The Science Behind ACUVUE® OASYS® Brand Contact Lenses

(senofilcon A)

New Research on Lens Performance

Part 2 of 2

REVIEW OF OPTOMETRY

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VISTAKON®

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The content of this supplement was developed by the *Review of Optometry* staff in consultation with, and with funding provided by, Johnson & Johnson Vision Care, Inc., the makers of ACUVUE® OASYS® Brand Contact Lenses.

INTRODUCTORY REMARKS

Dear Colleagues,

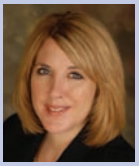
We're excited to share with you the latest research on lens performance and, specifically, a little of the history and science behind ACUVUE® OASYS® Brand Contact Lenses (senofilcon A). For well over two decades, VISTAKON®, Division of Johnson & Johnson Vision Care, Inc. has been associated with excellence and leadership in contact lenses. Our goal has been to work closely with the professional community to meet your needs and exceed the expectations of your patients.

ACUVUE® OASYS® Brand is the most prescribed contact lens in the world today and one of the latest in the evolution of cutting edge technologies that VISTAKON® has brought to the market. The ACUVUE® OASYS® lens is a clear reflection of our dedication to innovation and to promoting the health of the millions of patients whose lives we together touch each year. Our patients are better for the wonderful partnership that exists between VISTAKON® and eyecare professionals throughout the world.

This supplement brings some of the brightest minds in the contact lens field together to discuss several pressing issues of the day. It is intended to serve as an open forum for honest feedback and ideas from practicing clinicians and educators. We share this with you and welcome your feedback by phone (800) 876-6644 or via e-mail at pa@its.jnj.com.

It is our sincere hope that the insights shared in this publication will provide knowledge and understanding to help manage the challenges of compliance, highlight optimal wearing schedule, and maximize contact lens performance and comfort. We are committed to working together to achieve the best possible outcomes for patients.

Colleen M. Riley, OD, MS, FAAO
Vice President of Professional Development & Medical Affairs



Colleen M. Riley, OD, MS, FAAO is Vice President, Professional Development and Medical Affairs at VISTAKON®, Division of Johnson & Johnson Vision Care, Inc. Dr. Riley joined VISTAKON® in 2004, in the Research & Development group and was responsible for leading the development of innovative products, such as ACUVUE® OASYS® Brand Contact Lenses for ASTIGMATISM. Prior to 2004, Dr. Riley was in practice and a faculty member at Indiana University.

Dr. Riley received her Doctor of Optometry degree and her Master of Science in Physiological Optics from Indiana University School of Optometry. She is a Fellow and Contact Lens Diplomate in the AOA's Section on Cornea, Contact Lenses and Refractive Technologies and was recently named one of the top 20 Most Influential Women in the Optical Industry. An accomplished speaker and author, Dr. Riley also served as a Principal Investigator in the NEI-funded Collaborative Longitudinal Evaluation of Keratoconus Study.

Senofilcon A: A History of Success in Challenging Eyes and Environments

Robin L. Chalmers, OD, FAAO, FBCLA, and Colleen M. Riley, OD, MS, FAAO

In 2006 and 2007, together with our colleagues, we published several reports from a large study of soft contact lens wearers demonstrating the effects of refitting with senofilcon A daily wear silicone hydrogel lenses.

In the first of these reports, we estimated the prevalence of ocular surface symptoms and signs that compromise successful contact lens wear.[1] We found that a surprisingly high proportion of existing hydrogel contact lens wearers (ages 18-39 years) were only marginally successful with their contact lenses. Of 1,092 subjects enrolled in the multi-center study, more than half (52% or 564) were considered problem wearers because they met at least one of six qualifying criteria. The problem wearers were more likely to be female (75%) than those in the problem-free group (64%).

Qualifying criteria for problem wearer status included at least two hours of uncomfortable wear (determined by the difference between average wear time and comfortable wear time); frequent or constant discomfort; frequent or constant dryness symptoms; at least Grade 2 limbal or bulbar hyperemia, or at least Grade 3 corneal staining. One-quarter of the qualifying subjects met three or more of the criteria.

After refitting 112 of the problem wearers in senofilcon A daily wear silicone hydrogel lenses, success with lenses improved considerably. In fact, 75% had less dryness; 88% had better comfort ($p<0.0001$ each); and 76% had fewer uncomfortable hours of wear ($p=0.004$). Although the average wearing time was unchanged, comfortable wearing time increased significantly (10.4 to 11.6 hours) ($p=0.004$). All (35 of 35) eyes with qualifying limbal hyperemia before the refit improved ($p<0.0001$), as did 80% (40 of 50) of those with bulbar hyperemia ($p<0.0001$) and 76% (26 of 34) of those with corneal staining ($p=0.005$).

Most of the problem wearers (54%) were problem-free after 2 weeks in the senofilcon A lenses. Those who continued to experience problems most commonly continued to have reduced comfortable wear time, although their mean comfortable wear time increased significantly with the new lenses.

Prescribing of silicone hydrogel lenses has more than doubled since 2005. (Source: HPR Data, 2005-2009, Monthly Dispense Share)

Subjects did not know what lens type they were wearing nor the identity of the study sponsor. Clinical investigators were masked to the sponsor but not the lens type. All subjects used their habitual lens care system unless advised by the investigator to change to an alternative.

This study demonstrated that comfort was not optimized in many hydrogel lens wearers and that refitting with a new-generation silicone hydrogel lens, ACUVUE® OASYS® Brand Contact Lenses, could alleviate common problems associated with hydrogel lens wear.

