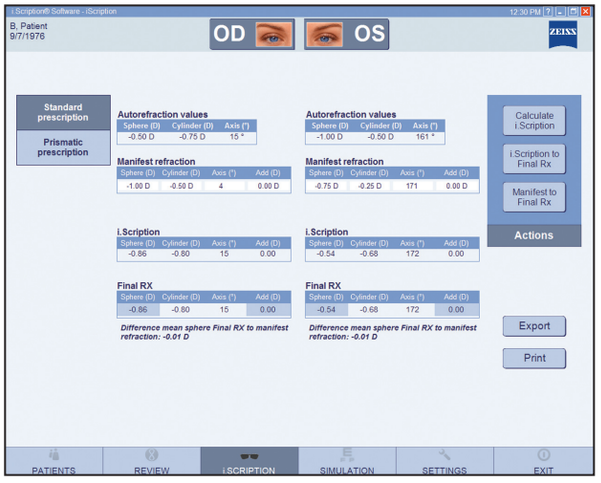

Figure 2. The i.Scription software user interface entry screen.

Subjects were required to fill out a daily study journal commenting on their visual experiences under specific visual conditions that were outlined in the journal.

RESULTS

• ***Comparison to Habitual Rx.*** We asked the subjects to compare the two pairs of study eyewear to eyewear with their habitual prescription prior to the study. Subjects were asked to rate the i.Scription Rx and manifest refraction Rx to their habitual Rx after they wore each pair independently for a minimum of 10 days. The overall preference for the i.Scription Rx vs. the Habitual Rx was 95%. The overall preference for the Manifest Rx vs. the Habitual Rx was 92%. This outcome indicates that both study prescriptions were preferred over the habitual Rx and there was an apparent need for prescription change.

• ***Overall Preference Final Choice.*** Subjects were asked which study spectacles they preferred overall as their final choice for visual quality and visual comfort, and to rate that choice. Answers were recorded on a 1 to 6 numerical scale and analyzed. A mean difference of 0.514 higher for the Test lenses resulted. Percentage analysis revealed that 59.5% of subjects preferred the Test lenses as their final choice for visual quality and visual comfort, compared to the Control. This difference was driven mainly by the subjects with high myopia and mid-myopia: 67% of subjects with high myopia and 59% of subjects with mid-myopia preferred the Test lenses and subjects with Hyperopia had an equal preference for the Test and Control lenses.

• ***Visual Acuity.*** The Test lenses provided better mean visual acuity in mesopic conditions when compared to the Control lenses. All visual acuity measurement conditions resulted in no statistically significant mean logMAR acuity differences with the Test and Control lenses. In each case, the difference was less than one line of vision improvement. A difference of one line or more is required to conclude that the difference is clinically significant.[5]

• ***Preference Under Lighting Conditions.*** Our subjects wore each pair solely for 10 days, and then were allowed to make a direct comparison with both study Test and Control spectacles for one week prior to their final visit where clinical measurements were also conducted with direct comparison. The comparison is reported in Figure 4.

Overall, the Test lenses were preferred for five of the seven visual conditions; for one visual condition the Test lenses were preferred equally to the Control and for the other visual condition the Control lenses were preferred over the Test.

• ***Adaptation Time.*** Our subjects were asked how quickly they adapted to the study spectacles after having worn each pair independently for a minimum of 10 days. Answers were recorded on a 1 to 5 numerical scale and analyzed. A mean difference of 0.027 resulted, indicating no significant difference and that the Test rated slightly higher than the Control. There were no cases of non-adaptation for either the Test or Control.

• ***Visual Conditions Questionnaire.*** Our subjects were asked which study spectacles they preferred overall for 17 different visual conditions (Figure 5). The Test lenses rated higher than the Control lenses for all 17 different visual conditions: distance vision; mid-range vision; near vision; active vision; brightness; brightness of environment; colors more vivid; edges sharper; less glare; peripheral vision; depth perception; adaptation; visual comfort for distance vision; visual comfort for near vision; quicker to change focus; night vision; natural vision.

