Objective Measurement of PAL Viewing Zones

CONTROVERSE DISCUSSIONS PART 1

Based on a lecture given at MAFO – The Conference in Paris, October 26, 2006

The optics of PALs are complex and vary from design to design. In theory, there can be an infinite number of PAL designs (Figure 1). Despite the large variability among PAL designs, the optical information that is provided to eye care practitioners (ECP) is largely limited to the location on the lens that the manufacturer recommends be fitted before the patient's pupil (fitting cross) and the locations on the lens at which the distance and near prescriptions can be verified. Manufacturers also provide a recommended minimum fitting height, but there are no established guidelines by which the minimum fitting height is related to the optics, nor do any standards address the minimum fitting height. ANSI Z80.12 specifies a reference method by which the spherical equivalent and astigmatism values across the lens can be measured; however, manufacturers generally do not report such contour plots for their lenses.

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There was also a strong, but mixed, response from the ophthalmic industry to the publication of my third study. In the past, PALs have been marketed largely with nontechnical messages intended to develop brand loyalty among eye care practitioners. The study results and the intended use of the reported ratings have potential to change the method by which ECPs select PALs for their patients and hence to change the marketing paradigm (Figure 2). Some companies have embraced the results of the previous study, whereas others have not.

The methods for measuring the sphere and cylinder powers used in the previous study and in this study are straightforward. The methods of analyzing those measurements and the rationale for developing the ratings are discussed and specified. However, there can certainly be other methods of measuring, comparing, and analyzing the various PAL designs.

The current study is a follow-up to the previous one in which one limitation was that only one lens of each design was measured and analyzed. We have subsequently developed software that enables us to analyze lenses in less time. Consequently, in this study, we are able to report mean and standard deviations based on measurements of several lenses of each design.

The main value is a better representative of the PAL design than the value based on a single lens. Measurement of multiple lenses of each design also allows statistical testing of the differences between the measurements and ratings of the various PAL designs. Also, the standard deviation of the measurements and ratings is a representative of the manufacturing consistency. Manufacturing consistency is important for clinical care. Inconsistency can negatively affect vision in terms of matching the characteristics of the right and left lenses, ordering a new prescription of the same