ACUVUE® OASYS® BRAND IN CHALLENGING ENVIRONMENTS

In another arm of this study, we queried contact lens wearers' comfort in challenging environments.[2] Patients were asked to rate how frequently they wore contact lenses in challenging environments such as airplane travel, dusty, polluted or smoky environments, high altitudes, while napping, and while driving in a car with heat or A/C vents blowing. They were then asked to subjectively rate their comfort in such situations, at the baseline visit with their habitual lenses and then again 2 weeks after refitting with silicone hydrogel lenses.

In this study, baseline data were collected from 496 hydrogel soft lens wearers. Comfort responses were compared for subjects who "always" or "frequently" used lenses in the specified challenging environments. Patients were re-fit with senofilcon A (ACUVUE® OASYS®, VISTAKON®), galyfilcon A (ACUVUE® ADVANCE®, VISTAKON®), or lotrafilcon B (O2Optix, CIBA VISION®) lenses.

Exposure to challenging environments in everyday life was common. Over 90% reported wearing their lenses while driving at night, 89% while using a computer, 87% in a heated or

air-conditioned car, and 79% while sitting under an air vent in a building.

Among the patients re-fit in senofilcon A lenses (n=228), comfort in all 12 challenging environmental situations improved after 2 weeks of wearing the senofilcon A lenses. This study showed that hydrogel lens wearers tolerated significant discomfort in challenging environments because they needed to continue wearing lenses in those situations. However, with more comfortable silicone hydrogel lenses, their discomfort decreased and in some cases went away entirely.

Silicone hydrogel lenses can help improve patients' comfort while wearing lenses in activities that are challenging for lens wear but are a normal part of their jobs and daily life experience.

ACUVUE® OASYS® BRAND IN CONTROLLED ADVERSE ENVIRONMENTS

Another study of senofilcon A lens performance in controlled adverse environments was conducted by Ousler and colleagues and published in 2008.[3]

In this laboratory based, double-masked, randomized, crossover trial, 11 subjects underwent three 75-minute exposures to a controlled adverse environment (CAE) over the course of three visits, one without lenses, one with senofilcon A (ACUVUE® OASYS®) lenses, and another with a new pair of their habitual contact lenses. All subjects experienced the CAE exposure without lenses at the first visit, and then were randomized in the order of either the senofilcon A or habitual lenses for the second and final CAE exposures. The CAE model has been used in many dry eye studies to exacerbate symptoms in a repeatable, controlled manner. It is sometimes referred to as a "provocative test" for contact lenses because the tightly controlled humidity, temperature, lighting, airflow, and visual tasking are very challenging for contact lens wearers.

More than 60% of new prescriptions in the U.S. are for 2-week lenses. Of those, ACUVUE® OASYS® Brand Contact Lenses with HYDRACLEAR® Plus is the No. 1 silicone hydrogel lens on the market. (Source: HPR Data, 2007-2009, Quarterly Dispense Share)

Before the second and third visits, subjects were required to refrain from contact lens wear for 72 hours and from using any artificial tears for 12 hours. At each visit, subjects reported their level of discomfort during the 75-minute CAE exposure on a scale of zero (none) to 4 (worst). Slit lamp biomicroscopy, tear film break-up testing, corneal and conjunctival staining, and evaluation of the tear meniscus and conjunctivae were also performed at each visit.

All patients reported that discomfort increased as CAE exposure time increased, which demonstrates responsiveness to the challenge. Subjects reported lower mean discomfort across all time points during CAE exposure while wearing senofilcon A lenses (1.62 ± 0.71 points) than while wearing their habitual contact lenses (2.21 ± 0.80 points, p=0.0068). Interestingly, subjects also reported lower mean discomfort with the senofilcon lenses than they did without lenses (2.73 ± 0.79 points, p<0.00001). There were no significant differences in the other parameters measured.

Just as the study of patients in their natural adverse environments reported, this study demonstrates that senofilcon A lenses can alleviate the acute symptomatology associated with exposure to controlled adverse environmental conditions.

Robin L. Chalmers, OD, FAAO, FBCLA, is a graduate of UC Berkeley School of Optometry, Dr. Robin Chalmers is an independent clinical trial consultant and Adjunct Professor at Indiana University School of Optometry. She is Co-Chair of the Contact Lens Assessment in Youth Study (CLAY) study of outcomes with soft contact lens wear in youth. Since 1985, she has conducted clinical trials on contact lens complications, dry eye, and the measurement of ocular surface symptoms by means of the long and short versions of the Dry Eye Questionnaire (DEQ and DEQ-5) and Contact Lens Dry Eye Questionnaire (CLDEQ and CLDEQ-8).

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2. Young G, Riley CM, Chalmers RL, Hunt C. Hydrogel lens comfort in challenging environments and the effect of refitting with silicone hydrogel lenses. Optom Vis Sci 2007;84(4):302-308.
3. Ousler GW III, Anderson RT, Osborn KE. The effect of senofilcon A contact lenses compared to habitual contact lenses on ocular discomfort during exposure to a controlled adverse environment. Curr Med Res Opin 2008;24(2):335-341.

Clinical Perspectives: The Science Behind ACUVUE® OASYS® Brand Contact Lenses Senofilcon A (Doctor Roundtable)

The following roundtable was compiled from recent phone interviews and is presented to you in the form of a virtual roundtable.

