

Pacific University

CommonKnowledge

College of Optometry

Theses, Dissertations and Capstone Projects

5-1999

Sagittal depth of the more common disposable and daily wear soft contact lenses

John W. Ellison
Pacific University

Recommended Citation

Ellison, John W., "Sagittal depth of the more common disposable and daily wear soft contact lenses" (1999). *College of Optometry*. 1275.
<https://commons.pacificu.edu/opt/1275>

This Thesis is brought to you for free and open access by the Theses, Dissertations and Capstone Projects at CommonKnowledge. It has been accepted for inclusion in College of Optometry by an authorized administrator of CommonKnowledge. For more information, please contact CommonKnowledge@pacificu.edu.

Sagittal depth of the more common disposable and daily wear soft contact lenses

Abstract

Inaccurate soft contact lens parameters can create a variety of problems for the practitioner and patient. Most soft contact lenses are dispensed to the patient without the benefit of verification. Of particular importance, sagittal depth best predicts tightness or looseness of fit. A tight or loose fitting lens can cause many problems for the patient. Manufacturer-published values of sagittal depth may vary from the actual measured parameter. Sagittal depth, diameter, and power of 215 soft contact lenses were measured for 11 of the more common disposable/daily wear brands. Measurements were made with a prototype of the Hydroscope™ contact lens analyzing device. Tables and graphs are included which can aid the practitioner in fitting these lenses. The effect of eye temperature, approximately 93°F, versus room temperature was analyzed. No significant change in the measured parameters was noted.

Degree Type

Thesis

Degree Name

Master of Science in Vision Science

Committee Chair

Patrick J. Caroline

Subject Categories

Optometry

Copyright and terms of use

If you have downloaded this document directly from the web or from CommonKnowledge, see the "Rights" section on the previous page for the terms of use.

If you have received this document through an interlibrary loan/document delivery service, the following terms of use apply:

Copyright in this work is held by the author(s). You may download or print any portion of this document for personal use only, or for any use that is allowed by fair use (Title 17, §107 U.S.C.). Except for personal or fair use, you or your borrowing library may not reproduce, remix, republish, post, transmit, or distribute this document, or any portion thereof, without the permission of the copyright owner. [Note: If this document is licensed under a Creative Commons license (see "Rights" on the previous page) which allows broader usage rights, your use is governed by the terms of that license.]

Inquiries regarding further use of these materials should be addressed to: CommonKnowledge Rights, Pacific University Library, 2043 College Way, Forest Grove, OR 97116, (503) 352-7209. Email inquiries may be directed to: copyright@pacificu.edu

SAGITTAL DEPTH OF THE MORE COMMON DISPOSABLE AND DAILY WEAR
SOFT CONTACT LENSES

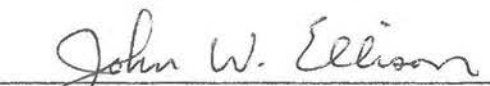
By

JOHN W. ELLISON

A thesis submitted to the faculty of the
College of Optometry
Pacific University
Forest Grove, Oregon
for the degree of
Doctor of Optometry
May, 1999

Adviser: Patrick J. Caroline, FAAO, COT

PACIFIC UNIVERSITY LIBRARY
FOREST GROVE, OREGON



John W. Ellison



Patrick J. Caroline, FAAO, COT

Biographical Sketch
John W. Ellison

John W. Ellison is a Senior Optometry student at Pacific University, Forest Grove, Oregon. He received the Bachelor of Science degree in Geology from Wichita State University in 1975, Master of Arts in geology from University of Missouri-Columbia in 1977, and Masters in Telecommunications from the University of Denver in 1991. He worked as a petroleum geologist for 18 years and also briefly taught geology at the community college level.

Mr. Ellison has been an active member of Amigos Eyecare, Inc., a humanitarian student organization, since coming to Pacific in 1995, serving on two trips to Mexico. He has also served on the Student Optometric Association Board from 1997-1998 and has been a member of Beta Sigma Kappa International Optometric Honor Fraternity since 1996. The American Foundation for Vision Awareness awarded their annual \$1000 scholarship to him in May 1997.

Abstract

Inaccurate soft contact lens parameters can create a variety of problems for the practitioner and patient. Most soft contact lenses are dispensed to the patient without the benefit of verification. Of particular importance, sagittal depth best predicts tightness or looseness of fit. A tight or loose fitting lens can cause many problems for the patient. Manufacturer-published values of sagittal depth may vary from the actual measured parameter. Sagittal depth, diameter, and power of 215 soft contact lenses were measured for 11 of the more common disposable/daily wear brands. Measurements were made with a prototype of the Hydroscope™ contact lens analyzing device. Tables and graphs are included which can aid the practitioner in fitting these lenses. The effect of eye temperature, approximately 93°F, versus room temperature was analyzed. No significant change in the measured parameters was noted.

Acknowledgments

I wish to thank the late Michael Wodis, OD, Park Ridge, Illinois for loaning and allowing the use of the Hydroscope™ for measurement of the soft contact lenses and for his guidance in the development of this thesis. Thanks also goes to Dr. Bruce Schaalje, Brigham Young University, for his assistance in statistical analysis.

Many thanks goes to Beta Sigma Kappa Honorary Fraternity for the full funding of the purchase of the lenses. I thank Mr. Patrick J. Caroline, FAAO, COT for his direction and many hours of review and discussion.

Finally, I thank my wife, Julia, for putting up with the long hours, lack of sleep, and “donating her husband” for a time to this research effort.

Introduction

Inaccurate soft contact lens parameters can create a variety of problems for the practitioner and patient alike. Most notably, sagittal depth (SD), best predicts the tightness or looseness of a lens.

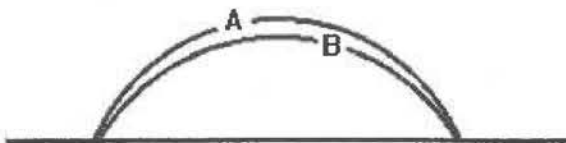
The sagittal depth of a lens is the perpendicular distance between the center of the back curve and the chord length of the lens (see Figure 1). The relationship of the sagittal depth of the lens and the sagittal depth of the anterior segment of the eye (often called ocular sagittal height) upon which it is placed is an important factor in determining the fit (positioning and movement) of the lens¹. A change in the design of the lens must be made to change the fit. Those parameters most often changed to effect a better fit are base curve (back optic zone radius) and/or diameter. A steeper base curve, larger diameter, or combination of both will increase the SD of the lens. Center thickness and to some extent water content affects the flexibility of the lens but not the SD as defined here.