They were asked which statement(s), out of eight, best described their study spectacles. They were allowed to select either or both study spectacles for each statement when applicable. The Test lenses rated higher than the Control for all eight statements as follows: Provides more comfortable vision; provides fewer headaches; provides good near vision; provides good intermediate vision; provides good distance vision; provides a feeling of more relaxed vision; provides less tiredness; provides less strain.

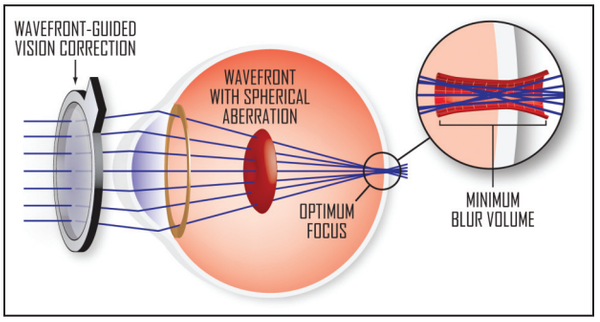

Figure 3. Diagrammatic explanation of the Volumetric Merit Function.

FIGURE 4

Preference Category Description	Test: i.Scription	Control: Manifest	No Difference
Distance visual acuity OU, under mesopic high contrast conditions	51%	41%	8%
Distance visual acuity OU, under mesopic low contrast conditions	38%	24%	38%
Near visual acuity OU, under mesopic conditions	22%	19%	59%
Point Spread Function Test under mesopic conditions OU	35%	27%	38%
Distance visual acuity OU, under photopic high contrast conditions	41%	35%	24%
Distance visual acuity OU, under photopic low contrast conditions	22%	22%	57%
Near visual acuity OU, under photopic conditions	16%	24%	59%

• ***Likelihood to recommend lenses.*** Our subjects were asked to rate on a scale from 1 (very unlikely) to 10 (very likely) how likely they would recommend the study spectacles to family or friends. A mean difference of 0.135 resulted, which indicates that the Test lenses rated higher than the Control. Percentage analysis of the number subjects who gave the highest rating (10) revealed that 41% of subjects would "very likely" recommend the Test lenses and 27% of subjects would "very likely" recommend the Control.

OUR CONCLUSIONS

As clinicians and practice managers, we try to make quantitative decisions for constant product and service improvements to meet our mission of providing the highest quality of care in our region. While we appreciate that our in-office studies may not have statistical power for 95% confidence, we endeavour to execute our studies to allow us to have more than anecdotal evidence.

In this study, we found that the blended or optimized prescription of the lenses with iScription technology prevailed in every category over the same Zeiss Individual lenses made according to our subjective refractions only. The overall preference rating was higher with the Test spectacles than with the Control spectacles. This difference was driven mainly by the subjects with high myopia and mid-myopia.

While not statistically or clinically significant, the preponderance of the evidence supports a trend for enhanced performance and patient satisfaction with the Test lenses. The finding that the visual acuity was better for the Test lenses under mesopic lighting conditions was consistent with a clear area where we wanted to improve our patients' visual performance. The preference for the Test lenses for the Point Spread Function test also supported our desire to improve visual comfort in the presence of point sources of light under dim light conditions.

Adaptation time was faster with the Test spectacles than with the Control spectacles. There were no cases of non-adaptation for either the Test or Control spectacles.

We were impressed that the Subjective ratings were higher with the Test spectacles than with the Control spectacles for all 17 visual conditions. This complements the discovery that the Test spectacles were more likely to be recommended than the Control spectacles.

Under direct comparison, the Test spectacles were preferred for visual quality over the Control spectacles under five of seven lighting and contrast acuity conditions. Further, the Test spectacles provided more comfortable vision; fewer headaches; good near vision; good intermediate vision; good distance vision; a feeling of more relaxed vision; less tiredness and less strain.

