POWER EFFECT ON TORIC CONTACT LENS ROTATIONAL STABILITY

By

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POWER EFFECT ON TORIC CONTACT LENS ROTATIONAL STABILITY

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ABSTRACT

Background: Eyecare practitioners currently fitting soft toric contact lenses are often limited by the parameters available in their in-office fitting set. To properly fit spherocylindrical lenses outside of the trial lens set parameters, multiple office visits are often required because practitioners need to order trial lenses of various powers and axis. This is due to the complexity of achieving rotational stability which can be influenced by many factors. The purpose of this study is to evaluate the effect of lens power on the rotation of blink stabilized contact lenses. *Methods:* Four Acuvue Oasys 1-Day for Astigmatism contact lenses of different spherical powers were assessed on the right eye of 33 subjects. The four different lenses powers were the following: +4.00 -1.25 x 180, pl -1.25 x 180, -4.00 -1.25 x 180, and -8.00 -1.25 x 180. After the manufacturer's recommended settling time, each contact lens was evaluated for rotation, centration, coverage, and movement. Then each subject was instructed to look in all positions of gaze and rotation was measured again to determine rotational stability. *Results:* Of all the lenses evaluated, 89% of the lenses were considered dispensable based on appropriate centration, coverage, and movement. Seventy-nine percent of the lenses exhibited excellent rotational stability of five or less degrees. Each lens power tended to rotate nasally, with no statistically significant difference between lenses. *Conclusions:* For practitioners, fitting a toric lens inside the trial lens set, of powers plano to -6.00D, can predict how a toric lens outside the trial lens set will react on the ocular surface.

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CHAPTER 1

INTRODUCION OF TORIC CONTACT LENSES

The first toric soft contact lens was approved for distribution in the United States in 1978.[1] At that time, the word "snowflake" was often used to describe their reproducibility. No two lenses, even of the same prescription, were alike. These lenses were unreliable, thick, and low in water-content. This led to patient and doctor dissatisfaction which limited the use of toric soft contact lenses.[2] Instead, doctors choose to treat contact lens-seeking patients with high astigmatism in options like corneal gas permeable lenses. For patients with less than one diopter of astigmatism, many doctors chose to mask astigmatism. Masking astigmatism involves fitting patients in spherical contact lenses based on the spherical equivalent of their spectacle correction resulting in less than optimal vision correction.[3]

Since their release, toric soft contact lenses have improved drastically. Substantial advancements have been made so that lenses are more stable and comfortable.[4] They have also become more reliably reproducible and available in a wider variety of parameters.[5] Improvements in materials, like silicone hydrogel, and frequency of replacement, like daily disposable, have also made these lenses healthier than ever before.[4] These developments have increased utilization of toric soft contact lenses.[5] In the late 1990s, the percentage of toric soft contact lenses was 12-14%[6] and increased to 24%

in 2018.[7] Over this same time period, there was a proportional decrease in the percentage of spherical contact lens fits.[6]

Patient success with toric soft contact lenses is dependent on a multitude of factors including comfort, ocular health, and consistently clear vision. Clear and stable vision always requires the toric lens cylinder axis to be aligned with the refraction's cylinder axis. Any deviation or rotation of the cylinder axis during the blink cycle or change in gaze direction will cause a variable reduction in vision due to cross-cylinder effects. Lack of rotational stability is often the primary reason for patient failure with toric soft contact lenses.[5] Rotation and alignment are often measured clinically by using a vertical reference marking etched into most toric soft contact lenses at the 6 o'clock position depending on the design, not at the cylinder axis.[4]

The rotational stability is more clinically relevant that the amount of rotation for toric soft contact lenses.[5] If the lens is consistently rotated a particular amount, compensate for leftward misalignment by adding the particular amount to the spectacle axis and rightward misalignment by subtracting the particular amount from the spectacle axis. This adjustment is known as LARS, for Left Add, Right Subtract, and used to eliminate axis misalignment, not rotation. In fact, this adjustment can only be done due to the improvements made in reproducibility of these lenses. Now the evaluator can assume that the next lens of the same design but different axis will rotate in the same way as the first.[4]