Full SD is the dimension most important in determining soft contact lens fit. Lenses with greater SD values fit tighter than those with a lesser value. Tight fitting lenses can cause poor vision, discomfort, and scleral compression, as well as corneal changes such as edema, striae, and neovascularization. Loose fitting lenses can produce discomfort, variable visual acuity, poor corneal coverage, and excessive lens movement². At least one study³ found that changing the back optic zone radius (8.2, 8.6, 9.0 mm) alone on 35 subjects showed no significant difference in tightness as assessed by the push-up test. The flatter radius showed slightly more post blink movement than the other two but, again, the difference was not significant.

The parameters of a contact lens govern the squeeze pressure that develops beneath the lens during wear and that, in turn is related to the lens' clinical fit. The main variable that affects the lens squeeze pressure, and therefore lens fit, is the lens SD⁴. Soft contact lens fitting can be thought of as a process of selecting the best lens SD for a given eye by choosing the best total diameter and base curve. The sagittal height (SH) of the anterior eye corresponding to the typical soft lens diameter is governed not just by the central corneal curvature (K's) but also by the degree of corneal asphericity, the diameter of the cornea, and the curvature of the paralimbal sclera. Frequently, however, the practitioner considers only the central corneal radius as measured by keratometry. This information is for the central 3 mm only of a cornea which is typically 12-13 mm wide.

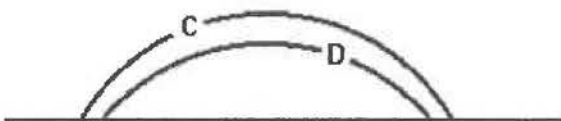
Garner⁵ noted that corneal asphericity has a significant effect on the fit of a soft contact lens. Young⁴ showed that the normal variations in corneal shape factor and corneal diameter each have a greater effect on corneal SH than does the normal variation in corneal curvature. SH varies by 0.187 mm across the central two standard deviations of corneal curvature. Compared with 0.304 mm for similar variation in corneal shape factor, and with 0.414 mm in corneal diameter. So, keratometry alone is a poor predictor of optimum soft contact lens base curve for a given eye. Changes in the sclera are insignificant in comparison with the normal variation in corneal shape. SH is likely to

**Same diameter
Different base curves**



Lens A has a "steep" base curve radius [ex. 8.4mm].
Lens B has a "flat" base curve radius [ex. 8.8mm].
Lens A has a larger sagittal depth and therefore
will fit tighter than Lens B.

**Different diameters
Same base curve**



Lens C has a larger diameter than Lens D.
Because Lens C has a larger sagittal depth
it will fit tighter than Lens D.

Figure 1. Soft lens sagittal depth is determined by base curve radius and diameter

correlate most closely with corneal shape factor rather than with any of the other ocular parameters. Young's study showed that the mean SH of the eye, based on mean corneal diameter (12.89mm), is 3.20 mm. Based on soft contact lens chord diameter of 13.5mm, SH is 3.37mm, 14.0mm is 3.52mm, and 14.5 mm is 3.67 mm.

In 1981, Lowther and Tomlinson⁶ found that the change in lens SD necessary to produce a significant change in lens fit was .20mm, but that, for most of the variables monitored, a change of at least .41mm was required. Their study looked at standard thickness HEMA lenses with center thickness of .11mm. Thinner lenses and lenses of higher water content have a wider critical fitting interval, as shown by the requirement for fewer lens fittings⁴.

Manufacturer values of SD, not always readily available, may vary from the actual measured parameter. The practitioner may be bewildered as to why two different lenses which report all the same parameters fit so differently on the patient's eye. This can be due to significantly different SD values.

Most soft contact lens parameters are not easily measurable in the practitioner's office. The base curve radius of a soft lens is the most difficult parameter to verify. Various instruments have been developed in an attempt to accurately measure the base curve radius; however, the inaccuracy, variability, or high cost of the instrument enables most practitioners to assume the base curve radius on the packaging is correct⁷. Unlike rigid gas permeable lenses, nearly always the doctor dispenses soft lenses without the benefit of verification. The doctor must rely on the manufacturer for quality control of the lenses. Many of the disposable/daily wear lenses are bubble-packed and not intended to be opened until ready for placement on the eye.

The purpose of this study is to develop a table of actual SD measurements and their variation for 11 of the most common soft contact lenses on the market. Such a table would be critical when fitting these lenses. In addition, overall diameter and power of the lenses was measured, as well as the effects of eye temperature (93°F) vs. standard room temperature on the lens parameters.

To date, studies of measured sagittal depth have focused on relatively few brands of soft contact lenses. No study was found which compared measured parameters of several of the leading soft contacts on the market. Wodis, et al.,² measured parameters of 21 Acuvue lens and found the SD's to be very consistent with standard deviation of only 0.02 mm. Four other lens brands tested showed larger variability in SD.

Methods

Soft contact lenses for this study were primarily obtained directly from the manufacturer. The exceptions include Surevue, Optima FW, Soflens66, and FreshLook which were ordered from a local distributor. The 11 brands of lenses, representing 21 different base curves, were drawn from 28 lots (Figure 2.) For some of the smaller sample sizes

