A comparison of RGP parameters to ANSI standards

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Abstract
Precise determination of parameters is essential to the proper fit of a rigid gas permeable contact lens. It is also important that the lens be manufactured to specifications ordered. One hundred rigid gas permeable lenses from four labs were verified, and their parameters compared to ANSI standards. A considerable number of the lenses studied had one or more parameters which failed to meet these standards. The percentages of lenses which failed to meet ANSI standards for a specific parameter were as follows: optic zone -- 7%; back vertex power-- 9%; overall diameter-- 10%; center thickness -- 15%; base curve -- 25%; and, peripheral curve widths - - 55%. Therefore, it is to the optometrist’s benefit to verify incoming lenses, and to be able to modify them when needed to help ensure a proper fit.

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A COMPARISON OF RGP PARAMETERS TO ANSI STANDARDS

By

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and

KEVIN WATTERS

A thesis submitted to the faculty of the
College of Optometry
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ABSTRACT

Precise determination of parameters is essential to the proper fit of a rigid gas permeable contact lens. It is also important that the lens be manufactured to specifications ordered. One hundred rigid gas permeable lenses from four labs were verified, and their parameters compared to ANSI standards. A considerable number of the lenses studied had one or more parameters which failed to meet these standards. The percentages of lenses which failed to meet ANSI standards for a specific parameter were as follows: optic zone -- 7%; back vertex power -- 9%; overall diameter -- 10%; center thickness -- 15%; base curve -- 25%; and, peripheral curve widths -- 55%. Therefore, it is to the optometrist's benefit to verify incoming lenses, and to be able to modify them when needed to help ensure a proper fit.

Key Words: ANSI standards, rigid gas permeable contact lenses, lens parameters, verification, modification.
INTRODUCTION

A proper rigid gas permeable contact lens fit is essential for patient comfort and clarity of vision. Furthermore, the very health of the patient's cornea is at stake. Consequently, considerable time and effort on the part of the optometrist is utilized to ensure a proper lens fit. Among other things, corneal topography must be accurately measured. The steepness or flatness of the cornea is significant, as is the amount of astigmatism and its orientation. Not only must the central cornea be considered, but the peripheral must be addressed as well. This is especially true with difficult-to-fit patients. The above is evidenced by the creation of methods to measure peripheral as well as central corneal topography, since the standard keratometer measures only the central cornea. With the aid of computerized corneal topographers, contact lens fitting is becoming more precise.¹

All the efforts to obtain precise measurements is futile if the lab fails to construct the contact lens accordingly. Rigid contact lens parameters influence how a lens will actually perform on the eye. For example, overall diameter, as well as other parameters, can effect the stability of the fit.² Peripheral curves serve to prevent the edge of the lens from digging into the cornea during movement. They also maintain corneal metabolism by allowing tear circulation beneath the lens. Further, the peripheral meniscus, which is supported by the peripheral curves, aids in lens centering.³ Also, an improper edge design can result in foreign body sensation, lid awareness, excessive and unpredictable lens movement, 3 and 9 o'clock staining, and peripheral abrasions.⁴

The American National Standards Institute (ANSI) is a private organization which issues voluntary standards designed to protect the
consumer. They have issued minimum standards for rigid contact lens parameters. From speaking with experienced clinicians, it is our contention that a number of rigid lenses are not meeting ANSI standards in all parameters. A study by El Hage and Bacigalupi which appeared in Contact Lens Spectrum during the onset of our study, further supports our hypothesis. The authors verified four rigid gas permeable lenses utilizing a computerized corneal topographer. They found that in all four lenses, one or more parameters varied from that which was ordered.

Although advancements have been made in the production of rigid gas permeable contact lenses by means of computer lathing, some parameters are sometimes hand-manufactured, such as blending and edging. This allows for error and may contribute to the lenses being out of ANSI standards. We set out to support our theory by verifying one hundred rigid gas permeable lenses.