Overall, our consideration of all the investigational categories supports a trend that i.Scription by ZEISS provides better visual quality and comfort for our patients, and our patients are more likely to recommend these lenses; thereby adding to the growth of our practice. We expect the use of this technology, combined with our other study-based decisions, will continue to support our valuable final product for the practice: *enthusiastic, satisfied patients*.

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The authors wish to acknowledge the assistance of Jerome A. Legerton, OD, MS, MBA, and Barbara H. Bytomski, OD, in the preparation of this manuscript and the research from which it was derived.

FIGURE 5

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The study of lens performance under varying light conditions

EXIT QUESTIONNAIRE – VISIT FIVE

[1] Which pair of eyeglasses did you prefer for distance vision (e.g. straight-ahead viewing; day-time driving)?

1st Pair Much Better	1st Pair Somewhat Better	1st Pair Slightly Better	2nd Pair Slightly Better	2nd Pair Somewhat Better	2nd Pair Much Better

[2] Which pair of eyeglasses did you prefer for mid-range vision (e.g., using a computer)?

1st Pair Much Better	1st Pair Somewhat Better	1st Pair Slightly Better	2nd Pair Slightly Better	2nd Pair Somewhat Better	2nd Pair Much Better

[3] Which pair of eyeglasses did you prefer for near vision (e.g. reading a book)?

1st Pair Much Better	1st Pair Somewhat Better	1st Pair Slightly Better	2nd Pair Slightly Better	2nd Pair Somewhat Better	2nd Pair Much Better

[4] Which pair of eyeglasses did you prefer for active vision (e.g. walking; going up and down stairs)?

1st Pair Much Better	1st Pair Somewhat Better	1st Pair Slightly Better	2nd Pair Slightly Better	2nd Pair Somewhat Better	2nd Pair Much Better

[5] With which pair of eyeglasses does your environment look brighter?

1st Pair Much Brighter	1st Pair Somewhat Brighter	1st Pair Slightly Brighter	2nd Pair Slightly Brighter	2nd Pair Somewhat Brighter	2nd Pair Much Brighter

[6] Which pair of eyeglasses did you prefer in terms of the brightness of your environment?

1st Pair Much Better	1st Pair Somewhat Better	1st Pair Slightly Better	2nd Pair Slightly Better	2nd Pair Somewhat Better	2nd Pair Much Better

[7] With which pair of eyeglasses do colors appear more vivid?

1st Pair Much More Vivid	1st Pair Somewhat More Vivid	1st Pair Slightly More Vivid	2nd Pair Slightly More Vivid	2nd Pair Somewhat More Vivid	2nd Pair Much More Vivid

[8] With which pair of eyeglasses do edges of objects look sharper?

1st Pair Much Sharper	1st Pair Somewhat Sharper	1st Pair Slightly Sharper	2nd Pair Slightly Sharper	2nd Pair Somewhat Sharper	2nd Pair Much Sharper

[9] With which pair of eyeglasses do you experience less glare (e.g. driving at night with oncoming headlights)

1st Pair Much Less Glare	1st Pair Somewhat Less Glare	1st Pair Slightly Less Glare	2nd Pair Slightly Less Glare	2nd Pair Somewhat Less Glare	2nd Pair Much Less Glare

[10] With which pair of eyeglasses do you have Brighter peripheral vision (e.g. moving your eyes to look at an object off to the side)?

1st Pair Much Brighter	1st Pair Somewhat Brighter	1st Pair Slightly Brighter	2nd Pair Slightly Brighter	2nd Pair Somewhat Brighter	2nd Pair Much Brighter

[11] With which pair of eyeglasses do you have Brighter depth perception (e.g. judging distances)?