MODERATOR:
Kirk Smick, OD, FAAO, *is co-owner and Chief of Optometry Services at Clayton Eye Center in Morrow, Ga. A frequent lecturer and author, Dr. Smick is also a past President of the Georgia Optometric Association, the Georgia State Board of Examiners in Optometry and the Southern Council of Optometrists.*

PARTICIPANTS:

Kim Castleberry, OD, *is President and CEO of Plano Eye Associates in Plano, Texas, and serves as adjunct faculty for the University of Houston College of Optometry.*

Harue J. Marsden, OD, MS, *is an associate professor at the Southern California College of Optometry and chief of the Stein Family Cornea and Contact Lens Service in the Eye Care Center at the Southern California College of Optometry.*

Joshua LaHiff, OD, *is a partner at Cheyenne Vision Clinic in Cheyenne, Wyo. and is a Clinical Instructor for the Illinois College of Optometry.*

Susan A. Resnick, OD, FAAO, *is a partner in Farkas, Kassalow, Resnick & Associates in New York City.*

All of the participants received compensation from Review of Optometry *for their involvement in the following roundtable discussion, with the funding provided by JJVCI.*

Kirk Smick, OD, FAAO: What are your key considerations when selecting a contact lens for a patient?

Kim Castleberry, OD: My philosophy is simple. I'm looking for a lens that looks good on the eye, feels good to the patient, and provides great vision.

Joshua LaHiff, OD: I agree. Patients can achieve reasonably good vision with most of the contact lenses on the market, and they take that as a given. But when we exceed their expectations by providing lenses that are exceptionally comfortable, it changes their whole lens-wearing experience from satisfactory to "wow." By selecting the most advanced contact lens materials, I can significantly raise my chance of achieving that.

Dr. Smick: How do you think patients' satisfaction with their contact lenses affects perceptions of you and your practice?

Harue Marsden, OD: Excellent contact lens performance only reflects well on the practice and the practitioner. When patients come in complaining about comfort or vision, of course they think you didn't get it right.

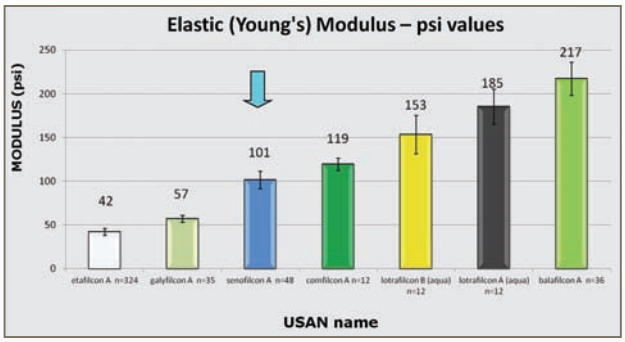
Susan Resnick, OD: Being able to satisfy hard-to-fit patients who have typically undergone several prior, yet unfulfilling, attempts is what sustains our referral based practice. If we achieve success with this type of patient, they are enthusiastic referral sources.

Dr. Smick: Patient retention is a huge challenge for most practices right now. If you start with a solid foundation of high-quality lenses and frequent replacement for fresher lenses, that leads to a better wearing experience and higher satisfaction for patients, which translates into satisfaction with the doctor. ***In your opinion, which specific lens characteristics or performance attributes best translate into patient success?***

Dr. Resnick: We have a unique patient population, comprised largely of people who are challenging to fit for one reason or another. So I'm always looking for lenses that are problem solvers. Parameter availability is a key factor, but that aside, I utilize materials that exhibit superior performance in dry eye patients. When I combine this with the most frequent replacement schedule possible, I feel I am optimizing physiologic factors conducive to success.

Dr. LaHiff: I fit silicone hydrogel lenses whenever possible, primarily for the oxygen those materials provide to the cornea. Additionally, several studies have shown that silicone hydrogel lenses in general,[1] and those made from senofilcon A in particular[2] improve patients' comfort level in challenging environments. That's important for me because I practice in Wyoming, a dry, windy, high-altitude environment that is really challenging for contact lens wear. After that, I am looking for a soft modulus to reduce lens awareness, a really smooth lens so there is less lid-lens friction, and a great wetting agent embedded in the material to keep the lenses feeling moist and comfortable throughout the day.

Dr. Smick: How well the lens wets is really important for long-term comfort and performance, so that is something I also look at closely. I'm also interested in the optical quality of the lens and the way patients' eyes look at follow-up visits. I want to see nice, clear corneas with no conjunctival injection.



ACUVUE® OASYS® with HYDRACLEAR® *Plus* modulus values are at least 50% lower than lotrafilcon B, lotrafilcon A, and balafilcon A. 1. JJVC, data on file 2010.

Dr. Castleberry: My prescribing habits are evidence-based. I depend on the peer-reviewed literature, particularly for evaluation of the risk of infiltrative and microbial keratitis, spoilage and soiling of the lenses, and fit.

Dr. Resnick: My approach is to rely on my own patients' feedback rather than manufacturer's claims when it comes to assessing subjective attributes of comfort and vision. When it comes to peer-reviewed literature I'm primarily interested in data on the scientific questions: Material characteristics, oxygen permeability, wettability, and solution compatibility. Rigorously conducted, independent studies have the most validity, and it's important to make sure the conclusions are actually justified by the study findings.

LENS OF CHOICE

Dr. Smick: What is your "go-to" or "first fit" lens?

Dr. Marsden: Based on our practice management data, ACUVUE® OASYS® Brand Contact Lenses is the most frequently prescribed lens in our clinic. The senofilcon A material is a second-generation silicone hydrogel that was a huge step up from the first generation in terms of comfort and deposits. From a practical standpoint, it's great to have a lens that is going to be successful for most patients.

Dr. LaHiff: ACUVUE® OASYS® is also my lens of choice for comfort and wettability. I also like the fact that patients can transition into a multifocal in the same material as they get older.

Dr. Smick: Is it your experience that patients who switch to ACUVUE® OASYS® typically stay with the lens?

Dr. Marsden: With refits, you really have to consider what the patient is currently wearing. The softer modulus of ACUVUE® OASYS® is one of the reasons patients who are switched from other lenses generally find it to be very comfortable.

