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GP NEWS AND INFORMATION FROM BAUSCH & LOMB

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Virtual Fitting of GP Lenses: A New Frontier

by Alex Cannella, RN, FCLSA

AMONG the reasons practitioners give for not fitting GP lenses is that there are too many variables and the diagnostic fitting process is too time-consuming. And indeed that may be the case if a diagnostic lens does not fit and one or more additional lenses must be tried in order to determine the best fit.

What if the practitioner was free to do the diagnostic fitting at his/her convenience? What if the GP lens diagnostic fitting process did not involve trying various lenses on eyes for evaluation before placing a lens order? What if the patient need not even be present to perform a diagnostic GP lens fitting? What if the best fitting lens could be determined quickly and that order sent electronically to the laboratory? And what if the patient lens received by the practitioner would fit each patient with a degree of accuracy that met or exceeded 90%?

Hard to believe? It's true and it's almost here. Virtual GP lens fitting using topography and a computer software fitting program will allow practitioners to fit a given eye

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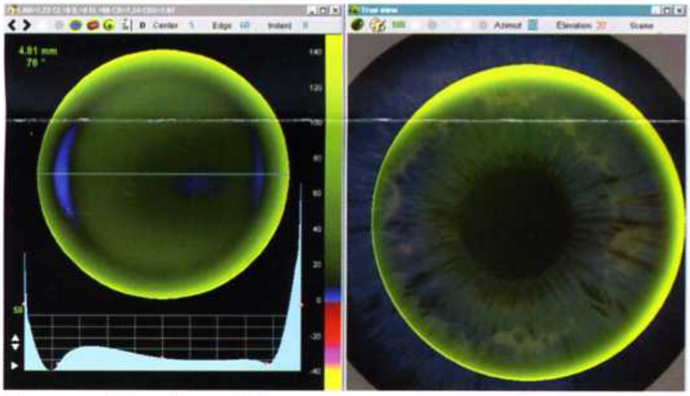

Figure 1a. Virtual lens fitting using simulated fluorescein pattern and on-eye evaluation.

Linking Standards with Product Performance

by Marianne Yarmey, Manager, New Business Technologies, Bausch & Lomb Wilmington

AS THE global marketplace expands, companies understand that conforming to international standards is necessary to improve their competitiveness in the world. Standards that once only defined product specifications are now expanding to focus on product performance. Ideally, GP material standards should allow eye care professionals to easily compare materials currently on the market and choose those most suited for their patient's vision needs. However, due to the variability in measuring these standard parameters, published product specifications can often be misleading. In addition, standards may not always reflect real life performance. In this article, we will explore two common standard parameters for GP materials, oxygen permeability and wetting angle. These standard parameters are often difficult to compare when published by different companies due to the large number of variables that can affect each measurement. In addition, while standard test methods

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DID YOU KNOW?

Did you know that Bausch & Lomb recently introduced its FDA-approved Vision Shaping Treatment™ (VST) system in the U.S.?

Vision Shaping Treatment is an "umbrella" concept for ortho-k fitting using a variety of methods and a series of tested and proven overnight orthokeratology designs.

VST will be distributed in the U.S. only through a select group of Authorized Boston Manufacturers, currently BE Retainer, Contex OK E-System, DreamLens, and Euclid Emerald.

FDA-required Certification Seminars are being held in major U.S. cities. Certification is also available online at: http://www.bausch.com/vst

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for operating oxygen permeability can be indicative of on-eye lens oxygen permeability, standard contact angle bench test methods have not shown high correlation to on-eye lens wettability.