**METHODS**

One hundred rigid gas permeable (RGP) contact lenses were verified and compared to ANSI standards. The lenses used in this study were those ordered for patients at Pacific University College of Optometry Clinics in Forest Grove and Portland, OR. The lenses were obtained from four reputable labs, although our data does not differentiate between these labs. The following parameters were verified: Back vertex power; base curve (BC); center thickness (CT); optic zone (OZ); overall diameter (OAD); edge shape; and, peripheral curve widths (PC).
Overall diameter and optic zone were measured using a 7x PEAK scale lupe, no. 1975. Peripheral curve widths and edge shape were verified using an American Optical dissecting scope, model 568. Back vertex power was determined using a Bausch and Lomb lensometer. An AO radiuscope, model 11200, was used to measure the RGP’s base curve. Using a Wesley Jessen Neitz-CG, model 671117, we were able to determine center thickness. Photographs were taken using a Nikon FS-2 anterior segment camera. Standard operating procedure was implemented for each piece of equipment by following the instructions given to us by Pacific University faculty in various classes. Results for each parameter were recorded and compared to that ordered to see if it fell within ANSI standards. Initially our results were compared to each other’s as well as checked by our advisor to ensure accuracy and reproducibility.

Peripheral curve radii measurements were attempted by inking a brass spinning tool having the same radius that was ordered by the optometrist. The lens was then spun on the tool, and the line left on the lens was observed using a PEAK scope to determine if the peripheral curve radius matched the radius ordered. Results of our "practice lenses" were variable, so we decided to exclude peripheral curve radius measurements from our thesis.

The technique used to find edge shape and peripheral curve widths relied on direct observation of the lens under magnification, using a dissecting scope. Light reflected by the peripheral curves allowed us to note the number of curves, the width of each curve, as well as the presence and extent of a blend. A full 360 degrees of each lens was observed to determine any variance or irregularity having to do with these curves.
Figure 1 (p. 13), for example, demonstrates a blended tricurve with a sharp inside edge. Each curve is shown by observing a break or width change in the light reflected from the posterior surface of the lens. A sharp, distinct break indicates the absence of a blend, whereas a fuzzy division between curves shows that a blend is present. In this case, the peripheral curve extends to the end of the lens, and leaves no room for a well-rounded or visible edge.

In contrast, notice in Figure 2 (p. 14) that there is a visible inside edge reflex that is absent in Figure 1. The inside edge in Figure 2 would have been considered acceptable in our study.

A very thin and sharp edge is represented in Figure 3 (p. 15). Notice that is very difficult to distinguish between the reflex of the peripheral curve and that of the edge. The other qualities of the lens, however, appear to be acceptable. The lens has three curves of appropriate width, as well as a blend between these curves. This lens would have been deemed out-of-tolerance concerning edge quality.

This technique of lens observation can only tell the characteristics of curves, blends, scratches, and inside edges, therefore, an edge profile must be looked at in order to determine the quality of the whole edge.

Since there are no numerical ANSI standards for edges, a subjective analysis was performed comparing those edges to what we deemed as "properly-constructed" edges. Patrick Caroline, C.O.T., F.C.L.S.A.; Craig Normon, C.O.T., F.C.L.S.A.; and Richard Martin in their article published in the April, 1991 Contact Lens Spectrum suggested that an edge of an RGP should be divided into three sections in order for it to be properly examined. These three sections are: anterior zone, apex, and posterior zone. We agreed with
their work and decided to use this philosophy in examining lens edges in our study.

The illustration in Figure 4 (p. 16) represents a preferred edge profile showing the three zones. This "properly-constructed" edge consists of a well-rounded and well-tapered anterior zone. This portion of the lens comes in contact with the upper lid, and is the main factor in patient comfort. The lens apex is the junction between the anterior and posterior zones, and should also be well-rounded to keep lens awareness to a minimum. The posterior zone is responsible for keeping the edge away from the cornea to allow for acceptable movement and ease in removal. This zone too should be well-rounded, and ideally should have a slight regression.

With the exception of the nick found in the edge of this lens, Figure 5 (p. 17) shows a well-rounded and acceptable profile and shape. This particular lens, however, would have been out-of-tolerance in our study because of the nick.

An example of a thin and sharp edge profile is shown in Figure 6 (p. 18). Notice that the anterior zone and apex are both sharp. This lens would be found out-of-tolerance in our study, because this lens would probably be unhealthy and uncomfortable for the patient. Staining of the cornea would likely occur, as well as an inadequate tear exchange. This lens would have been considered unacceptable in our study.

Thin or sharp edges are not the only undesirable edge shapes. Edges which are too thick, or which are left blunt and not tapered, are also unacceptable. These create excessive lid interaction, and discomfort for the patient. Fortunately, however, edges are among the easiest parameters to alter. Assuming other parameters are within ANSI standards, the lens in Figure 6
could probably be modified to fit the patient well, if the optometrist knows and uses the art of modification.