Dr. Castleberry: What is remarkable about new fits of ACUVUE® OASYS® in people who have worn other contact lenses is that patients are so pleasantly surprised at the utter lack of lens awareness.

Dr. Smick: How important is it to you that patients are satisfied with their lenses from the very first fit?

Dr. LaHiff: Patients put their trust in you as the doctor. If you can exceed their expectations at that first visit, you are more likely to see them for subsequent visits because they are confident in your clinical decision making. They are also more likely to be excited about wearing and purchasing their lenses from you.

Dr. Marsden: Getting it right the first time is important for the health of your practice. In teaching students, I emphasize that chair time is money. If that patient has to come back multiple times for you to tweak a base curve or change a care system, it does have an impact on the bottom line.

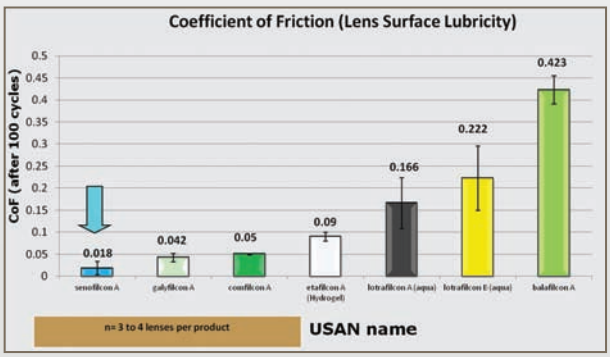
LENS MODALITY

Dr. Smick: Do you believe number of days the same lens is worn impacts lens performance? What modality do you prefer for your patients?

Dr. Castleberry: The literature clearly supports that a shorter wearing schedule is better. I think the current generation of lenses helps to enforce that goal of frequent replacement because comfort and vision do degrade after a couple weeks of wear. The only time I prefer a monthly lens is for patients who want a continuous wear schedule. If they can adapt to the initial lens awareness, they do well in monthly lenses. However, a significant number will develop intolerance over time and need to be refit in a softer-modulus lens.

Dr. Smick: About 75% of my patients are in 2-week lenses now and I'm fitting fewer monthly lenses than ever before. For me, this is a safety issue. I realized that the longer the replacement interval, the more exaggerated the noncompliance became, and I'm not comfortable with that risk if there is no good reason to take it.

Dr. Resnick: The replacement modality,



ACUVUE® OASYS® with HYDRACLEAR® *Plus* is more lubricious than nearly every other reusable silicone hydrogel contact lens on the market. 1. JJVC, data on file 2010.

unfortunately, is often by necessity a tertiary consideration for me, after material and prescription availability. In an ideal world, I would always choose a one-day lens, especially if I had a silicone hydrogel option. Otherwise, I opt for the shortest replacement schedule available.

Dr. LaHiff: Data that I've seen from a European survey of 434 monthly hydrogel and silicone hydrogel lens wearers indicate that 90% of them first experience discomfort in weeks 3 and 4. In my experience, monthly wearers just fight through that discomfort because they think they're "supposed" to. I would rather they just not get to that point. Studies have also shown a big difference in end-of-day comfort between 2- and 4-week lenses. That is an even bigger concern for me because it means they are uncomfortable at some point every day, not just at the end of the wearing cycle.

CONTACT LENS COMPLIANCE

Dr. Smick: How big a problem is patient compliance with replacement frequency? Which modality of lens wear do you believe leads to the highest compliance?

Dr. Resnick: Compliance is highest, by far, with one-day lenses. I can count on one hand the number of patients who try to "stretch" with this modality.

Dr. LaHiff: Compliance is a problem in health care overall, not just among contact lens wearers. After all, we know that patients aren't always compliant with insulin or glaucoma medications, which potentially have much more significant consequences.

Dr. Marsden: As contact lens practitioners, we have to take some of the responsibility for noncompliance on ourselves. Regardless of modality, I think it's important that practitioners consistently remind patients not to wear lenses beyond the recommended schedule—and reinforce that message every time the patient comes in.

Dr. LaHiff: Shorter replacement schedules boost compliance, because patients are thinking about the lenses more often. In my experience, patients that are going to be noncompliant will typically stretch a 2-week lens by a week and a monthly lens by a month.

Dr. Smick: My personal observation is similar—the longer I prescribe the lens for, the longer the lack of compliance. With a 2-week lens, the average overwear I see in

Compliance with Contact Lens Replacement Schedules

A survey of contact lens wearers highlights differences in contact lens replacement compliance between 2-week replacement wearers and monthly replacement wearers.

In an online survey conducted from October 2008 to March 2009, 645 frequent replacement contact lens wearers were asked about their contact lens replacement habits.[1] (The sturdy was sponsored by VISTAKON®, Division of Johnson & Johnson Vision Care, Inc., but the sponsor was not revealed to the study participants.) The participants included hydrogel and silicone hydrogel wearers from 12 to 39 years old. Out of the 645 people surveyed, 448 wore contact lenses that were indicated for 2 weeks of use and 197 wore contact lenses that were indicated for monthly replacement.

Reported replacement results were grouped into three categories: perfect replacement compliance (replaced on or before prescribed replacement interval), minor stretching of the replacement interval (up to 1 week beyond the replacement interval), and extreme stretching (a replacement interval of 8 or more weeks).

Low rates of perfect replacement compliance were noted for both groups (43% for 2-week lens wearers and 36% for monthly lens wearers). Some difference between the groups was noted regarding minor stretching, with more 2-week wearers reporting that they replace contact lenses up to 1 week after the recommended replacement interval. By far the greatest differences were seen in the extreme stretching category. Twenty-three percent of the monthly replacement lens wearers reported that they wore lenses for 8 weeks or more while just 4% of 2-week-replacement lens wearers reported the same (Figure 1).