DK MEASUREMENTS

In 1996, ISO established the international standard for measuring oxygen permeability (Dk) of contact lens materials (ISO/DIS 9913-1 *Determination of Oxygen Permeability and Transmissibility by the FATT Method*). This method, developed by Dr. Irving Fatt Ph.D. at the University of California, Berkeley, USA, measures the oxygen permeability of GP lenses under wet conditions and simulates the Dk performance of a lens on the cornea. During the test, a lens is placed on an oxygen probe with the other side of the lens exposed to an oxygen saturated, buffered saline solution. As the probe measures the concentration of oxygen, it depletes the oxygen on the probe side of the lens causing an oxygen differential across the lens (Figure 2). Oxygen will then diffuse from a region of high oxygen concentration through the lens toward the probe side where the oxygen concentration is low. This rate of oxygen flow or Dk can then be calculated through a series of equations. Similarly when a lens is worn on the eye, the cornea depletes the oxygen on one side of the lens causing oxygen to diffuse through the lens towards the cornea to replenish this oxygen. The ability of a lens material to allow oxygen to pass through it is very important to corneal health, closely linking this ISO/Fatt Dk measurement with actual on-eye performance.

Figure 1.
Dr. Irving Fatt PhD, 1920–1996

In 1998, the Contact Lens Manufacturers Association (CLMA) became increasingly concerned that inaccurate permeability measurements were still being reported by manufacturers. They commissioned the Eye Physiology & Ocular Prosthetics Laboratory at the University of Alabama Birmingham to derive the Dk values of contact lens materials marketed in the U.S. by the ISO 9913-1 method. As new GP materials continue to enter the market, the CLMA recommends that manufacturers submit the new material to this laboratory for confirmation of the Dk.

In a recent study using the standard ISO/Fatt Dk method, we measured the permeability of some of our own materials and newer materials from other companies that have recently entered the market. We found some discrepancies between the Dk values that are currently reported in the manufacturers' literature and those that we measured (Table 1). To verify the accuracy of our results, standards were obtained from the Permeability Reference Material Repository (custodian Dr. William J. Benjamin, University of Alabama, Birmingham, Alabama). Measurements carried out by our lab and official repository values are presented in Table 2, showing close agreement. From these findings, we would suggest that our results are closer to the real Dk value of these materials than Dk values currently reported in the literature. This difference in Dk values leads us to the conclusion and recommendation that Dk measurements should be confirmed for all new materials by an impartial recognized laboratory, such as that of the repository lab at he School of Optometry, University of Alabama at Birmingham, through blind submission of the material from an independent source.

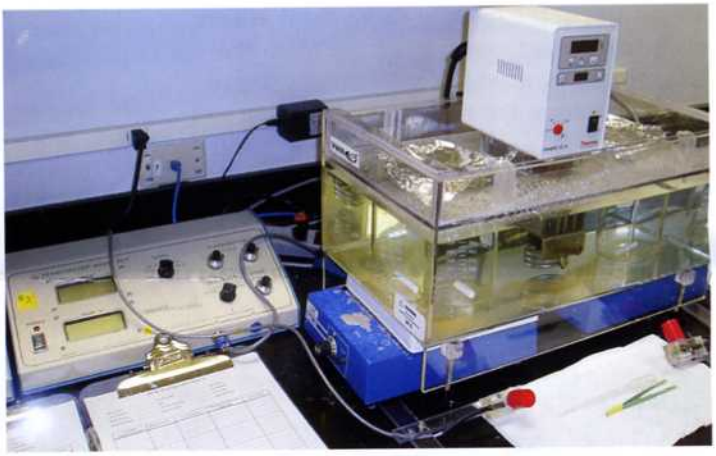


Figure 2. Rehder Polarographic Oxygen Permeability Unit

TABLE 1. OXYGEN PERMEABILITY MEASURED USING ISO/FATT METHOD

Material	Average Dk*	95% Confidence Limits*	Published Values
PARAGON HDS	41	39.4 – 43.1	58*
BOSTON EQUALENS® II	85	76.5 – 93.5	85*
OPTIMUM EXTREME	96	86.2 – 107.9	123.8*
VISTA OPTICS HiRI	9	8.1 – 9.8	50†
ONSI-56	33	30.4 – 34.9	56*