Toric soft contact lenses are available in a variety of designs that aim to promote proper alignment of the correcting cylinder and minimize rotation during or after a blink. These methods include prism-ballast, periballast, dynamic stabilization, truncation, back-surface toricity, and several combinations of these designs.[5] Most of these designs rely on the interaction between the lids and the contact lens to align and stabilize.[3]

The oldest and most common stabilization design is termed prism-ballast. It utilizes the inclusion of prism, usually in the 0.75-2 prism diopter range, creating thickness differences across the lens profile.[5] The upper lid applies pressure to the wedge and squeezes the thicker portion of the lens out from under the upper lid.[4] This design effectively induces base down prism into the optic zone of the soft toric contact lens. If the patient is prescribed this toric lens design in only one eye, the result is likely to be vertical prism imbalance which may exacerbate symptoms of a vertical phoria. Another problem with this design is the reduction in oxygen transmissibility in the areas of the lens that are thickened. If the lens is oriented properly, the central and inferior cornea will receive less oxygen than the superior cornea, especially in lenses of low Dk/t materials.[5]

To enhance the oxygen transmissibility of the traditional prism-ballast design, a periballast lens design utilizes a high minus power lenticular carrier. In this design, there is no prism in the optic zone of the lens. This allows the central lens profile to be thin and avoids inducing unwanted vertical prism.[5] Other modifications have been made to the traditional prism-ballast design, such as the optimized ballast design of CooperVision's Biofinity Toric. In a study conducted in 2013 by Momeni-Moghaddam et al., the optimized ballast design had the best rotation and orientation recovery speed on eye of the five lens designs studied.[3]

Dynamic stabilization designs have also been available since the 1970s. They have also been commonly known as double slab-off, thin-zone, and accelerated stabilization designs. This design relies on increases in lens thickness in four areas located between the upper and lower lids within the palpebral aperture.[8] It has been reported that this design is adversely affected by low lens power and with-the-rule and oblique lens' cylinder axes[8] which could explain why this design exhibits poorer orientation in primary gaze than prism-ballast designs in multiple research studies.[3] Contrarily, these designs have a reputation for being comfortable, having thin optic zones, and providing enhanced oxygen transmissibility.[5]

Another traditional stabilization design was truncation. The truncated area was usually 0.5-1.5mm in width and located inferiorly, but some designs used inferior and superior truncation. In general, truncation designs incorporated prism-ballast thickness differences to assist in alignment and stability. There remains conflicting research if truncation substantially contributed to rotational stability. Ultimately, the use of truncation was discontinued due to patient discomfort and corneal exposure.[5] Back-surface toricity has also been tried as a method to control lens rotation. It was hypothesized that a back-surface toric lens could align its flatter base curve with the flatter corneal meridian and its steeper base curve with the steeper corneal meridian. This idea was based on the successful use of back-surface toricity in gas permeable contact lenses. It has since been found that this theory does not hold true for toric soft contact lenses due to the draping characteristics of soft contact lenses.[5]

It is true that many toric soft contact lens designs combine multiple of the previously stated stabilization designs to control lens alignment and rotational stability. In a study by Jurkus et al. that compared a front-toric with prism-ballast, a back-toric with superior thin-zone and inferior prism, a front-toric, and a back-toric thin-zone without prism designs, there was no statistically significant difference in interblink rotational stability.[5]

In addition to toric lens design, many other factors contribute to the overall fit of a toric soft lens, rotation, and rotational stability. For example, steepening the base curve results in a tighter fitting relationship which decreases movement and rotation with the blink, but also slows the rate of reorientation.[5] In a study conducted by Young, et al., the effect of lid anatomy on rotational stability was evaluated. Using lid topography results, it was found that most of the 45 participants had an outer canthus located higher than the inner canthus. If this angle was >5 degrees, it was found to be an indicator of infero-temporal rotation of the lens. If the inner canthus was higher than the outer canthus, this was an indicator for infero-nasal rotation. It was also found that the smaller the palpebral fissure, the less a lens rotated likely due to increased lid interaction with the lens.[8]

It has also been theorized that overall lens diameter, axis of cylinder, asphericity, lens flexure, corneal topography, and lens power also affect rotation, but research in this area thus far is limited and inconclusive.[5] The purpose of this research study was to evaluate the effect of lens power on toric lens rotation and rotational stability.