These results indicate generally low compliance across both groups. Monthly replacement contact lens wearers, however, were more prone to extreme overwear of lenses, potentially leading to problems with comfort and/or vision.

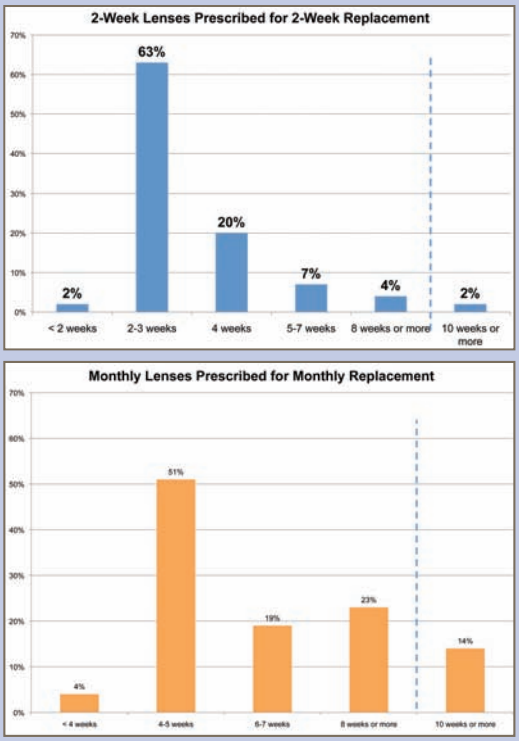
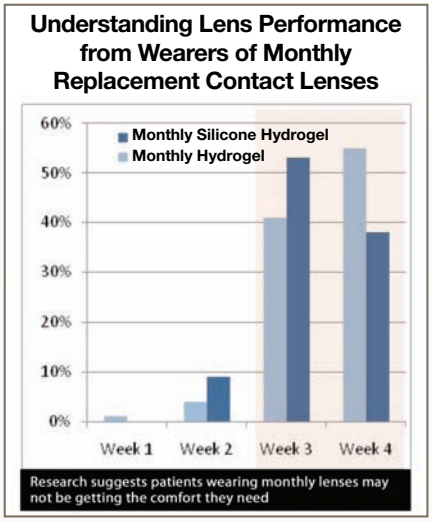


Figure 1. Reported replacement frequency is charted among both groups surveyed: 2-week-replacement contact lens wearers and monthly replacement contact lens wearers.

Reference
1. Hickson-Curran SB, Chou P, Gardere J. Longer Prescribed Replacement Intervals Leads to More Stretching of Frequent Replacement Lenses. Poster presented at American Academy of Optometry 2009 Annual Meeting in Orlando, FL, Nov. 11-14, 2009.



In a European survey, more than 90% of monthly lens wearers reported first experiencing discomfort in weeks 3 and 4. Frangie, J., Schiller, S., and Hill, Lisa Ann, "Understanding Lens Performance from Wearers of Monthly Replacement Contact Lenses", Optometry Today, 48:12, June 13 2008.

my practice is 3-5 days. On those patients we fit with 1-month lenses, it is not unusual at all for them to go 2 months. Studies bear out what Dr. LaHiff and I have seen with extreme overwear.[4]

If a patient is noncompliant with the wear schedule, my inclination is to switch them to one-day lenses, rather than a longer wearing schedule. Just going by what is "easier" to remember doesn't make sense to me. Putting in a new lens every January 1st would be easy to remember but it doesn't accomplish my real goal, which is to change their lenses frequently to avoid potential problems. ***At what point of overwear do you believe the likelihood of adverse events and patient discomfort with contact lenses increases?***

Dr. Castleberry: A month of daily wear is at the outer limits of what I think is comfortable and safe. Overwearing a 2-week lens may lead to problems, but not likely as severe as those we see arising from overwearing a monthly lens.

Dr. Resnick: I don't like to see any more than 25% overwear. What I'm most concerned about are the things patients can't see or feel. The older the lens, the greater the risk that it has been exposed to other non-compliant behaviors such as topping off solutions or a dirty case.

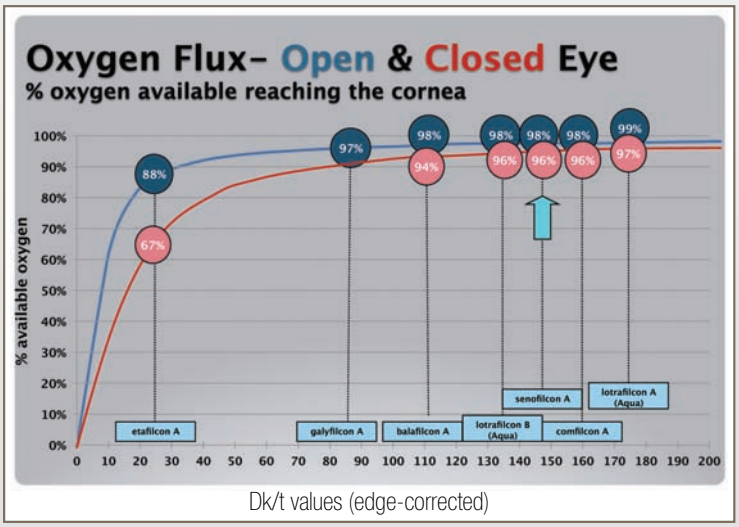
Dr. Marsden: Dr. Resnick makes a really important point. You have to consider replacement compliance in the context of overall compliance. In a 2-week lens wearer, I can be a little more tolerant of poor cleaning habits if the patient is replacing the lenses on schedule. But when a patient wears a lens for longer than 2 weeks, I really want to see excellent hygiene, good daily digital cleaning and frequent lens case replacement.