**RESULTS**

The distributions to follow will give the reader an idea of how well the optical labs in our study design a lens to the specification of the parameters ordered by the optometrist. A number above the dot in each distribution indicates that there were multiple lenses ordered with the same specifications. To determine if a parameter was "over" or "under" that ordered, we used the following strategy: The absolute value of the parameter received was compared to the absolute value of the parameter ordered. If the absolute value of that received was less than that ordered, the parameter was deemed "under".

The ANSI standard for optic zone diameter is ± 0.20 mm, as represented by the lines A and B in Figure 7 (p. 19). Also shown in this figure is that five of the sixty-four experimental lenses failed to meet the ANSI standard requirements.

Figure 8 (p. 20) shows the ANSI standard for back vertex power to be ± 0.12 diopters. At ten diopters, however, the range for ANSI standards increases to ± 0.25 diopters. Nine of the one hundred lenses in this study were out of tolerance, and eight of the nine fell "under" the power ordered (less plus for plus – less minus for minus).

In Figure 9 (p. 21), thirteen of the eighty-eight lenses verified for center thickness fall outside the range of ± 0.02 mm set by ANSI standards, as shown by lines A and B in the distribution. Twelve out of the thirteen lenses are "over" (too thick).
A ± 0.05 mm tolerance given by ANSI standard for overall diameter is represented in Figure 10 (p. 22). Ten of the one hundred experimental lenses fall outside the acceptable range. The distribution of lenses that are "over" and "under" show to be equally distributed.

The ANSI standard for base curve is ± 0.025 mm, represented in Figure 11 (p. 23) as lines A and B of the distribution. Twenty-five of the one hundred lenses verified fall outside ANSI standards for this parameter.

Figure 12 (p. 24) is a composite bar graph showing the percent of lenses out of ANSI standards for each parameter. The following results are shown: OZ -- 7%; POWER -- 9%; OAD -- 10%; CT -- 15%; BC -- 25%; and, PC -- 55%. Forty-four percent of the lenses in our study show to be out of tolerance in edge thickness and/or shape.

**DISCUSSION and CONCLUSION**

For some parameters the number of lenses in the sample varies from one hundred. This is due to some of the lenses having parameters simply ordered as "standard". In some cases, we were not able to determine what "standard" was for a particular lab. There was also a small number of failures to record a given finding, but these could have altered the results by less than one percentage point.

The lenses that fell out of ANSI standards concerning peripheral curves had one or more of the following: curve widths that did not meet standards; a different number of curves than ordered; an oval shape to the curves; and, in
some lenses the peripheral curve only present on a portion of the lens circumference.

During the verification process, the lens orders were not reviewed to see if the center thickness ordered was feasible when combined with the other specified parameters. If an unrealistic center thickness was ordered, the lab would have been unable to manufacture the lens as specified. Our data would perhaps show that lens as being out-of-tolerance, when in fact, it was not the lab's problem, but rather the designer's error. The same holds true for peripheral curves. The effect this may have on our findings is limited, however, as the majority of the lenses were ordered as "standard".

An RGP's parameters, especially center thickness, can influence the final outcome of the edge. For example, if an intern ordered a plus lens with a thin center thickness and a large overall diameter, we would expect the outcome to be that of a lens having a thin edge. In our study, however, RGP edges were judged independent of other parameters. Therefore, if a doctor ordered an improper combination of parameters, this could have resulted in an unacceptable edge. This edge would have been considered out-of-tolerance in our study, even though it was the doctor's error in lens design, rather than the lab involved. This could possibly overestimate the number of "out-of-tolerance" edges in our findings.

From our results it is obvious that, as we predicted, a number of rigid lenses were out of ANSI standards. This appears to be even more common with those parameters where hand technology is sometimes utilized, such as peripheral curves and edges. However, even those parameters which are computer-generated show need for improvement. This trend may change in the
future with the advent of technology that will precisely make a lens to more exactly match the parameters ordered.

Since there is a chance the lab will manufacture a lens that is out of ANSI standards on one parameter or another, it is important that the optometrist verify the lenses returning from the lab. It is also pertinent that the optometrist know the art of modifying the parameters of a rigid gas permeable contact lens, and utilize this knowledge to custom fit the lens to the patient's cornea. This includes the knowledge of which parameters can be modified and to what degree. For example, if a lens is verified as having too much much plus power then minus power can be added via modification. The amount of minus which can be increased depends upon the other lens parameters. Although modification has its limitations, this skill will help ensure the proper fit of lenses, allowing for healthy and satisfied patients.
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REFERENCES


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