For this study, the Acuvue Oasys® Brand Contact Lenses 1-day with HydraLuxe™ Technology for Astigmatism were used. These lenses are made of a silicone hydrogel material (senofilcon A), an internal wetting agent, a UV absorbing monomer (benzotriazole), and a visibility tint (Reactive blue Dye #4) for handling. Each lens has a 14.3 mm diameter and 8.5 mm base curve. The powers available are outlined in Appendix B. The powers chosen to use in the study were: +4.00 -1.25 x 180, pl – 1.25 x 180, -4.00 -1.25 x 180, and -8.00 -1.25 x 180. These lenses are indicated for daily disposable wear and are not to be worn while sleeping. Each lens is etched with two primary marks approximately 1 mm from the lens edge representing the vertical position on opposite ends of the lens at 6 and 12 o'clock. The lens features a type of dynamic stabilization design termed the BLINK STABILIZED® Design.[9]

CHAPTER 2

METHODS

The purpose of this study was to assess how different spherical powers of a toric soft contact lens affects the rotation of that lens. In this study, four Acuvue Oasys Toric Daily soft contact lenses of different spherical powers were placed on the right eye of thirty-three participants. The 4 lenses assessed were +4.00 -1.25 X 180, pl -1.25 X 180, -4.00 -1.25 X 180 and -8.00 -1.25 X 180. The first contact lens was initially inserted into the right eye and a timer was set for three minutes to allow the lens to settle into position based on the manufacturers settling recommendation. Once the lens had settled, the amount of rotation and direction of rotation of the lens were measured. Next, the participant was directed to move their eyes up, down, left and right to assess the rotational stability. The rotation and direction of rotation of the lens were measured again. If the difference between the initial and end rotation was five degrees or less, then the lens was considered rotationally stable. Lastly, the centration, coverage and movement of each lens was assessed, and the lens was removed from the participant's eye. It was then determined if the lens was dispensable based on its rotational stability, centration, coverage and movement. This was repeated for the three other lenses on the thirty-three participants. Each lens was then compared against the other lenses using a paired t-test to determine whether the spherical power of the contact lens had a statistically significant effect on the rotation of the lens.

CHAPTER 3

RESULTS

Of the 132 lenses evaluated in this study, 89% of the lens fits were considered dispensable or safe for daily wear. Of the 14 lenses that fit poorly, there was an approximately equal distribution between the four different lens powers. This indicates that lens power has an insignificant effect on centration, coverage, and movement of each lens. It is likely that patient attributes such as corneal shape and lid involvement have a more significant impact on unsuccessful fits, as five of the 33 participants in the study were responsible for 12 of the 14 poor fits.

Seventy-nine percent of the lenses were considered rotationally stable or rotated five degrees or less with eye movement. The number of rotationally unstable lenses was six, four, eight and 10 out of 28 lenses for the +4.00 -1.25 X 180, pl -1.25 X 180, -4.00 -1.25 X 180 and -8.00 -1.25 X 180 lenses, respectively. This shows that the higher power lenses may tend to be slightly more rotationally unstable than the spherically plano astigmatic lenses.