Dr. Smick: Are there tools or tips you use to better support patient compliance?

Dr. Marsden: I like to give them specific dates, such as the 1st and 15th of the month or every payday. Electronic reminder services are a great opportunity to use technology to achieve better compliance.

Dr. LaHiff: I'm a firm believer in controlling as many compliance factors as I can. We try to set patients up with an annual supply of lenses and provide an annual supply of free solution so they don't have any reason to stretch the products out. The more convenient you make it for patients the more compliant they are going to be.

Dr. Resnick: We tell patients to change their case when they open a new bottle of solution. I also think it's important to tie compliance to what patients really want, which is uninterrupted lens wear. While I don't use "scare tactics," I do share with patients my clinical findings, especially if there are signs that better cleaning or attention to the wear schedule could help them achieve their goals.



Dk/t values (edge-corrected)

JJVCI Data on file, 2004-2010.

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1. Young G, Riley CM, Chalmers RL, Hunt C. Hydrogel lens comfort in challenging environments and the effect of refitting with silicone hydrogel lenses. Optom Vis Sci 2007;84(4):302-308.

2. Ousler GW, Anderson RT, Osborn KE. The effect of senofilcon A contact lenses compared to habitual contact lenses on ocular discomfort during exposure to a controlled adverse environment. Curr Med Res Opin 2008;24(2):338-341).

3. Galileo Consumer Quantitative Survey, France, 2007.

4. Hickson-Curran SB, Chou P, Gardere J. Longer prescribed replacement intervals leads to more stretching of frequent replacement lenses. Poster presented at American Academy of Optometry 2009 Annual Meeting in Orlando, Fla., Nov. 11-14, 2009.

How Do Silicone Hydrogel Lenses Perform Across Their Recommended Wear Cycle?

Charissa Lee, OD, and Sheila Hickson-Curran, BSc(Hons), MCOptom, FAAO

As practitioners, we make clinical decisions for our patients based on both prior experience and evidence-based findings. In the past, we may have accepted contact lens-related issues, like limbal hyperemia, palpebral roughness, corneal staining, and end-of-day discomfort as inevitable. But given all of the new contact lenses at our disposal, we need to ask ourselves whether accepting these complications is in our patients' best interest.

In a large clinical study that was conducted in 2009 and sponsored by Johnson & Johnson Vision Care, Inc., researchers found that some of these clinical complications may be alleviated by the type of lens worn. The researchers compared a disposable silicone hydrogel lens with a recommended replacement cycle of every 2 weeks (ACUVUE® OASYS® Brand Contact Lens) to a disposable silicone hydrogel lens with a monthly (4-week) recommended replacement cycle (AIR OPTIX® Aqua) and found strong evidence that the contact lens type and performance not only affects patients' comfort, but it can also affect contact lens-related clinical signs.

STUDY DESIGN

The researchers enrolled 379 subjects in a single-masked multi-center study across 24 optometric offices in the United States. The subjects were all non-presbyopic, daily wear soft contact lens wearers with healthy eyes. They were randomly selected to wear a 2-week or monthly replacement silicone hydrogel lens for a single wear cycle, with 185 subjects in ACUVUE® OASYS® Brand (2-week lens) and 194 subjects in AIR OPTIX® Aqua (monthly lens). The mean age was 29.5 years old, and 69% of the subjects were women. During the study, patients continued to use their habitual lens care system.

All subjects were evaluated at their initial/dispensing visit and at 2 weeks; the monthly replacement wearers were also evaluated at a 4-week visit. Patient interviews were conducted at 1 week, 2 weeks and 4 weeks (for the monthly replacement subjects) to assess subjective measurements such as comfort, vision, and dryness. During the interviews, a series of questions were posed, and subjects responded using a 5-point Likert scale (Excellent, Very Good, Good, Fair and Poor). Data were analyzed to compare the overall response to their lenses at each time point. Also, the percentage of patients who were satisfied with the lenses (defined as either ratings of "Excellent" or "Very Good") were compared, as were the percentage of "dissatisfied" patients (defined as those expressing that the lenses were either "fair" or "poor").

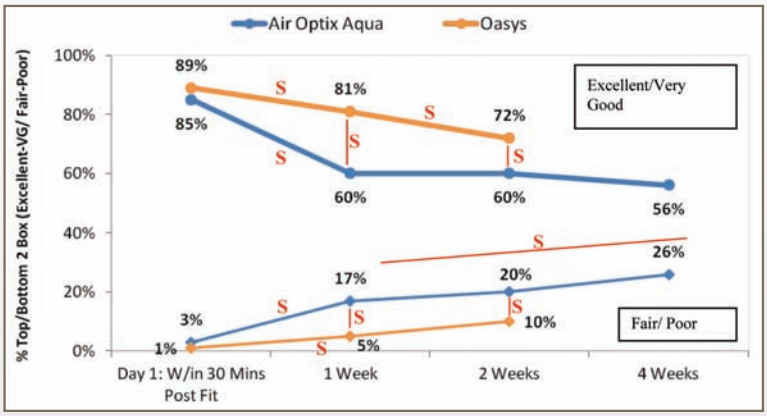

Figure 1: Overall Comfort Satisfaction. S=Significant differences $p<0.05$

STUDY RESULTS

The study found that the 2-week lens was superior to the 4-week lens in terms of subjective Overall Comfort, subjective Overall Vision, and subjective Dryness, at both the 1- and 2-week marks.