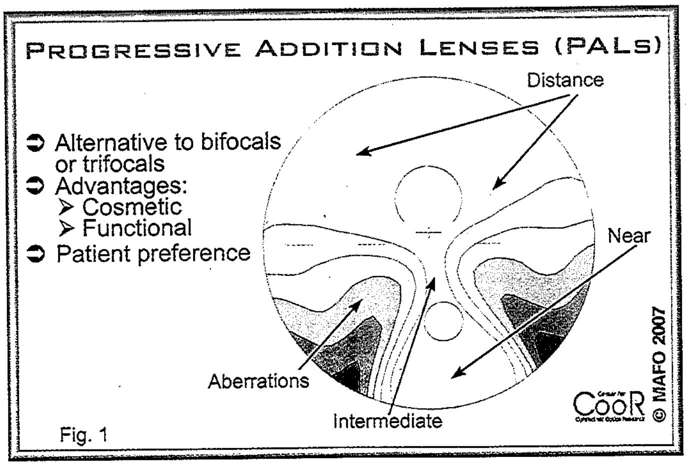

Fig. 1

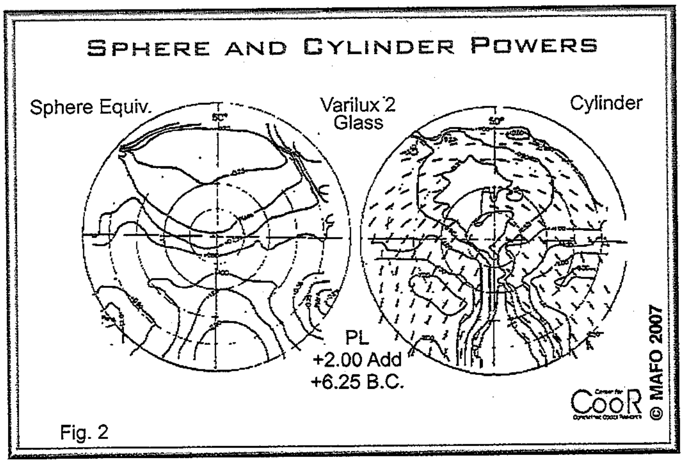

Fig. 2

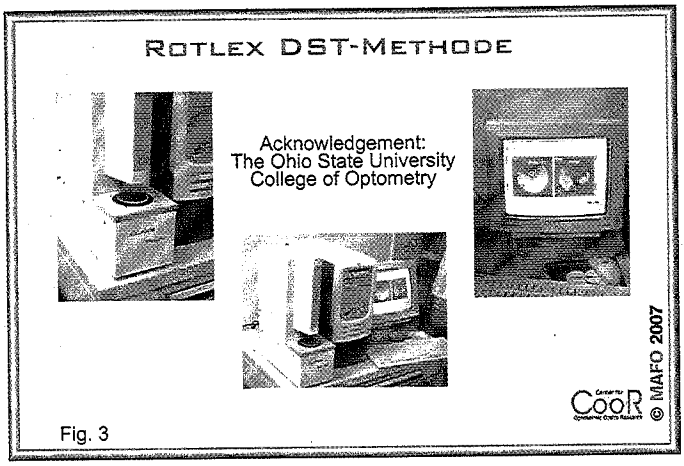

Fig. 3

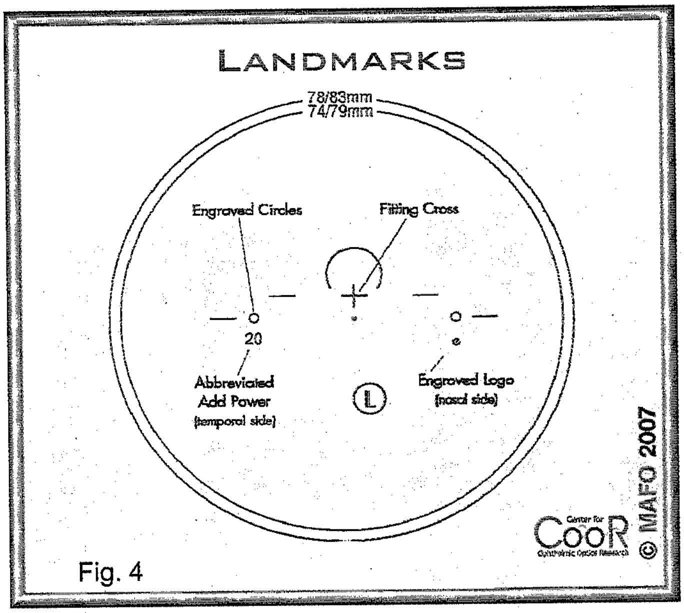

Fig. 4

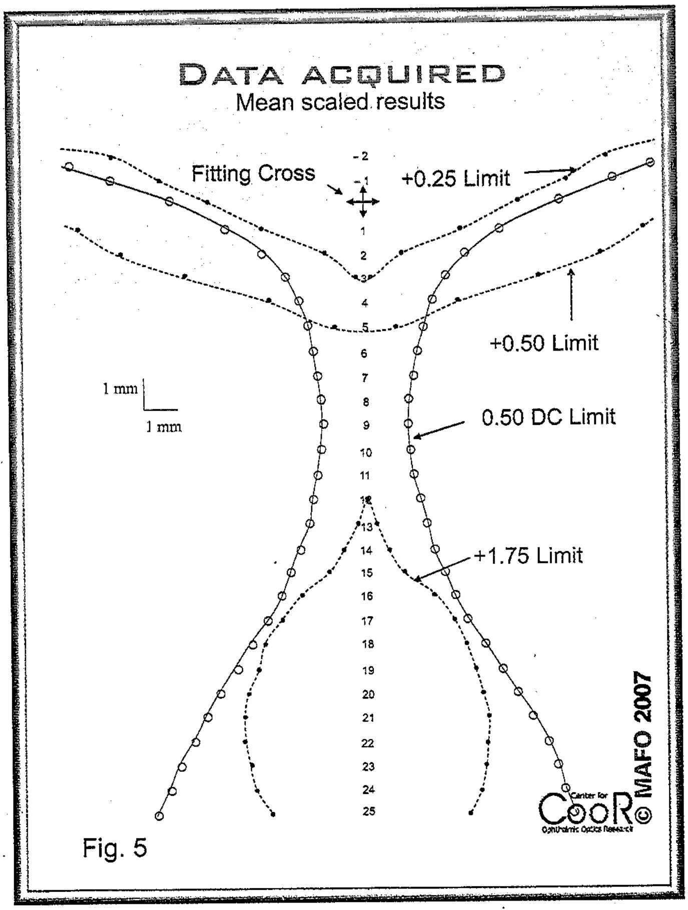

Fig. 5

PAL design for a patient, or replacing a single lens for a patient.