Soft Lens (BC)	Mfr Diam	Mfr Power	Mfr CT	Mfr % H2O	Material	FDA Group #	n	# of lots
Acuvue 1-day (8.5)	14.2	-3.00	.07	58	etafilcon A	4	35	2
Acuvue 1-day (9.0)	14.2	-3.00	.07	58	etafilcon A	4	29	1
Acuvue 2-wk (8.4)	14.0	-3.00	.07	58	etafilcon A	4	12	2
Acuvue 2-wk (8.8)	14.0	-3.00	.07	58	etafilcon A	4	12	3
Biomedics 38 (8.6)	14.0	-3.00	.04	38	polymacon	1	6	1
Biomedics 55 (8.6)	14.2	-3.00	.07	55	ocufilcon D	4	6	1
Fresh Look (Median)	14.5	-3.00	.08	55	phemfilcon A	4	12	1
Newvue (8.4)	14.0	-3.00	.06	55	vifilcon A	4	6	1
Newvue (8.8)	14.0	-3.00	.06	55	vifilcon A	4	6	1
Optima FW (8.4)	14.0	-3.00	.035	39	polymacon	1	6	1
Optima FW (8.7)	14.0	-3.00	.035	39	polymacon	1	6	1
Optima FW (9.0)	14.0	-3.00	.035	39	polymacon	1	6	1
Preference (8.4)	14.4	-3.00	.07	43	tetrafilcon A	1	9	3
Preference (8.7)	14.4	-3.00	.07	43	tetrafilcon A	1	10	2
Proclear (8.2)	14.2	-3.00	.07	59	omafilcon A	2	6	1
Proclear (8.5)	14.2	-3.00	.07	59	omafilcon A	2	6	1
Proclear (8.8)	14.2	-3.00	.07	59	omafilcon A	2	6	2
Soflens 66 (F/M)	14.2	-3.00	.10	66	alphafilcon A	2	6	1
Soflens 66 (S/M)	14.2	-3.00	.10	66	alphafilcon A	2	6	1
Surevue (8.4)	14.0	-3.00	.105	58	etafilcon A	4	6	1
Surevue (8.8)	14.0	-3.00	.105	58	etafilcon A	4	6	1
n=sample size								

Figure 2. Soft lenses in this study

(smallest sample size is six), only one lot was represented. Ideally, no two contacts would come from the same lot and lots would all be drawn randomly. It is very possible that one or two lots may be bad and may not be representative of the whole. However, we believed that to request that each lens be from a different lot would have required a detailed explanation to the manufacturer. We believed that if the supplier of the lenses knew they were going to be in a study of measured parameters that special care to provide lenses made to specs would taint the samples.

Full sagittal depth and overall diameter was measured using a prototype of the Hydroscope™ (Figure 3). This hydrophilic lens analyzing device was designed by the late Michael Wodis, OD, Park Ridge, Illinois. The Hydroscope is battery operated and measures 8" wide, 10" deep, and 12" high. Parameters are measured with the lens fully hydrated. The lenses were removed from their packaging and placed in Unisol 4 (Alcon Laboratories, Ft. Worth, Texas) buffered saline solution for approximately 15 minutes. Measurements were then taken while the lenses remained submerged in the saline. My evaluation took about two minutes per lens.

The Hydroscope's key component is a lens holder which immerses lenses in saline for measurement. The lower part of the holder is a transparent, variable sized chamber. Other components are two saline tanks, optics for viewing the lens, and calibrated mechanisms for remotely contacting and moving the lens while in the chamber.

To use the Hydroscope, the lens is placed concave side down in the chamber of the lens holder, which is then placed in a small hand held tank containing the saline. The tank and the lens holder is made of transparent plastic. The tank, now containing the lens holder and lens, is placed over the instrument's inspection light. The lens can now be viewed through the holder's built-in magnifier. The chamber size is remotely adjusted to the size of the lens. Care was taken to insure the lens was not inside out and could move freely as it rested gently on the chamber floor. Diameter is then measured from a calibrated scale to an accuracy of 0.1 mm. Diameter was measured only once per lens.

The chamber size adjustment centers the concave down lens over a small opening in the chamber floor. After the diameter is measured the lens holder is then moved to a second tank at the top of the Hydroscope. The full sagittal depth of the lens is then measured by raising a probe through the opening in the chamber floor, until the probe just touches the underneath side of the center of the lens. The height of the probe above the chamber floor represents the full sagittal depth of the lens. Calibration of the probe was done for each new brand of lens using a small plastic platform of know sagittal depth. The maximum calibration adjustment needed was 0.05 mm and many times no adjustment was necessary. Repeated measurements on the same sample lens typically results in a variation of 0.03 mm.

Power was measured last. The soft lens is removed from the Unisol 4 saline and placed between two layers of blotting paper. One finger is used to roll over the top of the lens pressing it gently between the layers once. The lens is removed and placed on the Toriccek



Figure 3. The Hydroscope™ hydrophilic lens analyzing device. The lens holder is to the right of the scope. The soft lens is placed in the holder and submerged in saline in tank #1 (at base of scope) for diameter measurement. The holder is then removed and submerged in tank #2 (at top of scope) for sagittal depth measurement.

lens holder device, also designed by Dr. Wodis. This hand held plastic device holds the lens in place concave side down over an opening. The lens is then easily held on a Bausch and Lomb lensometer for power measurement. Front vertex power was measured on all lenses. Within about 30 seconds after the lens is dried power is measured. With proper dryness, the focusing lines within the lensometer are clear and crisp. Three measurements were taken on each lens and averaged. Variation between measurements was never more than 0.12 D.

Care must be taken to measure power within 30 seconds or so after blotting. If the lens is allowed to dry for several minutes it was found that the power will increase by 0.12 - 0.50 D. A lens measuring -3.00 D could measure up to -3.50 D after drying. If the lens was too wet, good focusing of the lensometer was not possible. A reblotting was done which usually resulted in clear, crisp mires.

Diameter, sagittal depth, and power were measured at room temperature monitored at 70°-72°F. The temperature of the eye is approximately 93°F. To see what effect this higher temperature would have on the lenses 12 Acuvue (2 week) lenses, six at base curve 8.4 and six at 8.8 mm were remeasured at 93°F. Unisol 4 saline was placed in clean glass jars and placed in a water bath over a hot plate. Temperature rise of the saline was carefully monitored and adjusted until a uniform 93°F was obtained for 30 minutes. The Acuvue lenses sat in small glass vials within the Unisol 4 saline for 60 minutes. Enough saline was then withdrawn to fill the small tanks in preparation for measurement. The lens was immediately removed from the vial and placed into the tank of 93°F Unisol for measurement. Both diameter and sagittal depth was measured and recorded within two minutes. Additional saline (at 93°F) was drawn for each additional lens. The drop in temperature while the lens is being measured is believed to be minimal.