In terms of Overall Comfort, there were statistically significant differences in the deterioration of comfort, described by the percent of satisfied and dissatisfied patients, over the lifespan of the lenses. In the 2-week replacement lens, Overall Comfort slowly declined across the entire wearing schedule ($p<0.05$). In contrast, the monthly lens showed a sharp drop in the proportion of patients who were satisfied during the first week of wear (85% to 60%, $p<0.05$), and the proportion of patients who were dissatisfied with Overall Comfort increased over the remaining three weeks ($p<0.05$, post-hoc analysis). There was no statistical difference in comfort between the two and four week time points.

In addition, the researchers found a statistically significant difference in Overall Comfort between the 2-week and 4-week replacement lenses at the 1-week and 2-week marks where they were compared (p-values of <0.0001 and 0.0017, respectively). These results are summarized in Figure 1.

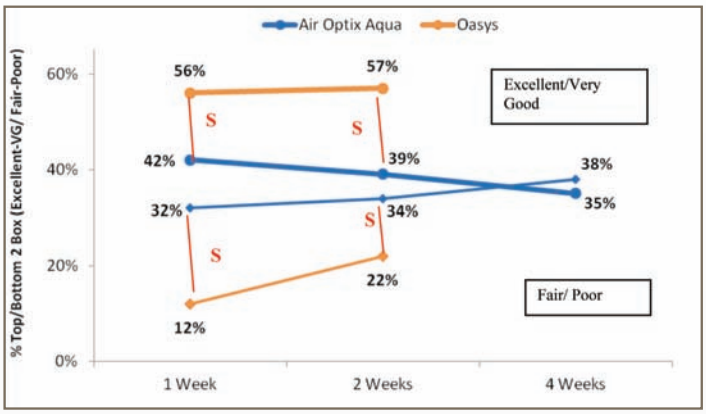

Figure 2: End-of-Day Comfort Satisfaction. S=Significant differences p<0.05

Another important component of contact lens performance is End-of-Day Comfort. The researchers found a similar distribution in End-of-Day Comfort as they did with Overall Comfort. At the end of week 1, 56% of the 2-week lens subjects rated End-of-Day Comfort "Excellent to Very Good", whereas only 42% of the 4-week lens wearers rated their lenses "Excellent to Very Good". By the end of the second week, this number was stable at 57% of the 2-week wearers, and reduced slightly to 39% in the 4-week wearers (Figure 2). Not surprisingly, researchers saw an inverse trend in the "Fair to Poor" rating as wearing time progressed in both the 2-week and 4-week lenses. At the end of the 4-week wearing period, more subjects expressed dissatisfaction ("Fair" and "Poor" ratings) with End-of-Day Comfort with the monthly replaced lens, than expressed satisfaction ("Excellent" and "Very Good" ratings) with this variable.

Comfort—whether we are talking about overall or end-of-day comfort—is such a significant consideration for our contact lens patients. Studies and surveys have shown repeatedly that symptoms of discomfort are the main reason that patients drop out of contact lens wear in this country.[2,3]

The study also evaluated Overall Quality of Vision to assess performance of this 2-week replacement lens versus the 4-week replacement lens. They found that in both the 2-week and 4-week replacement groups, the percentage of patients rating their quality of vision "Excellent or Very Good" decreased with each week the lenses were worn. There was also a statistically significant difference in Overall Vision Quality ratings between the two groups at weeks 1 and 2 (p=0.0067 and p=0.01 respectively). Eighty-two percent of the 2-week replacement lens subjects rated their vision as "Excellent or Very Good", while only 74% of the 4-week replacement lens subjects rated their vision in the same category after 1 week of wear. At week 2, 76% of subjects in the 2-week group and 68% of subjects in the 4-week group rated their vision "Excellent to Very Good" (NS) (Figure 3). At the end of the 4-week wear period, a surprising 13% of monthly patients rated their Overall Quality of Vision as "Fair or Poor". Given that the primary purpose of contact lenses is to correct vision, it is an important consideration that more than one in 10 of the monthly lens wearing subjects in this study gave a rating indicating dissatisfaction with vision at the end of the recommended wear cycle.

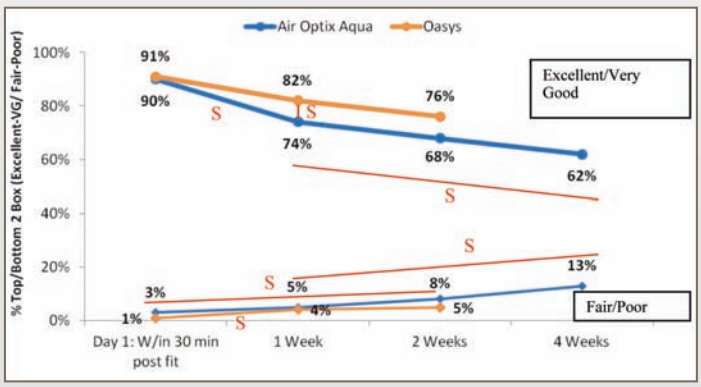

Figure 3: Overall Quality of Vision Satisfaction. S=Significant differences p<0.05

A third comparison between the two groups was how patients rated their dryness symptoms. The subjects were given the reduced Contact Lens Dry Eye Questionnaire (CLDEQ-8), a questionnaire that evaluates frequency and intensity of dryness symptoms, at each visit. In terms of both frequency and intensity of dryness, subjects rated the 2-week lens less dry than the 4-week replacement lens at both the 1 and 2 week time points. The difference was statistically significant, with p-values of 0.0001 for both measurements.