* x $^{10\text{-}11}$ (cm^3 O$_2$) (cm) / [(sec)(cm^2)(mmHg)]
† No units given

CONTACT ANGLE MEASUREMENTS

Contact angle is a measure of the ability of a liquid to wet a solid surface producing a uniform, continuous film. The standard test method for measuring the contact angle of contact lens materials is defined in ANSI Z80.20-1998, Section 8.11. Two techniques are described in this standard, the sessile drop method and the captive bubble method. The sessile drop method measures the angle of

TABLE 2. OXYGEN PERMEABILITIES OF REFERENCE MATERIALS MEASURED BY ISO/FATT METHOD

Material	Dk*	95% Confidence Limits*	Repository Value*†
FLUOROPERM 30	25.8	24.6 – 27.2	26.0
BOSTON® EQUALENS I	47.0	43.1 – 57.1	51.2
MENICON EX	57.3	52.2 – 63.5	62.4

* x 10^{-11} (cm^3 O_2) (cm) / [(sec)(cm^2)(mmHg)]

† Repository values were complied from the measurements at four different laboratories. Individual labs values were within 8.8% of the above repository values.

contact between a liquid and solid when a drop of standard saline solution is placed on a flat polymer surface in air. The captive bubble method measures the angle of contact between a gas bubble and a polymer surface when a bubble of air floats up against the underside of a flat polymer surface in standard saline solution (Figure 3). The CLMA has adopted this method as their standard for determining wetting angles on GP materials. Due to the wide number of variables that can influence wetting angle measurements, the ANSI standard clearly defines the sample preparation, sample conditioning, experimental apparatus, and environmental conditions under which these tests must be run. In a recent study, we measured the wetting angle of some our own materials and materials from other manufacturers by the captive bubble method. All materials were cleaned with Boston Laboratory Lens Cleanser and rinsed with distilled water. Boston GP materials were then cleaned with Boston Advance Cleaner, rinsed with water, and soaked in Boston Advance Comfort Formula Conditioning solution for 7 days. Contamac Optimum GP materials were cleaned in Optimum by Lobob Cleaning/Disinfecting/Storage Solution and then soaked in this solution for 7 days. All materials were rinsed with distilled water before making captive bubble measurements in phosphate buffered saline solution (PBS). Table 3 shows the contact angle values and different methods published for several GP materials of different manufacturers. A more dynamic method of measuring contact angle is the Wilhelmy plate method where wetting angles are not measured directly, but are calculated from force measurements as a function of immersion depth of the lens material in saline solution (Figure 3).

TABLE 3. CONTACT ANGLE RESULTS FOR GP MATERIALS USING VARIOUS TECHNIQUES

Material	Contact Angle	
BOSTON® EQUALENS II	🟨 30°	
BOSTON® EO	🟨 49°	
BOSTON® XO	🟨 49°	
PARAGON HDS	🟧 14.7° (receding angle)	
PARAGON HDS 100	🟧 42° (receding angle)	
OPTIMUM COMFORT	🟧 6°	🟨 60°
OPTIMUM EXTREME	🟧 6°	🟨 66°
MENICON Z	🟩 24° (after soaking)	
VISTA OPTICS HiRI	🟩 <25°	

🟨 Captive Bubble, ISO/ANSI 🟧 Receding angle 🟩 Not specified

It is our opinion that, due to the dynamic nature of the Wilhelmy plate method, two contact angles, an advancing and a receding angle, for a single lens material can be easily measured. The difference between these two angles is called the contact angle hysteresis. Both angles are needed to completely describe the wetting properties dynamically.

We investigated the dynamic advancing and receding contact angles of these same GP materials using a Cahn Dynamic Contact Angle (DCA) Analyzer DC315. The motor speed was set to 100 microns/sec. The immersion depth for all samples was 6 mm. Samples were cleaned and conditioned prior to the contact angle measurements. All measurements were done in PBS (phosphate buffered saline solution). The results of this study are shown in Graphs 1 and 2. Only small differences were observed in contact angle measurements when comparing the various GP materials. The biggest difference in contact angle measurements was observed when comparing care solutions. The samples soaked in Boston Advance Conditioning Solution demonstrated lower advancing contact angles and hysteresis values than the Optimum care solutions and the PBS.