Probably the major limitations of this study are two. Samples sizes in most cases are small from a minimum of 6 to a maximum of 30 for any one lens. Secondly, some samples are all from the same lot. Ideally, each lens studied would have a minimum of 30 samples and they would be selected randomly from 30 different lots. Time and budget limitations didn't allow this.

Results

A statistical analysis of sagittal depth, diameter, and power of the 21 soft lenses was conducted. A total of 215 samples were analyzed. In addition, the effects of eye temperature vs. room temperature on the measured parameters were noted on 12 of the samples. The largest sample size for any one lens was 35, for the Acuvue 1-day, base curve 8.5. The 1-day Acuvue with base curve 9.0 had 29 samples. Sample size for all other lenses ranges from 6 to 12 (see Figure 2).

Only the Biomedics 38, Optima FW (formerly Seequence 2) and Preference lenses are considered low water content, 38, 39, and 43% respectively. These lenses are from FDA

group # 1. All other lenses in this study are high water content, 55-66% water, representing FDA groups #'s 2 and 4.

All lenses ordered were labeled power -3.00. Manufacturer's diameter ranged from 14.0 mm to 14.5 mm. Labeled base curves range from 8.2 mm to 9.0 mm. However, the Fresh Look base curve is labeled Median and the Soflens66 comes in F/M (flat/median) and S/M (steep/median). A typical soft lens will come in two or three choices of base curves. Manufacturer's center thickness ranges from a low of 0.035 mm for the Optima FW to a high of 0.105 for the Surevue's. Most of the lenses are labeled 0.06-0.08 for center thickness (see Figure 2).

Statistical Analysis Methods

For sample sizes of 30 or larger we can approximate the population standard deviation σ by s , the sample standard deviation. Then we can use the Central Limit Theorem to find bounds on the error of estimate and confidence intervals for the mean (μ).

Because 21 different lenses were studied it would have been unwieldy to analyze and funds did not permit acquiring 30 samples of each lens. The smallest sample size is six. To avoid the error involved in replacing σ (population standard deviation) by s (sample standard deviation), i.e. approximating σ by s , when the sample size is small (less than 30), it is necessary to use a new variable called Student's t variable. The t variable and its corresponding distribution is called Student's t distribution⁸. Tables are available which give the values of the t variable corresponding to the number of *degrees of freedom*. The number of *degrees of freedom*, $d.f.$, is given by the formula

$$d.f. = n - 1$$

where n is the sample size used. Each choice for $d.f.$ gives a different t distribution. However, for $d.f.$ larger than about 30, the t distribution and the standard normal z distribution are almost the same. The graph of a t distribution is always symmetrical about its mean, which (as for the z distribution) is 0. The main observable difference between a t distribution and the standard normal z distribution is that a t distribution has somewhat thicker tails.

Critical values of t for a c confidence interval can be found in statistics tables. For instance, t , for a 0.95 confidence interval and 5 degrees of freedom is 2.571. The error of estimate, E , of the sample mean for a c confidence interval is given by

$$E = \frac{t \times s}{\sqrt{n}}$$

For example, the Biomedics 38 sample size is 6, therefore df is 5, and t for a confidence level of 0.95 is 2.571. The standard deviation, s , of the sagittal depth of this particular sample is 0.04 mm. The error of estimate of the sample mean is:

$$E = \frac{2.571 \times 0.04}{\sqrt{6}} = 0.04mm$$

For sample sizes between about 6 and 10 the error of estimate turns out to be very near one standard deviation.

In the Biomedics 38 example, the mean sagittal depth from the six samples is 3.74 mm. Combining this with the error of estimate, E , we have a 95% confidence level that the population mean is between 3.70 and 3.78 mm. In other words,

$$\bar{x} - E \leq \mu \leq \bar{x} + E$$

where \bar{x} is the sample mean and μ is the population mean.

One can also calculate the distribution of the population within a 95% prediction interval. The standard error of prediction ($S.E.P.$) is given by:

$$S.E.P. = t \times s \sqrt{1 + \frac{1}{n}}$$

The 95% prediction interval of the sagittal depth is then the mean, \bar{x} , \pm S.E.P. Using the Acuvue 8.8 as an example, the mean sagittal depth is 3.59 mm with S.E.P. of 0.14 mm. Selecting another Acuvue from another lot one can predict at 95% confidence that the sagittal depth will fall between 3.45 mm and 3.73 mm.

Sagittal Depth

Figure 4 shows the mean sagittal depths of the 21 lenses analyzed. Sagittal depth ranges from a low of 3.46 mm for Proclear (8.8 base curve) to a high of 4.35 mm for Soflens66 (S/M base curve). Error of estimates of the mean ranges from 0.01 mm to 0.08 mm. Even considering the largest error of estimate for the smallest sagittal depth, in this case an error of 0.08 mm for the Surevue (8.8 base curve) with a mean depth of 3.50 mm represents only a 2.3% error.

Also displayed is the 95% prediction interval. Prediction intervals range from a low of \pm 0.03 mm for the Newvue 8.8 to \pm 0.22 mm for the Surevue 8.8 and Optima FW 8.4. Figure 5 illustrates the mean sagittal depth and the 95% prediction interval for the 21 soft lenses. They are sorted according to increasing sagittal depth.