In the current study, the measurement methods and analysis criteria are the same as those used previously. Results are reported as the main and standard deviation based on measurements of 12 lenses comprised of six right/left pairs acquired separately through laboratory channels. Several of the measured PAL designs are newly introduced since the last study, and some of the measured designs are the same as in the previous study.

Measurement Method

The lens measurement method was identical to that previously reported. All lenses were measured using the Rotlex Class Plus lens analyzer to provide sphere, cylinder, and axis values across the surface of the lens (Figure 3). The lenses were measured by aligning the prism reference line markings appropriately in the instrument. All of the measurements were made using the Rotlex 'DST' mode; hence, all measurements were normalized to an assigned power of plano at the location recommended by the manufacturer (Figure 4).

The criteria for determining zone width and area were also the same as in the previous study, but the implementation was different. In the previous study, the Rotlex software was used to analyze each lens file. Widths were measured by an operator who recorded each width in 1 mm steps up and down the corridor. Areas were calculated by summing the widths, thereby integrating area in 1 mm steps (Figure 5).

In the current study, the ASCII data file for each lens was exported into a parser software program developed for this purpose. The data file contained X and Y coordinates and sphere, cylinder, and axis values in a 1/2 mm grid. Linear interpolation was performed to create data points in a 1/32 mm grid. The data file could be parsed according to specific values or ranges of each of the values (X, Y, sphere, cylinder, or axis) separately or in combination. The data files were parsed using the same criteria as in the previous study3 to define zone widths and areas.

The distance zone widths and areas were constrained by 1.5 mm above the fitting cross, and by 0.25 dioptersphere (DS) and 0.50 dioptercylinders (DC). The intermediate zone was constrained by adds of 0.75 DS and 1.50 DS and by 0.50 DC. The near zone was constrained by 1.75 DS and by 0.50 DC (Figure 6).

Determining Sample Size

It was necessary to determine the number of lenses of each design that would be required for testing to achieve a desired

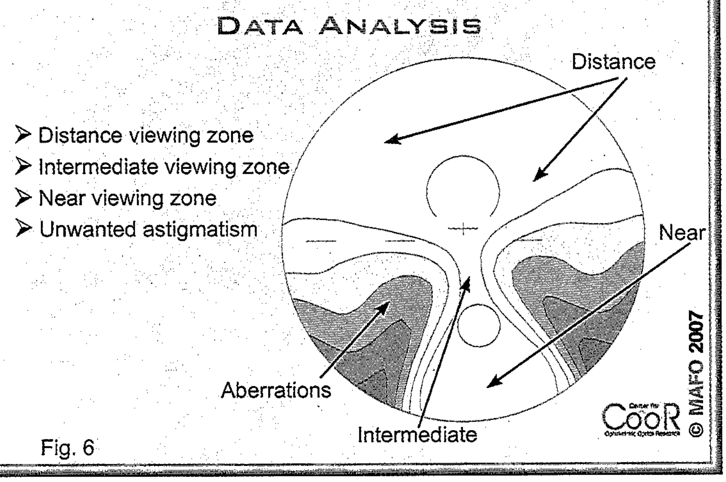

Fig. 6

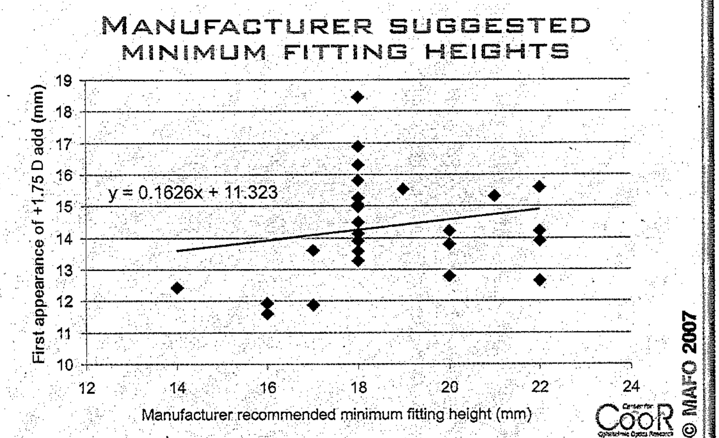

Fig. 7

level of confidence. There are two sources of variability when measuring several lenses of the same design: the method variability is variability as determined by measuring and analyzing the same lens repeatedly and the manufacturing variability is the variability in lenses of the same design and prescription. The method variance was tested by measuring and calculating ratings twice for each of 10 different PALs. The 10 PALs were AO b'activ, Hoyalux ECP, Pentax AF Mini, Rodenstock Life XS, Signet-Armorlite Navigator Precise, Shamir Genesis, SOLA XL, SOLAMax, Vision Ease Outlook, and Younger Image.