1st Pair Much Brighter	1st Pair Somewhat Brighter	1st Pair Slightly Brighter	2nd Pair Slightly Brighter	2nd Pair Somewhat Brighter	2nd Pair Much Brighter

[12] Which pair of eyeglasses did you find it easier to adapt to wearing?

1st Pair Much Easier	1st Pair Somewhat Easier	1st Pair Slightly Easier	2nd Pair Slightly Easier	2nd Pair Somewhat Easier	2nd Pair Much Easier

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[13] With which pair of eyeglasses did you have less eye strain, fatigue, dizziness or other feelings of visual discomfort during general, straight-ahead day-time viewing?

1st Pair Much Less Discomfort	1st Pair Somewhat Less Discomfort	1st Pair Slightly Less Discomfort	2nd Pair Slightly Less Discomfort	2nd Pair Somewhat Less Discomfort	2nd Pair Much Less Discomfort

[14] With which pair of eyeglasses did you have less eye strain, fatigue, dizziness or other feelings of visual discomfort during near work?

1st Pair Much Less Discomfort	1st Pair Somewhat Less Discomfort	1st Pair Slightly Less Discomfort	2nd Pair Slightly Less Discomfort	2nd Pair Somewhat Less Discomfort	2nd Pair Much Less Discomfort

[15] With which pair of eyeglasses do you find it quicker to change your focus to a nearby object

1st Pair Much Much Quicker	1st Pair Somewhat Much Quicker	1st Pair Slightly Much Quicker	2nd Pair Slightly Much Quicker	2nd Pair Somewhat Much Quicker	2nd Pair Much Much Quicker

[16] Which pair of eyeglasses did you prefer for night vision or viewing in dim light?

1st Pair Much Better	1st Pair Somewhat Better	1st Pair Slightly Better	2nd Pair Slightly Better	2nd Pair Somewhat Better	2nd Pair Much Better

[17] With which pair of eyeglasses does the view of your surroundings feel more natural?

1st Pair Much Better	1st Pair Somewhat Better	1st Pair Slightly Better	2nd Pair Slightly Better	2nd Pair Somewhat Better	2nd Pair Much Better

[18] With your FIRST pair of eyeglasses, did you notice any unnatural magnification, where objects appear too big or too small, or appear closer or farther away than normal?

Yes, I noticed this very strongly | Yes, I noticed this a little bit | No, I didn't notice this

[19] With your SECOND pair of eyeglasses, did you notice any unnatural magnification, where objects appear too big or too small, or appear closer or farther away than normal?

Yes, I noticed this very strongly | Yes, I noticed this a little bit | No, I didn't notice this

[20] Which pair of eyeglasses did you prefer overall?

1st Pair Much Better	1st Pair Somewhat Better	1st Pair Slightly Better	2nd Pair Slightly Better	2nd Pair Somewhat Better	2nd Pair Much Better

What are your reasons for this choice? What are your reasons for disliking the other pair?

[21] On a scale of 1 to 10, how likely would you be to recommend your FIRST pair of eyeglasses to family or friends?

1 (Very UNLIKELY) 2 3 4 5 6 7 8 9 10 (Very LIKELY)

[22] On a scale of 1 to 10, how likely would you be to recommend your SECOND pair of eyeglasses to family or friends?

1 (Very UNLIKELY) 2 3 4 5 6 7 8 9 10 (Very LIKELY)

[23] Select which of the following best describe your FIRST and SECOND pair of eyeglasses. You are allowed to select more than one option per pair of eyeglasses.

	1st Pair	2nd Pair
Provides more COMFORTABLE vision overall		
Makes my eyes feel LESS TIRED overall		
Makes my eyes feel LESS STRAINED overall		
Experience LESS HEADACHES overall		
Provides good NEAR vision e.g. when reading		
Provides good INTERMEDIATE vision e.g. on the computer		
Provides good DISTANCE vision e.g. when driving		
Makes my eyes feel more RELAXED overall		