Soft Lens (BC)	Mfr	Mfr	n	t	P.I.		Mean	Std Dev	S.E.P. *
	Diam	Power			0.95	High	Low	Sag	Sag
				conf lvl			Depth	Depth	
Proclear (8.8)	14.2	-3.00	6	2.571	3.57	3.35	3.46	0.04	0.11
Surevue (8.8)	14.0	-3.00	6	2.571	3.72	3.28	3.50	0.08	0.22
Acuvue 1-day (9.0)	14.2	-3.00	29	2.048	3.69	3.39	3.54	0.07	0.15
Optima FW (9.0)	14.0	-3.00	6	2.571	3.71	3.43	3.57	0.05	0.14
Acuvue 2-wk (8.8)	14.0	-3.00	12	2.201	3.73	3.45	3.59	0.06	0.14
Newvue (8.8)	14.0	-3.00	6	2.571	3.64	3.58	3.61	0.01	0.03
Proclear (8.5)	14.2	-3.00	6	2.571	3.69	3.57	3.63	0.02	0.06
Biomedics 38 (8.6)	14.0	-3.00	6	2.571	3.85	3.63	3.74	0.04	0.11
Surevue (8.4)	14.0	-3.00	6	2.571	3.93	3.55	3.74	0.07	0.19
Acuvue 2-wk (8.4)	14.0	-3.00	12	2.201	3.86	3.64	3.75	0.05	0.11
Optima FW (8.7)	14.0	-3.00	6	2.571	3.84	3.68	3.76	0.03	0.08
Acuvue 1-day (8.5)	14.2	-3.00	35	2.031	3.93	3.69	3.81	0.06	0.12
Preference (8.7)	14.4	-3.00	10	2.262	3.95	3.71	3.83	0.05	0.12
Proclear (8.2)	14.2	-3.00	6	2.571	4.03	3.65	3.84	0.07	0.19
Biomedics 55 (8.6)	14.2	-3.00	6	2.571	3.97	3.75	3.86	0.04	0.11
Newvue (8.4)	14.0	-3.00	6	2.571	4.00	3.78	3.89	0.04	0.11
Fresh Look (Median)	14.5	-3.00	12	2.201	4.05	3.77	3.91	0.06	0.14
Optima FW (8.4)	14.0	-3.00	6	2.571	4.16	3.72	3.94	0.08	0.22
Preference (8.4)	14.4	-3.00	9	2.306	4.06	3.86	3.96	0.04	0.10
Soflens 66 (F/M)	14.2	-3.00	6	2.571	4.20	3.86	4.03	0.06	0.17
Soflens 66 (S/M)	14.2	-3.00	6	2.571	4.46	4.24	4.35	0.04	0.11
n=sample size									
t=Student's t variable for a 95% prediction interval									
* Standard Error of Prediction. A 95% prediction interval for the sagittal depth is the mean plus or minus the error of prediction.									

Figure 4. Mean sagittal depth and standard error of prediction (95% prediction interval)

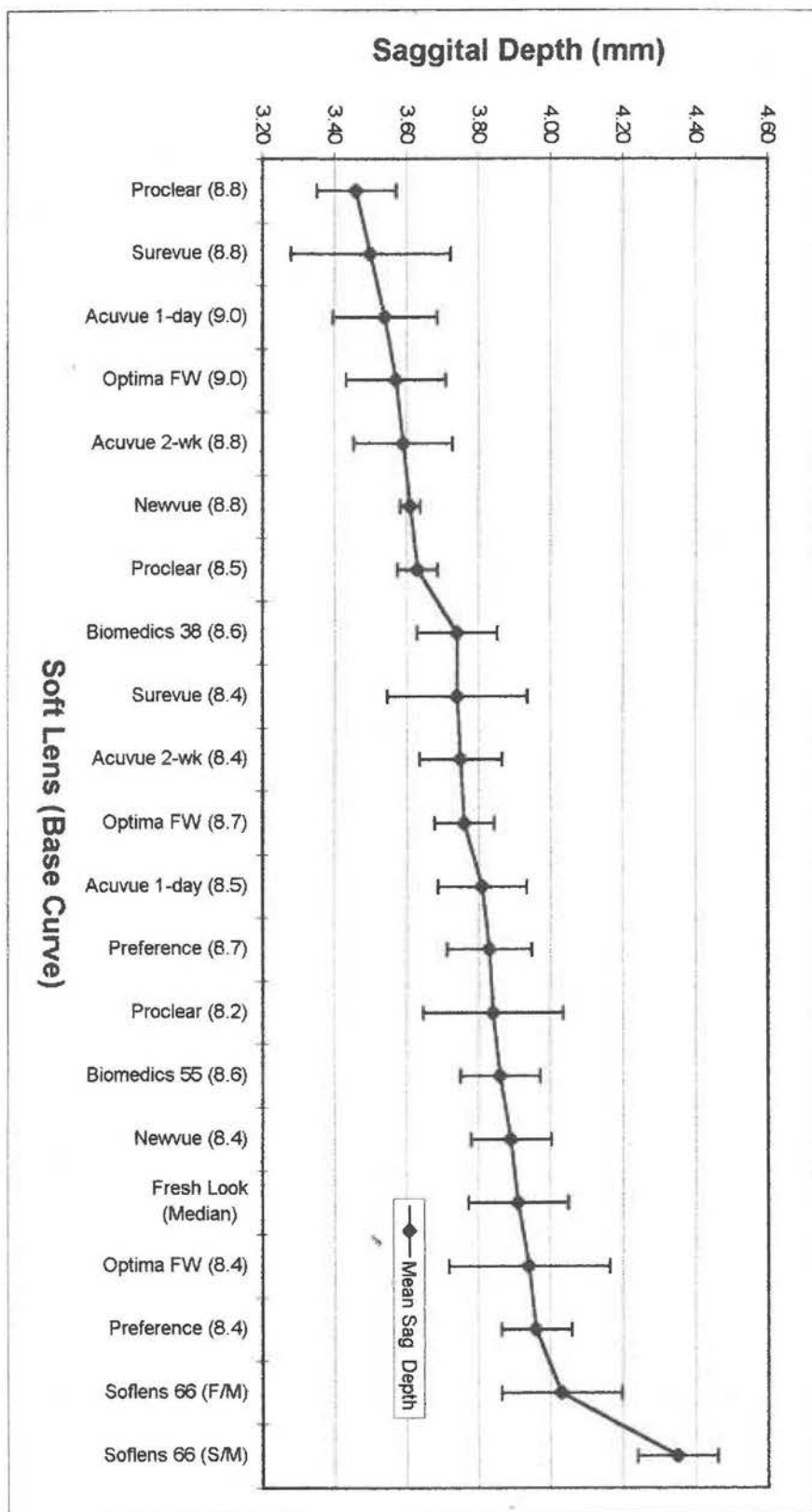


Figure 5. Mean sagittal depth and standard error of prediction (95% prediction interval)

Mean Diameter

Mean diameter of the 21 various soft lenses is shown in Figure 6. The Optima FW (8.7 BC) measured 13.26 mm in diameter on the low end vs. Preference (8.4 BC) which averaged 14.02 mm. Diameter is more difficult to measure with the Hydroscope, and seems to be more sensitive to human error. The largest error of estimate of the mean diameter, as calculated by the t distribution, was on the Proclear (8.5 BC) with error of ± 0.18 mm, 1.3%. Most error of estimates vary less than 1% from the measured mean diameter.