The manufacturing variance, i.e., across lenses of the same design, was evaluated by measuring and analyzing three pairs each of five different designs: AO Compact, Hoyalux ECP, Shamir Genesis, SOLA VIP, and Varilux Panamic. Each lens pair was obtained from a different optical laboratory to minimize possible batch effects. All lenses were plano distance with a +2.00 diopters (D) add. The order of lens measurement and analysis for both variance tests was randomized and data files coded so that the experimenter was not aware of the lens being analyzed.

Reliability is the consistency of measurement as determined by the correlation coefficient using data from a mixed model repeated measures analysis of variance. The method covariance was determined from the data obtained by measuring each of 10 lenses twice. The manufacturing correlation coefficient is the covariance between lenses of the same design divided by the sum of the manufacturing covariance plus the method covariance.

The methods for measuring and analyzing data had reliability values of 0.95 or better for all measurement categories except the intermediate width and intermediate rating, which had reliabilities of 0.943 and 0.926, respectively. Only two lenses of each design are required to obtain at least 0.95 method reliability. The manufacturer reliability data are considerably lower than the method reliability data, ranging from 0.892 to 0.930 for the intermediate and near measures and ratings and from 0.346 to 0.538 for the distance measures and ratings. Only three lenses are required to obtain at least 0.95 manufacturer reliability for the intermediate and near measures and ratings; however, 11 lenses are required for 0.90 manufacturer reliability for the distance rating. Therefore, 12 different lenses (six pairs) of the each design were measured.

RESULTS

Distance Viewing Zone

The width values are for the zone width at the level of the fitting cross – hence they represent the width that the patient receives in the straight-ahead gaze position when fitted as recommended by the manufacturer. The zone width is limited on both sides by 0.50 DC or +0.25 DS, whichever occurs first. The area of the distance viewing zone includes the area up to 1.5 mm above the fitting cross. The side and lower boundaries of the distance area are constrained by 0.50 DC or +0.25 DS.

Intermediate Viewing Zone

The width and area are both constrained by 0.50 DC. The zone width is at the vertical location at which the add power is +1.25 D in the center of the corridor. The area of the intermediate zone is constrained by 0.50 DC and by add amounts of +0.75 D to +1.50 D.

Astigmatism

It has been shown that the maximum amount of astigmatism on the lens correlates highly with the amount of astigmatism elsewhere on the lens and that the magnitude of unwanted astigmatism is a fundamental measure of the lens design.

Near Viewing Zone

The near widths and areas are constrained to have less than 0.50 DC and also to have more than a +1.75 D add. An add level of +1.75 D was used instead of the nominal add power of +2.00 D, because many lenses do not attain an add amount of +2.00 D. The near zone width and area values depend on the downward distance from the fitting cross.

In practical use, the amount of the near zone available to the patient depends on the fitting height of the lens in the spectacle frame. Because any given PAL design can be fitted over a range of fitting heights. Fitting height, however, must also include additional height for the frame bevel and to allow for some pupil coverage. Therefore, 2 mm is added to the distance from the fitting cross to derive fitting height values.

Minimum Fitting Heights

In this study, we measured the highest level at which +1.75 D add occurred in each lens design (Figure 7). Of course, the minimum fitting height will be greater than the highest occurrence of the +1.75 D add because of the frame bevel and the fact that some minimum amount of the near zone must be exposed above the frame to enable a minimum level of functional near vision. To determine the amount by which the minimum fitting height should exceed the highest occurrence of the +1.75 D add, we subtracted the highest occurrence of the +1.75 D from the manufacturer recommended minimum fitting height across all designs.

Across all designs, the average difference was 4.1 mm. Therefore, the criterion we used to develop our recommended minimum fitting height was to add 4.0 mm to the highest occurrence of the +1.75 D add. In this manner, the minimum fitting heights recommended herein are, on average, the same as those currently recommended by manufacturers, but the minimum fitting height recommended for any particular design is related to the measured highest occurrence of +1.75 add for that design.

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Appointments and Employment

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