A CONTACT LENS APPROACH TO THE MANAGEMENT OF DRY EYE

by

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ABSTRACT

BACKGROUND: To determine whether the water gradient technology of Alcon Dailies Total 1 soft contact lenses can reduce non-contact lens related dry eye symptoms.

METHODS: Thirty subjects contributed; 22 females (73.3%) and 8 males (26.7%) ranging in age from 18 to 69. The Ocular Surface Disease Index (OSDI) questionnaire was administered to each subject, and those responding positively were enrolled in the study. Subjects were disqualified from the study if they had worn contact lenses or used artificial tears in the 5 hours leading up to the study. The subjects that were found to be symptomatic were asked to wear a daily contact lens, Dailies Total 1, in both eyes for a 4 hour time period. Schirmer II testing was done before and after contact lens wear, and a final symptom survey was repeated at the end of the study.

RESULTS: For all subjects, the OSDI questionnaire showed a reduction in dry eye symptoms (28% mean score decrease) after wearing the Dailies Total 1 contact lens. For those whose Schirmer II test results were less than 10mm, tear volume measured after wearing the contact lenses increased by 64%. Both subjective and objective measures improved with contact lens wear.

CONCLUSIONS: Although traditional contact lenses are known to generally increase dry eye symptoms, water gradient contact lenses appear often to have the opposite effect. Advancements in contact lens technology may provide new management strategies for patients suffering from ocular surface disease.

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INTRODUCTION:

Dry eye disease is one of the most common conditions encountered by optometrists and is challenging to treat due to its varied etiologies. The International Dry Eye Workshop defines dry eye as: "a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage of the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface". [1]

There are many known etiologies of ocular surface disease, including: increasing age, hormonal changes, contact lens wear, smoking, refractive surgery, medications and systemic diseases. [1]

Dry eye has classically been treated with topical lubricants and medications, punctal plugs, and scleral contact lenses. While these methods have improved vision and comfort for some patients, many patients' symptoms are not well controlled due to the multifaceted nature of ocular surface disease.

This study aims to determine if new technology in soft contact lenses could be used to treat dry eye. Many soft lenses are currently being used as bandage contact lenses, but to our knowledge have never been researched as a possible management of dry eye disease until now.[2] Typically, high water content lenses are contraindicated in those with dry eyes due to the nature of the lens drawing fluid from the tear film. [2,3]

There were great advancements in the contact lens industry with the development of the new Dailies Total 1 daily contact lens. The technologically advanced daily lens was developed to be a water gradient contact lens, the first of its kind. This new style silicone hydrogel lens has a core water content of 33%, with the water content reaching almost 100% at the surface of the lens, making it a more breathable and comfortable lens. Alcon states that the lubricious nature of this lens makes it more comfortable than it's competitors.[4]

Due to its' unique material and water content, Dailies Total 1 may become a new management option for those with ocular surface disease.

METHODS:

Thirty subjects (8 males and 32 females), who ranged in age from 19 to 69 (mean ± SD: 37.1 ± 13.8) with symptoms of dry eye, who had discontinued topical medication and contact lens wear at least 5 hours before testing, were enrolled in the study. Subjects were removed from the study if they were pregnant or breastfeeding.

After completion of an OSDI survey, a binocular Schirmer II test was performed on all subjects. Schirmer II testing allowed for the measurement of basal tears after instilment of 1 drop of proparacaine hydrochloride ophthalmic solution 0.5%. The Schirmer II test uses a Whatman number 41 strip placed ⅓ of the distance from the temporal canthus of the lower eyelids. Subjects were instructed to close their eyes and maintain primary gaze during Schirmer II testing.[5] The test strips were carefully removed and the amount of basal tearing was recorded. The test results were considered positive if the length of wetting obtained was less than 10mm in 5 minutes.

After the initial Schirmer II test, Alcon Dailies Total 1 contact lenses were inserted binocularly for 4 hours of continuous wear. All lenses used had a power of -0.50 diopters, and subjects requiring vision correction wore their own spectacle lenses in addition to the contact lenses. After 4 hours, subjects were asked to repeat the OSDI questionnaire and Schirmer II test before removal of the contact lenses.

RESULTS:

For each subject, the OSDI score after wearing the Dailies Total 1 contact lenses was reduced. The mean score before contact lens wear was 23.19 ± 19.2 and the mean score after contact lens wear was 9.53 ± 11.09 ($p<0.001$). There was

an overall 28% mean decrease in the OSDI score. The results showed that subjects experienced statistically significant reduction in dry eye symptoms after contact lens wear. The mean and associated standard deviation values for the OSDI questionnaire are shown in Table 1.

For subjects with initial Schirmer II scores <10mm there was a statistically significant increase in basal tear measurements after contact lens wear. Mean initial scores were 5.67 ± 1.86 and mean final scores were 9.27 ± 5.91 ($p<0.001$). For these subjects, the mean increase in basal tear volume was 64%.