Despite the vastly different spherical powers, all the lenses rotated similarly ($P>0.05$). It was found that the +4.00 -1.25 X 180 lens rotated an average of 6.88 degrees to the right with 81% of lens fits of this power considered rotationally stable. The pl -1.25 X 180 lens rotated an average of 5.78 degrees to the right with 87% of lens fits of this power being rotationally stable. The -4.00 -1.25 X 180 lens rotated an average of 6.67

degrees to the right with 75% of lens fits of this power being rotationally stable. The -8.00 -1.25 X 180 lens rotated an average of 8.30 degrees to the right with 69% of lens fits of this power being rotationally stable. Since these lenses were evaluated on the right eye of all subjects, it can be concluded that the Acuvue Oasys® Brand Contact Lenses 1-day with HydraLuxeTM Technology for Astigmatism tend to rotate nasally and exhibit excellent rotational stability 79% of the time.

CHAPTER 4

DISCUSSION OF RESULTS

The results of this study showed that there was no statistically significant difference between the amount and direction of rotation of the Acuvue Oasys® Brand Contact Lenses 1-day with HydraLuxeTM Technology for Astigmatism when comparing 4 different spherical powers. As stated in the results, the overall rotation differed by a few degrees between the different lenses. This means that the rotation of that lens is expected to be approximately the same for the lens spherical powers ranging from -8.00 to +4.00, which can be very helpful in clinical practice.

Most types contact lenses, whether spherical or toric, have fitting sets that ease the contact lens fitting process. Unfortunately, most fitting sets do not include every lens available because there is such a large range of parameters, especially for toric lenses. Toric lenses have a spherical, cylinder and axis component that can be of any combination depending on the patient's refraction. For this reason, it would be impractical to have a toric fitting set with every possible combination. When the fitting set does not include the desired contact lens prescription, trial lenses need to be ordered and the patient usually returns for another visit. Although this is necessary, it is likely the doctor and the patient would like to keep the number of follow-up appointments to a minimum. The results from this study provides insight to the practitioner as to which trial contact lenses will be needed to successfully fit their patient. The spherical power of the

Acuvue Oasys® Brand Contact Lenses 1-day with HydraLuxeTM Technology for Astigmatism, no matter how large, will not affect the way the lens rotates on the patient's' eye. This will allow for successful toric contact lens fittings with the least amount of follow-up visits.

As previously stated, the lack of rotational stability is often the primary reason for patient failure with toric soft contact lenses.[6] The results of this study show that the higher spherical power lenses tend to be slightly more rotationally unstable than the pl -1.25 x 180 lenses. This means that higher powered lenses may cause patients to experience intermittent blur based on the rotational stability. If the criteria for rotational stability was increased to a difference of nine degrees or less, then 90% of these lenses would be rotationally stable. This is an objective way of measuring the rotational stability, but in practice, rotational stability can often be subjectively assessed. If the patient notices intermittent blur, it's possible that the lens is rotating on the eye. Due to blur tolerance, patients may experience this with more or less rotation than the criteria in this study. Therefore, even though 79% of the lenses were objectively considered rotationally stable, in clinical practice, the patient's blur tolerance may help to determine if the lens' rotation stability is adequate for the patient.

In this study, toric lenses were only place on the participant's right eye. It is known that eyes are often times mirror images of each other. For example, if a patient has a cylinder axis of 10 degrees in the right eye, it is likely that the axis of the left eye will be around 170 degrees. It was found that the Acuvue Oasys® Brand Contact Lenses 1-day with HydraLuxe™ Technology for Astigmatism lenses tend to rotate nasally. Since eyes are mirror images of each other, it can be assumed that the lenses on the left eye will also rotate nasally. This offers more information to practitioners when they are deciding which lenses to order for an efficient and successful toric contact lens fitting.