The most significant finding in measuring overall diameter is that nearly every lens measured smaller than the labeling (see Discussion). All means are smaller than manufacturer's reported diameter. Most of the lenses measure a few tenths of millimeters smaller than expected. The exception is the Newvue (8.4) which averaged 13.97 mm vs. the labeled 14.0. The Newvue (8.8), also labeled 14.0, came in second closest to its manufacturer's reported diameter, at 13.82 mm.

Power

Figure 7 illustrates mean power and error of estimate of the mean. All lenses were ordered with a power of -3.00 D. Mean power ranged from -3.23 D (Optima FW 8.4 BC) to -2.87 D (Soflens66 F/M BC). Fourteen of the lenses averaged less than -3.00D, six averaged higher, and one, the Proclear 8.8 BC averaged right at -3.00D. Fifteen of the lenses average within 0.12 D of the manufacturers labeling. The other six lenses are within 0.25 D of -3.00 D.

Effect of Temperature on Diameter and Sagittal Depth

Twelve Acuvue lenses were studied for the effect of temperature on mean diameter and mean sagittal depth. Six Acuvues 8.4 BC and six 8.8 BC were measured as part of this 215 total soft contact lens study. These 12 lenses were then remeasured for diameter and sagittal depth within a saline bath @ 93°F (approximate eye temperature).

Diameter of the 8.4 BC Acuvues averaged 13.53 mm at room temperature vs. 13.58 mm at eye temperature. The error of estimate is 0.10 and 0.12 mm respectively. The 8.8 BC Acuvues measured 13.57 mm vs. 13.58 mm at the higher temperature. Error of estimates are 0.27 and 0.13 mm respectively. Although diameter is slightly larger in both Acuvues the difference is within the error of estimate and is statistically insignificant.

Likewise, sagittal depth averages 3.74 vs. 3.76 mm (room temperature vs. eye temperature) in the 8.4 Acuvues. This .02 mm difference is well within the respective error of estimates of .04 and .05 mm. Sagittal depth averages 3.54 vs. 3.59 mm in the 8.8

Soft Lens	Mfr Diam	Mean Measured Diam	% difference	Std Dev Diam	Error of Estimate of Mean Diam
Acuvue 1-day (8.5)	14.2	13.82	-2.7	0.13	0.05
Acuvue 1-day (9.0)	14.2	13.85	-2.5	0.15	0.06
Acuvue 2-wk (8.4)	14.0	13.51	-3.5	0.12	0.08
Acuvue 2-wk (8.8)	14.0	13.61	-2.8	0.23	0.15
Biomedics 38 (8.6)	14.0	13.48	-3.7	0.04	0.04
Biomedics 55 (8.6)	14.2	13.92	-2.0	0.08	0.08
Fresh Look (Median)	14.5	13.99	-3.5	0.07	0.04
Newvue (8.4)	14.0	13.97	-0.2	0.08	0.08
Newvue (8.8)	14.0	13.82	-1.3	0.10	0.10
Optima FW (8.4)	14.0	13.43	-4.1	0.08	0.08
Optima FW (8.7)	14.0	13.26	-5.3	0.11	0.12
Optima FW (9.0)	14.0	13.35	-4.6	0.05	0.05
Preference (8.4)	14.4	14.02	-2.6	0.04	0.03
Preference (8.7)	14.4	13.90	-3.5	0.08	0.06
Proclear (8.2)	14.2	13.77	-3.0	0.08	0.08
Proclear (8.5)	14.2	13.58	-4.4	0.17	0.18
Proclear (8.8)	14.2	13.50	-4.9	0.00	0.00
Soflens 66 (F/M)	14.2	13.90	-2.1	0.14	0.15
Soflens 66 (S/M)	14.2	13.98	-1.5	0.04	0.04
Surevue (8.4)	14.0	13.67	-2.4	0.12	0.13
Surevue (8.8)	14.0	13.72	-2.0	0.17	0.18
		Average	-3.0		

Figure 6. Mean Diameter, Standard Deviation, and Error of Estimate

Soft Lens	Mfr	Mean	%	Std Dev	Error of
	Power	Measured	difference	Power	Estimate
		Power			of Mean
					Power
Acuvue 1-day (8.5)	-3.00	-3.15	-5.0	0.13	0.05
Acuvue 1-day (9.0)	-3.00	-3.20	-6.7	0.15	0.06
Acuvue 2-wk (8.4)	-3.00	-3.14	-4.7	0.15	0.10
Acuvue 2-wk (8.8)	-3.00	-3.05	-1.7	0.11	0.07
Biomedics 38 (8.6)	-3.00	-3.02	-0.7	0.28	0.29
Biomedics 55 (8.6)	-3.00	-3.02	-0.7	0.05	0.05
Fresh Look (Median)	-3.00	-3.08	-2.7	0.18	0.11
Newvue (8.4)	-3.00	-3.04	-1.3	0.17	0.18
Newvue (8.8)	-3.00	-3.04	-1.3	0.13	0.14
Optima FW (8.4)	-3.00	-3.23	-7.7	0.09	0.09
Optima FW (8.7)	-3.00	-2.98	0.7	0.15	0.16
Optima FW (9.0)	-3.00	-3.02	-0.7	0.09	0.09
Preference (8.4)	-3.00	-2.90	3.3	0.12	0.09
Preference (8.7)	-3.00	-2.87	4.3	0.13	0.09
Proclear (8.2)	-3.00	-3.06	-2.0	0.10	0.10
Proclear (8.5)	-3.00	-3.10	-3.3	0.18	0.19
Proclear (8.8)	-3.00	-3.00	0.0	0.14	0.15
Soflens 66 (F/M)	-3.00	-2.87	4.3	0.11	0.12
Soflens 66 (S/M)	-3.00	-2.89	3.7	0.12	0.13
Surevue (8.4)	-3.00	-2.98	0.7	0.17	0.18
Surevue (8.8)	-3.00	-3.04	-1.3	0.13	0.14

Figure 7. Mean Power, Standard Deviation, and Error of Estimate

Acuvues. This .05 mm greater sagittal depth in the lenses measured at eye temperature is, again, not statistically significant. Errors of estimate are .03 mm and .06 mm respectively.