For subjects with initial Schirmer II scores ≥10mm there was no statistically significant change in scores after contact lens wear. Mean initial scores were 17.85 ± 5.69 and mean final scores were 16.37 ± 6.98. There was no statistically significant change between the before and after contact lens wear values. The mean values for before and after contact lens wear Schirmer II tests are shown in Table 2.

Table 1:

	Mean OSDI Score	Standard Deviation
Before Contact Lens Wear	23.19	19.21
After Contact Lens Wear	9.54	11.09

Table 2:

	Mean Schirmer II (<10mm)	Mean Schirmer II (≥10mm)
Before Contact Lens Wear	5.67 ± 1.86	17.85 ± 5.69
After Contact Lens Wear	9.27 ± 5.91	16.37 ± 6.98

DISCUSSION:

The OSDI questionnaire was used in this study to allow for subjective comparison of dry eye symptoms before and after contact lens wear. This survey has been recognized to reliably measure the severity of a patient's dry eye and has proven validity in clinic trials.[1,6] In this study there was statistically significant improvement in dry eye symptoms with the use of Dailies Total 1 contact lenses.

Schirmer II testing was used in this study to allow for an objective comparison of dry eye symptoms before and after contact lens wear. Schirmer II testing has been classically used to evaluate basal tear production, and has been shown to be more objective and reliable than Schirmer I testing. Studies have shown that testing with eyes in primary gaze and closed lids decreases variability among subjects.[1]

The values resulting from Schirmer II testing were divided into two groups based on tear production <10mm or ≥10mm. For subjects with initial results <10mm the use of Dailies Total 1 contact lenses increased tear volume. The increase in tear volume may be a result of lid interaction with the lens causing reflex tearing; however all contact lenses interact with the lids and would produce similar results if this was the mechanism behind the increase in tear volume. Alternately, the increase in tear volume could be due to the water content of the lens surface decreasing tear evaporation. Further testing is necessary to determine the exact mechanism behind the improvement in Schirmer II scores following contact lens wear.

For subjects with initial results ≥10mm with Schirmer II testing there was no statistically significant change after contact lens wear. As previously mentioned, traditional soft contact lenses sequester fluid from the tear film producing symptoms of contact lens related dry eye. This study suggests that a water gradient contact lens does not withdraw fluid from the tear film, but maintains tear volume in patients with adequate tear volume.

CONCLUSION:

Advancements in contact lens technology may provide new management strategies for patients suffering from ocular surface disease. Water gradient contact lenses do not appear to interact with the tear film in the same way as traditional contact lenses. By stabilizing and even increasing tear volume, the Dailies Total 1 contact lens decreased symptoms of dry eye in all subjects.

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Ferris State University

Institutional Review Board (FSU - IRB)
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To: Dr. Dean Luplow, Craig Norman, Roxanne Rottiers and Jennifer Sowers
From: Dr. Stephanie Thomson, IRB Chair
Re: IRB Application #140701 (Title: *A Contact Lens Approach to the Management of Dry Eye*)
Date: July 25, 2014

The Ferris State University Institutional Review Board (IRB) has reviewed your application for using human subjects in the study, *"A Contact Lens Approach to the Management of Dry Eye"* (#140701) and has determined that it meets Federal Regulation category, *Expedited –2D*. This approval has an expiration date of one year from the date of this letter. **As such, you may collect data according to procedures in your application until July 25, 2015**. It is your obligation to inform the IRB of any changes in your research protocol that would substantially alter the methods and procedures reviewed and approved by the IRB in this application. Your application has been assigned a project number (#140701), which you should refer to in future correspondence involving the same research procedure.

We also wish to inform researchers that the IRB requires follow-up reports for all research protocols as mandated by Title 45 Code of Federal Regulations, Part 46 (45 CFR 46) for using human subjects in research. We will send a reminder to complete either the Final Report Form or the Extension Request Form to apply for a study continuation. Both forms are available on the IRB homepage. 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,

S. Thomson

Ferris State University Institutional Review Board
Office of Academic Research, Academic Affairs

Ocular Surface Disease Index© (OSDI©)[2]

Ask your patients the following 12 questions, and circle the number in the box that best represents each answer. Then, fill in boxes A, B, C, D, and E according to the instructions beside each.

Have you experienced any of the following *during the last week*?	All of the time	Most of the time	Half of the time	Some of the time	None of the time
1. Eyes that are sensitive to light? . .	4	3	2	1	0
2. Eyes that feel gritty?	4	3	2	1	0
3. Painful or sore eyes?	4	3	2	1	0
4. Blurred vision?	4	3	2	1	0
5. Poor vision?	4	3	2	1	0

Subtotal score for answers 1 to 5 (A)

Have problems with your eyes limited you in performing any of the following *during the last week*?	All of the time	Most of the time	Half of the time	Some of the time	None of the time	N/A
6. Reading?	4	3	2	1	0	N/A
7. Driving at night?	4	3	2	1	0	N/A
8. Working with a computer or bank machine (ATM)?	4	3	2	1	0	N/A
9. Watching TV?	4	3	2	1	0	N/A

Subtotal score for answers 6 to 9 (B)