This study only looked at one cycle of wear per lens type and also evaluated clinical, contact lens-related ocular signs across the wear cycle. They found that subjects who wore the 2-week replacement lens had statistically lower levels of limbal hyperemia than

those who wore the 4-week replacement lens when both were compared at the 2-week clinic visit (p=0.0001). In addition, a higher percentage of patients in the 2-week replacement lenses reported that their eyes looked whiter at that time point (p=0.0005). There were also more film deposits on the 4-week replacement lenses than the 2-week replacement lenses at the 2-week visit (p<0.0001): 40% and 36% respectively. For the monthly replacement lens, those deposits further increased to 52% at the 4-week visit. Although palpebral roughness decreased from baseline in both groups at the 2-week visit, it increased significantly between the 2-week and 4-week visit in the 4-week replacement subjects (p<0.05).

DISCUSSION

With both subjective and objective measurements performed, this study demonstrates that with ACUVUE® OASYS®, a 2-week replacement lens, subjects experienced superior comfort, better vision and improved ocular signs compared to the monthly replacement AIR OPTIX® Aqua subjects. Further, there was lower frequency of symptoms of dryness in the 2-week replacement group.

These findings may be attributable to multiple differences between the two lenses that were studied: modality of wear, modulus of the lens, edge design, surface wettability, or surface treatment versus embedded wetting agent (HYDRACLEAR® *Plus*). An interesting note is that the 4-week replacement lens is made of the same material (lotrafilcon B) that was used in O2 Optix®, a lens that for years was recommended by the manufacturer as a 2-week replacement lens. The monthly replacement modality for this lens is a surprising choice, given that the "satisfaction with comfort" findings drop so rapidly during the first week of wear.

The researchers' findings are also consistent with other contact lens studies evaluating the amount of protein and other deposition on contact lenses over time.[4,5] Protein deposition is thought to have contributed to problems we saw clinically with conventional contact lenses; we observed numerous clinical complications, such as giant papillary conjunctivitis, when patients were changing their lenses annually. This prompted us to fit patients into contact lenses that are replaced more frequently, and subjectively, patients consistently feel more comfortable when they insert a fresh new lens. Although silicone hydrogel lenses all show differences in their in vitro deposition profile, all show increasing in vitro deposition over time, and this study also found deposition that was clinically observable. For many patients, recommending lenses that are thrown away and replaced before their clinical performance deteriorates will result in a more consistent, sustained lens-wear experience.

CONCLUSIONS

With the high quality silicone hydrogel lenses available today, most of our patients need not experience discomfort. Moreover, this clinical trial shows that we as practitioners can alleviate many contact lens signs and symptoms simply by choosing a lens with material properties and performance that can be sustained across its recommended replacement schedule.

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- *Jan Beiting*

References

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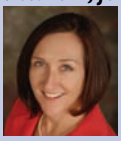
Charissa Lee, OD, is a graduate of SUNY State College of Optometry and has a broad experience working in a wide range of practice modals. She has a private practice in Irvine, CA. Dr. Lee is actively involved in her optometric community and has served as a consultant for various contact lens companies. Dr. Lee is a member of the COA and AOA, but her main area of focus is the Asian American Optometric Society, where, for the past five years, she has served as an active board member. Dr. Lee is currently a Medical and Professional Affairs Consultant for VISTAKON®, Division of Johnson and Johnson Vision Care, Inc.



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ACUVUE® BRAND CONTACT LENSES SPECIFICATION INDEX

	ACUVUE® OASYS® BRAND	ACUVUE® OASYS® BRAND for ASTIGMATISM	ACUVUE® OASYS® BRAND for PRESBYOPIA
			
Recommended Replacement	2 Weeks	2 Weeks	2 Weeks
Wearing Indication	DW/EW	DW/EW	DW/EW
Lens Material Dk/t Value1 (non-edge-corrected)	senofilcon A 174×10^{-9}	senofilcon A 152.5×10^{-11}	senofilcon A 174×10^{-9}
Lens Material Dk/t Value2 (edge-corrected)	senofilcon A 147×10^{-9}	senofilcon A 128.7×10^{-11}	senofilcon A 147×10^{-9}
Water Content	38% (Group 1)	38% (Group 1)	38% (Group 1)
Visibility Tint	Yes	Yes	Yes
UV Blocking	Yes >90% UVA >99% UVB (Class 1 UV Blocker)	Yes >90% UVA >99% UVB (Class 1 UV Blocker)	Yes >90% UVA >99% UVB (Class 1 UV Blocker)
Inside-Out Mark	Yes 123	No	No
Center Thickness (@-3.00D)(mm)	0.070	0.080	0.070
Parameters **BC (mm)/Diameter (mm)** **Powers**	8.4 and 8.8/14.0 -0.50D to -12.00D (in 0.50 steps above -6.00) +0.50D to +8.00D (in 0.50 steps above +6.00)	8.6/14.5 <u>Minus Powers</u> Plano to -6.00D (in 0.25D steps) Cyl: -0.75, -1.25, -1.75 Axis: 10° to 180° (in 10° increments) Cyl: -2.25D Axis: 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180° <u>High Minus Powers</u> -6.50D to -9.00D (in 0.50D steps) Cyl: -0.75, -1.25, -1.75 Axis: 10° to 180° (in 10° increments) Cyl: -2.25D Axis: 10°, 20°, 90°, 160°, 170°, 180° <u>Plus Powers</u> +0.25D to +6.00D (in 0.25D steps) Cyl: -0.75, -1.25, -1.75 Axis: 10°, 20°, 70°, 80°, 90°, 100°, 110°, 160°, 170°, 180° Cyl: -2.25D Axis: 10°, 20°, 90°, 160°, 170°, 180°	8.4/14.3 +6.00D to -9.00D (in 0.25 steps) Adds: LOW: +0.75 to +1.25 MID: +1.50 to +1.75 HGH: +2.00 to +2.50