A word of caution must be raised when attempting to use these contact angle results to predict actual on-eye wetting characteristic of a GP lens. Although we feel that the DCA method is a more accurate way of

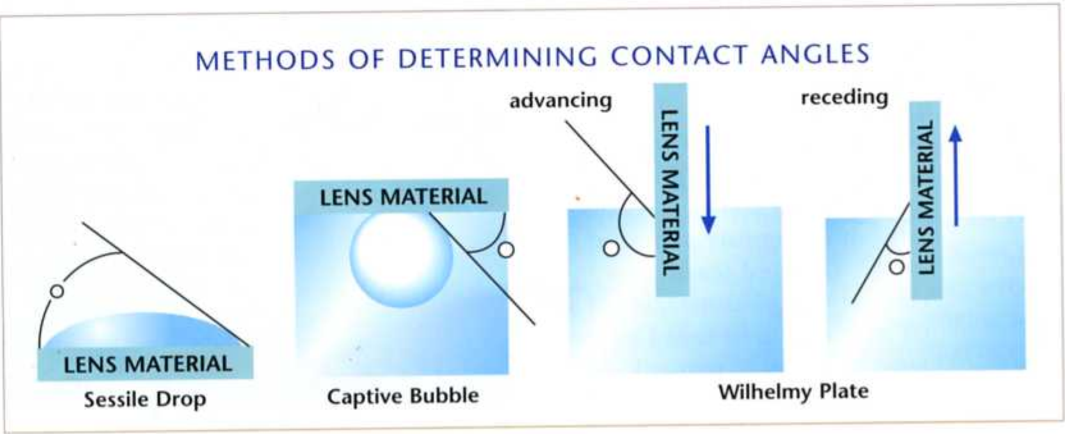
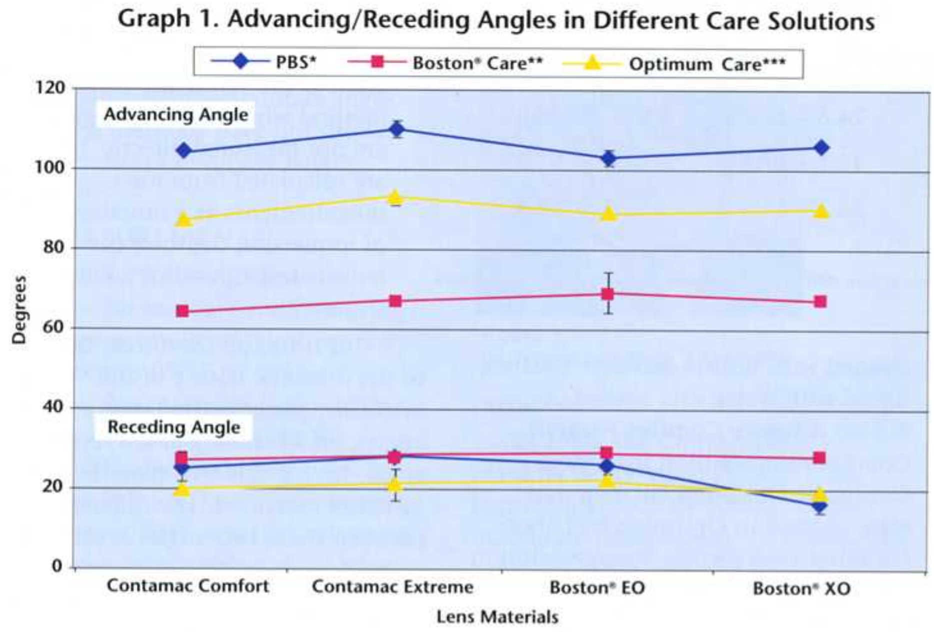

METHODS OF DETERMINING CONTACT ANGLES

Figure 3



* Samples were cleaned with Boston® Laboratory Lens Cleanser, rinsed with distilled water, and then soaked for 7 days in Phosphate Buffered Saline.