Discussion

When SD results are sorted from low to high two distinct breaks in the trend occur (see Figure 5). The Proclear (diameter 14.2, BC 8.5) has SD 0.11 mm smaller than the next higher lens, Biomedics 38 (diameter 14.0, BC 8.6). However, the most obvious break in the trend is between the two lenses with the largest SD. Soflens66 (diameter 14.2, BC F/M) has SD of 4.03 mm whereas, BC S/M (also diameter 14.2) has a SD of 4.35 mm. The Soflens66 S/M should fit significantly tighter than any other lens in this study. And possibly even fit noticeably tighter than the next closest lens, its cousin, Soflens66 F/M. The S/M version is 0.32 mm larger in SD than the F/M lens.

Recall that a change in SD of at least 0.20 mm is necessary to produce a significant change in lens fit. Switching to the next steeper or flatter base curve in the same lens will not always result in a SD difference of 0.20 mm. For instance, the Preference 8.4 measures only 0.13 mm larger in SD than the flatter 8.7 lens. Or the SD of the Acuvue 8.4 is only 0.16 mm larger than 8.7 lens.

Figure 8 was designed to be an easy guide for the practitioner to check when needing to change the tightness or looseness of lens fit. This figure shows which lenses should exhibit significant changes in fit based on 0.20 mm and 0.40 mm changes in SD. For instance, if the Acuvue 8.4 is too tight on the patient, switching to the Proclear 8.8 or the Surevue 8.8 should show is more likely to invoke a significant change in fit than just switching to the Acuvue 8.8. And paradoxically, if the Acuvue 8.4 is a little loose fitting, one can switch to the Soflens66 F/M, which has a SD 0.28 mm greater. Recall that the Soflens66, both the F/M and S/M, have the largest SD's of any lenses in this study. For large diameter corneas (>13.0 mm) or very steep corneas, which will usually exhibit large SD's, the lens of choice is either of the Soflens66 base curves or the Preference 8.4.

What if the doctor fits a Proclear (14.2 diameter, BC 8.8), SD 3.46 mm, and finds too much movement in the fit? The obvious solution would be to step up to the Proclear 8.5. However, Figure 8 reveals that this provides only 0.17 mm of additional SD. This change may very well be too small to be significant to the fit. If the practitioner tries the Proclear 8.2, however, at SD of 3.84 mm, a distinct tightening should be evident.

Just how much difference in SD is there between the two base curves of the most popular lens on the market? Acuvue 8.4 shows only 0.16 mm more SD than it's companion, Acuvue 8.8 (both lenses reported as 14.0 diameter). Is this enough to effect a noticeable change in fit?

Lens #	Soft Lens (BC)	Mfr Diam	Mean Sag	Mean Sag Depth	Mean Sag Depth	Mean Sag Depth	Mean Sag Depth
				0.2 mm	0.2 mm	0.4 mm	0.4 mm
			Depth	shallower	deeper	shallower	deeper
1	Acuvue 1-day (8.5)	14.2	3.81	2,4,9,12,17,21	18,19	none	19
2	Acuvue 1-day (9.0)	14.2	3.54	none	1,3,5-8,10,11,13-15,18-20	none	10,13,18,19
3	Acuvue 2-wk (8.4)	14.0	3.75	2,17,21	13,18,19	none	19
4	Acuvue 2-wk (8.8)	14.0	3.59	none	1,6-8,10,13-15,18,19	none	18,19
5	Biomedics 38 (8.6)	14.0	3.74	2,17,21	10,13,18,19	none	19
6	Biomedics 55 (8.6)	14.2	3.86	2,4,9,12,16,17,21	19	17	19
7	Fresh Look (Median)	14.5	3.91	2,4,9,12,16,17,21	19	none	19
8	Newvue (8.4)	14.0	3.89	2,4,9,12,16,17,21	19	17	19
9	Newvue (8.8)	14.0	3.61	none	1,6-8,10,13-15,18,19	none	18,19
10	Optima FW (8.4)	14.0	3.94	2,4,5,9,12,16,17,20,21	19	2,17,21	19
11	Optima FW (8.7)	14.0	3.76	2,17,21	13,18,19	none	19
12	Optima FW (9.0)	14.0	3.57	none	1,6-8,10,13-15,18,19	none	18,19
13	Preference (8.4)	14.4	3.96	2-5,9,11,12,16,17,20,21	19	2,17,21	none
14	Preference (8.7)	14.4	3.83	2,4,9,12,16,17,21	18,19	none	19
15	Proclear (8.2)	14.2	3.84	2,4,9,12,16,17,21	19	none	19
16	Proclear (8.5)	14.2	3.63	none	6-8,10,13-15,18,19	none	18,19
17	Proclear (8.8)	14.2	3.46	none	1,3,5-8,10,11,13-15,18-20	none	6-8,10,13,18,19
18	Soflens66 (F/M)	14.2	4.03	1-5,9,11,12,14,16,17,20,21	19	2,4,9,12,16,17,21	none
19	Soflens66 (S/M)	14.2	4.35	1-18,20,21	none	1-12,14-17,20,21	none
20	Surevue (8.4)	14.0	3.74	2,17,21	10,13,18,19	none	19
21	Surevue (8.8)	14.0	3.50	none	1,3,5-8,10,11,13-15,18-20	none	7,10,13,18,19

Figure 8. Soft lens guide for selecting shallower or deeper sagittal depths

The ever increasingly popular 1-day Acuvue shows a larger difference in SD. The steeper 1-day Acuvue, BC 8.5, is 0.27 mm, larger than the flatter, 9.0 version (both lenses labeled 14.2 diameter).

No surprises in SD were found among any one brand. That is, within any one brand, the smaller base curve radius had a larger SD. The Biomedics 55 with labeled diameter of 14.2 has a SD 0.12 mm greater than the Biomedics 38 with diameter of 14.0, as expected. Both lenses are reported to have BC's of 8.6, but different center thicknesses and water content. These other parameters may well have a larger effect on fit on the eye than the slight difference in SD. The Biomedics 38 being low water, center thickness 0.04 mm, vs. the 55 being high water with thickness of 0.07 mm.