Have your eyes felt uncomfortable in any of the following situations *during the last week*?	All of the time	Most of the time	Half of the time	Some of the time	None of the time	N/A
10. Windy conditions?	4	3	2	1	0	N/A
11. Places or areas with low humidity (very dry)?	4	3	2	1	0	N/A
12. Areas that are air conditioned? . . .	4	3	2	1	0	N/A

Subtotal score for answers 10 to 12 (C)

Add subtotals A, B, and C to obtain D
(D = sum of scores for all questions answered) (D)

Total number of questions answered
(do not include questions answered N/A) (E)

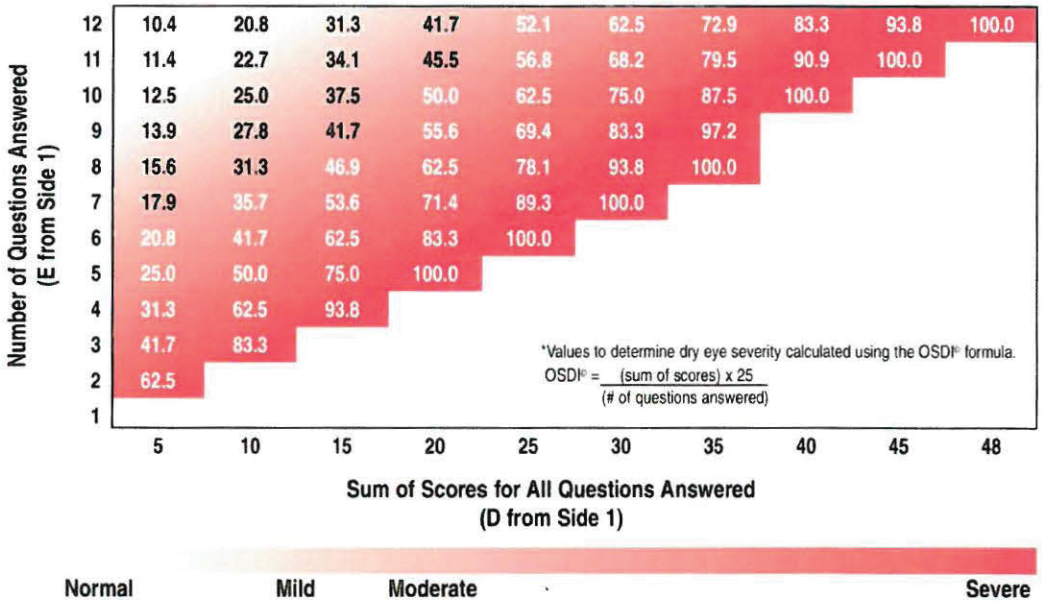
Please turn over the questionnaire to calculate the patient's final OSDI© score.

Evaluating the OSDI® Score[1]

The OSDI® is assessed on a scale of 0 to 100, with higher scores representing greater disability. The index demonstrates sensitivity and specificity in distinguishing between normal subjects and patients with dry eye disease. The OSDI® is a valid and reliable instrument for measuring dry eye disease (normal, mild to moderate, and severe) and effect on vision-related function.

Assessing Your Patient's Dry Eye Disease[1, 2]

Use your answers D and E from side 1 to compare the sum of scores for all questions answered (D) and the number of questions answered (E) with the chart below.* Find where your patient's score would fall. Match the corresponding shade of red to the key below to determine whether your patient's score indicates normal, mild, moderate, or severe dry eye disease.



Patient's Name: _____ **Date:** _____

How long has the patient experienced dry eye disease? _____

Eye Care Professional's Comments: _____

1. Data on file, Allergan, Inc.
2. Schiffman RM, Christianson MD, Jacobsen G, Hirsch JD, Reis BL. Reliability and validity of the Ocular Surface Disease Index. *Arch Ophthalmol.* 2000;118:615-621

_____
Date

_____
Subject Number

1. Gender:

□ Male
□ Female

2. Age:

□ <20
□ 20 – 29
□ 30 – 39
□ 40 – 49
□ 50 – 59
□ 60 – 69
□ >70

3. Have you worn contact lenses within the past 5 hours?

□ Yes
□ No

4. Have you used artificial tears within the past 5 hours?

□ Yes
□ No

5. Are you currently taking any of the following medications (check all that apply)?

□ Contraceptives
□ Antihistamines
□ Blood Pressure
□ Asthma/COPD
□ Heart Disease
□ Diuretics
□ Decongestants
□ Sleeping pills
□ Antidepressants
□ Acne (Isotretinoin)
□ Analgesics (Morphine, Ketorolac)
□ Overactive Bladder (Oxybutynin, Tolterodine)
□ Thyroid
□ Antibiotics
□ Artificial Tears
□ Hormone Replacement Therapy
□ None

6. Do you have any of the following systemic/ocular conditions (check all that apply)?

- □ Stevens-Johnson Syndrome
- □ Vitamin A Deficiency
- □ Rheumatoid Arthritis
- □ Sjogren's Syndrome
- □ Thyroid Disease
- □ Acne Rosacea
- □ HIV/AIDS
- □ Diabetes
- □ Lupus
- □ History of LASIK
- □ None