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APPENDIX A

IRB APPROVAL FORM

FERRIS STATE UNIVERSITY

Date: Sep 14, 2017

To: Amy Dinardo
From: Gregory Wellman, R.Ph, Ph.D, IRB Chair
Re: IRB Application *IRB-FY16-17-22 Power Effect on Toric Contact Lens Rotational Stability*

The Ferris State University Institutional Review Board (IRB) has reviewed your application for using human subjects in the study, " *Power Effect on Toric Contact Lens Rotational Stability" (IRB-FY16-17-22)* and Approved this project under Federal Regulations Expedited Review Category 1b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Approval has an expiration date of one year from the date of this letter . **As such, you may collect data according to the procedures outlined in your application until Sep 14, 2018 .** Should additional time be needed to conduct your approved study, a request for extension must be submitted to the IRB a month prior to its expiration.

Your protocol has been assigned project number IRB-FY16-17-22. Approval mandates that you follow all University policy and procedures, in addition to applicable governmental regulations. Approval applies only to the activities described in the protocol submission; should revisions need to be made, all materials must be reviewed and approved by the IRB prior to initiation. In addition, the IRB must be made aware of any serious and unexpected and/or unanticipated adverse events as well as complaints and non-compliance issues.

Understand that informed consent is a process beginning with a description of the study and participant rights with assurance of participant understanding, followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document and investigators maintain consent records for a minimum of three years.

As mandated by Title 45 Code of Federal Regulations, Part 46 (45 CFR 46) the IRB requires submission of annual reviews during the life of the research project and a Final Report Form upon study completion. Thank you for your compliance with these guidelines and best wishes for a successful research endeavor. Please let us know if the IRB can be of any future assistance.

Regards,

Gregory Wellman, R.Ph, Ph.D, IRB Chair
Ferris State University Institutional Review Board
Office of Research and Sponsored Programs

APPENDIX B

LENS PARAMETERS

ACUVUE OASYS® Brand Contact Lens with HydraLuxe™ Technology has the highest daily disposable sphere and toric power combinations

		Low Minus (25) 0.00D to -6.00D (in 0.25D Steps)				High Minus (6) -6.50D to -9.00D (in 0.50D Steps)				Plus (16) +0.25D to +4.00D (in 0.25D Steps)			
		-0.75	-1.25	-1.75	-2.25	-0.75	-1.25	-1.75	-2.25	-0.75	-1.25	-1.75	-2.25
Obliques	30°	✓	✓	✓									
	40°	✓	✓	✓									
	50°	✓	✓	✓									
	60°	✓	✓	✓									
Against the Rule	70°	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	
	80°	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	
	90°	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	
	100°	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	
	110°	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	
Obliques	120°	✓	✓	✓									
	130°	✓	✓	✓									
	140°	✓	✓	✓									
	150°	✓	✓	✓									
With the Rule	160°	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	
	170°	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	
	180°	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	
	10°	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	
	20°	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	

2260
PARAMETERS

Widest coverage of astigmatic patients

- 2260 parameters and coverage for 87% of eyes
- 40% more than any other competitive daily disposable brand of contact lenses

Around the clock coverage where you need it most- in low minus, plano to -6.00 D, through -1.75 DC*

NEARLY
96%
COVERAGE FOR
SPHERICAL & ASTIGMATIC EYES

ACUVUE OASYS® Brand Contact Lenses 1-Day with HydraLuxe™ Technology family provide coverage for nearly 96% spherical and astigmatic eyes.

*JJVC data on file. Astigmatic coverage in Low Minus (-0.75, -1.25, -1.75DC across all axes in 10° increments) accommodated with ACUVUE OASYS® 1-Day for ASTIGMATISM.

ACUVUE® Brand Contact Lenses are indicated for vision correction. As with any contact lens, eye problems, including corneal ulcers, can develop. Some wearers may experience mild irritation, itching or discomfort. Lenses should not be prescribed if patients have any eye infection, or experience eye discomfort, excessive tearing, vision changes, redness or other eye problems. Consult the package insert for complete information. Complete information is also available by visiting acuvueprofessional.com, or by calling Johnson & Johnson Vision Care, Inc. at 1-800-843-2020.

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NEW ACUVUE® 1-Day oasys WITH HydraLuxe™ BRAND CONTACT LENSES ASTIGMATISM