What is not so obvious from manufacturer labeling is differences between brands. For example, Surevue (14.0, 8.8) has a significantly smaller SD than the Optima FW (14.0, 8.7), 3.50 mm vs. 3.76 mm, respectively. This wouldn't be predicted from the reported diameters and base curves. Mathematically, the difference in SD should be only about .06 mm, not the .26 mm measured.

What effect does having small samples of lenses, many times from one lot, have on the results of this study? To test this potential source of error we evaluated the 1-day Acuvue 8.5 and the Acuvue 8.4. The 1-day Acuvue 8.5 samples came in two lots, sample size of 30 and 5. The Acuvue 8.4 also came in two lots, of 6 each. Following are the results:

Soft Lens	Lot #	n	Mean Sag	Std Dev	Error of Estimate
			Depth	Sag Depth	of Mean Sag Depth
1-day Acuvue (8.5)	1351620374	30	3.81	0.06	0.02
1-day Acuvue (8.5)	1050340771	5	3.80	0.03	0.04
Acuvue (8.4)	563607	6	3.78	0.06	0.06
Acuvue (8.4)	421297	6	3.74	0.04	0.04

If all we had were the 5 samples of the 1-day Acuvue we would predict a mean sagittal depth of 3.80 mm with an error of estimate of the mean of 0.04 mm. Measuring the 30 sample lot we find a mean of 3.81 mm, well within the error of estimate calculated. Likewise, the Acuvue 8.4 (lot # 563607) with sample size 6 predicts a mean sagittal depth of 3.78 mm with an error of estimate of 0.06 mm. The second lot, also of size 6, measure 3.74 mm, again within the calculated error of estimate. These examples show that measuring mean sagittal depth from just one lot and calculating errors of estimate is valid using the t distribution as discussed in the statistics section of this study.

It's highly unlikely that all of the 21 various lenses would each average less than the manufacturer's labeled diameter. One would expect a normal distribution about the manufacturer's diameter. This can possibly be explained through the diameter measurement technique. The lens is placed in saline within the lens holder tank. The small

tank is then held at about a 10° angle to the horizontal, down towards the operator, as the centering tabs are remotely operated manually. The centering mechanism slowly closes in around the lens until they just touch the outer edge of the lens. Because of the 10° tilt the lens is resting slightly on the lower side of the centering pieces. This could cause a slight bow in the lens and result in a smaller diameter measured.

It's interesting that the three lenses measuring smallest in diameter are all Optima FW's. This happens to be the lens with the thinnest center thickness, .035 mm as reported by the manufacturer. The next smallest measured average diameter is the Biomedics 38 which is also the next thinnest (center thickness .04 mm). These two brands are both low water (39 and 38%, respectively), FDA Group #1, lenses.

The power of a soft lens is a little more difficult to obtain than with rigid gas permeable lenses. The dryness of the lens must be just right to get a clear focus within the lensometer. Care must be taken to not let the lens dry too much or readings higher in minus will result. Power consistency, as well as consistency in diameter and SD, is important to the practitioner and patient alike. 71% of the lens brands tested measured within .12 D of their -3.00 label (Figure 7). The remainder, 29%, were within .25 D of -3.00. Most patients will not notice a .12 D change in their prescription. Some patients will notice a lens power off by .25 D and, therefore, this group of lenses we find to be insufficient in power accuracy.

Conclusions

Sagittal depth values can aid the practitioner in soft contact lens fitting. Relying on K's alone for selecting a soft lens, although widely practiced, is likely to result in more refits and customer dissatisfaction. Referral to a table of sagittal depth values, such as in this report (Figure 8), may help to explain why certain lenses fit as they do. For large and/or steep corneas, the Soflens66 brand might be fit first to vault the large ocular sagittal height. Both Soflens66 base curves (F/M, S/M) have the largest sagittal depths, 4.0 - 4.4 mm range, in this study of 21 various lenses. Small and/or flat corneas might accept a lens with a relatively small sagittal depth such as the Proclear (8.8), Surevue (8.8), or the 1-day Acuvue (9.0) which range from about 3.45 to 3.55 mm.

Overall diameter, which affects the sagittal depth, was consistently measured smaller than the manufacturer's label. This may be due to the measurement technique or to a possible bias in manufacturing.

Power was found to be consistent. Most brands showed accuracy to within 0.12 D. A rise in temperature to 93°F , reported temperature of the eye, from room temperature was found to have no significant effect on diameter or sagittal depth. It's effect on power was not measured. Clinicians and researchers can measure these two parameters with some confidence knowing that their measurements aren't changing significantly due to temperature while on the eye.

References

1. Spinell, Michael R., A clinical guide to soft contact lenses, 1979 Chilton Book Company, Radnor, Pennsylvania
2. Wodis, Michael, Hodur, Neil, and Jurkus, Janice, Disposable lens safety: The reproducibility factor, Mar/Apr 1990 ICLC, Vol 17,.
3. Young, G., Holden, B., Cooke G., Influence of soft contact lens design on clinical performance, 1993 Optometry and Vision Science, Vol 70, No 5, pp. 394-403.
4. Young, G., Ocular sagittal height and soft contact lens fit, 1992 J. of the British Contact Lens Association, Vol 15, No 1, pp 45-49
5. Garner, LF, Sagittal height of the anterior eye and contact lens fitting, 1982 American Journal of Optometry & Physiological Optics, vol 59, No 4, pp 301-305
6. Lowther, GE, Tomlinson, A, Critical base curve and diameter interval in the fitting of spherical soft contact lenses, 1981 American Journal of Optometry and Physiological Optics, Vol 58, pp 355-360
7. Biddle, SP, Janoff LE. Verification of hydrogel lenses. In: Bennett, ES, Henry, VA, eds. Clinical manual of contact lenses. Philadelphia, PA: J. B. Lippincott Company, 1994, p. 216.
8. Brase, CH, Brase, CP. Understandable statistics, concepts and methods, 4th ed. Toronto: D. C. Heath Company, 1991.