** Samples were cleaned with Boston Laboratory Lens Cleanser, rinsed with distilled water, cleaned with Boston ADVANCE Cleaner, rinsed with distilled water, soaked in Boston Advance® Comfort Formula Conditioning Solution for 7 days.

*** Samples were cleaned with Boston Laboratory Lens Cleanser, rinsed with water, cleaned with Optimum by Lobob Cleaning/Disinfecting/Storage Solution (C/D/S), rinsed with water, soaked in Optimum C/D/S for 7 days, rinsed with distilled water, placed in Optimum by Lobob Wetting/Rewetting Drop and in-the-eye lubricant for 20 minutes.

Graph 1. Advancing and receding contact angles measured for various GP materials soaked in different care solutions. All samples were first cleaned with Boston Laboratory Lens Cleanser and rinsed with water. The samples were then cleaned using the appropriate cleaner and were placed in separate vials to soak in the appropriate conditioning solution for seven days. Just prior to testing each wafer was removed from solution and rinsed by dipping it 10 times into 15 ml of PBS. All dynamic contact angle measurements were made in PBS.

measuring contact angle, none of these techniques provide results that correlate well with on-eye wetting of GP lenses. For example, although most GP contact lens materials have a lower wetting angle than PMMA, most clinicians would agree that PMMA has probably the best on-eye wetting properties for a rigid contact lens material. This is due to the fact that a drop of conditioning solution applied to a lens is quickly replaced by tear fluid upon insertion of the lens in the eye. Tear fluid contains proteins and lipids that greatly affect the wetting characteristic of a lens. Tear components can vary significantly from person to person and therefore, it is difficult to develop a laboratory standard that accurately predicts on-eye wetting performance.

CONCLUSIONS

Ideally, the eye care professional should be able to compare and choose the most appropriate GP material when fitting a patient with contact lenses using the data from the material properties reported by the manufacturer. For example, oxygen permeability is a key indicator in determining product performance for particular applications such as Extended Wear and Overnight Ortho-K/corneal reshaping. However, due to the variability, it is often difficult to compare published Dk values. The need remains for the permeability measurements of all GP materials to be tested by the same impartial recognized laboratory so that this parameter can be compared on an equal basis.

On-eye wetting characteristics of a GP material are also very important to the eye care professional in choosing a GP material. Unfortunately, although the captive bubble method for determining contact angle has become the industry standard, it is not indicative of real life performance. Other methods for measuring contact angle, perhaps more accurate than captive bubble, also do not reliably predict on-eye wetting. The need still exists for a standard test method that directly correlates material surface properties with on-eye wetting performance.

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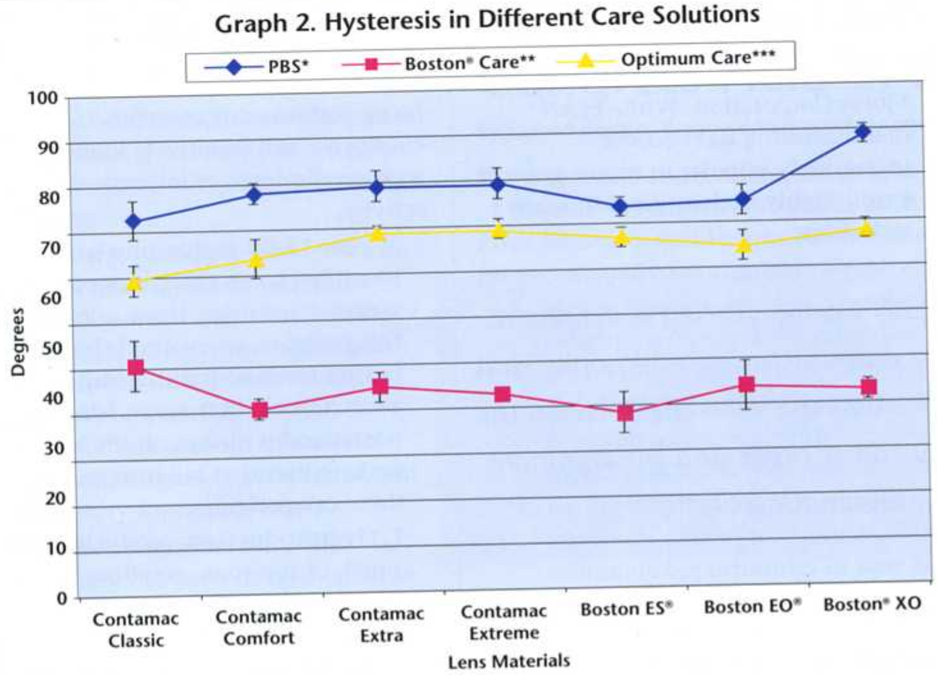
Figure 4. Cahn Dynamic Contact Angle Analyzer DC315


Graph 2. Hysteresis in Different Care Solutions

* Samples were cleaned with Boston® Laboratory Lens Cleanser, rinsed with distilled water, and then soaked for 7 days in Phosphate Buffered Saline.

** Samples were cleaned with Boston Laboratory Lens Cleanser, rinsed with distilled water, cleaned with Boston ADVANCE Cleaner, rinsed with distilled water, soaked in Boston Advance® Comfort Formula Conditioning Solution for 7 days.

*** Samples were cleaned with Boston Laboratory Lens Cleanser, rinsed with water, cleaned with Optimum by Lobob Cleaning/Disinfecting/Storage Solution (C/D/S), rinsed with water, soaked in Optimum C/D/S for 7 days, rinsed with distilled water, placed in Optimum by Lobob Wetting/Rewetting Drop and in-the-eye lubricant for 20 minutes.

Graph 2. Contact angle hysteresis was obtained by subtracting the receding contact angle from the advancing contact angle for each GP material. Lower hysteresis values correlate with better wetting properties under the conditions of the study.

Spotlight on Jim Lunkley

Editor's note: Jim Lunkley is Boston's Technical Field Representative, based in Fountain Hills, Arizona, who travels around the globe to assist and advise customers.

Would you tell our readers briefly about your background, education, job experience, and positions held?

After graduating from college in the early 1970s, my wife and I moved to Phoenix. I worked for a motorcycle rental business for a few months and then purchased the business. This business happened to be located in the same building as Guaranteed Contact Lens, the developers of the Polycon GP material. By the late 1970s, I was out of the motorcycle business and was contacted by Syntex Ophthalmics, the company that purchased Polycon from Guaranteed Contact Lens, and asked if I would consider working for them. Starting in 1978, I worked for Syntex as a Process Engineer and Production Manager until 1989 when I moved to my present position.

How do you see the GP industry evolving from a technical perspective over the next 5 to 10 years?

I think the GP industry will become an industry of specialty products. This will mean that it will become increasingly important for GP manufacturers to implement equipment and processes that can accurately and consistently produce and evaluate the more complicated designs.

Tell us little about your family, your hobbies, and what you like to do in your free time.

My wife and I met in high school and got married when we were in college. We have been happily married for 36 years. In my spare time I like to get on my motorcycle and ride. I also like to do some woodworking and landscape oil painting.

What part of your job gives you the most personal satisfaction?

I find it very satisfying to meet and work with our customers on a one-to-one basis. I especially enjoy helping them solve problems and improve their manufacturing systems.

What do you find most challenging about your work?

The amount of travel I do can sometimes be challenging. Working with people new to the industry is also quite challenging because there are many terms and processes unique to this industry. This can also lead to some of the most rewarding experiences.