

SHORT-TERM CLINICAL COMPARISON OF TWO PEROXIDE BASED
DISINFECTING CONTACT LENS SOLUTIONS

by

Hannah Woodke and Sara Nonhof

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Hannah Woodke and Sara Nonhof

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ACCEPTED:

Faculty Court


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CONTACT LENS SOLUTIONS

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ABSTRACT

Background: Currently, Alcon Clear Care® dominates the market as the leading peroxide based disinfecting contact lens solution. Bausch & Lomb PeroxiClear® was released March 13, 2014 as an alternative to Clear Care®. The purpose of this study was to assess patients' preferences and ease of use between the two solutions in a comparative review. *Methods:* 6 current soft contact lens wearers on a monthly disposable schedule were selected to participate. Three participants used Clear Care® for a one month duration, and another three participants used PeroxiClear® for a one month duration. At the end of the first month, the participants filled out an online survey that asked questions regarding the ease of use of the solution and case as well as the comfort of the contact lenses. Following the survey, a detailed analysis and comparison of the two solutions was conducted. *Results:* The goal of the study was to measure the patients' assessments of comfort, average wear time, ease of use of the solution and case, and portability of the system. *Conclusions:* Since PeroxiClear® is new to the market, many practitioners do not have experience prescribing it. However, all practitioners are familiar with Clear Care®. This study will serve as a clinical review of what patients prefer and help guide practitioners in prescribing the most appropriate solution on an individual basis.

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CHAPTER 1: INTRODUCTION

Peroxide based disinfecting contact lens solutions have been on the market for decades. Using a dilute peroxide and buffer solution, as well as surfactants to aid in comfort, the simple self-neutralizing solutions have overcome the ancient two-step peroxide solutions that required more work by the wearer. These solutions have clear benefits over multipurpose solutions. Not only are they considered the “gold standard” in disinfecting lenses, they are preservative free, which is beneficial to patients with solution sensitivities. After several recalls of multipurpose solutions due to infections, the market for peroxide based solutions has grown immensely.¹ ClearCare by Alcon has had a large share of the market for some time, and now, new peroxide solutions are surfacing to compete. One competitor, PeroxiClear by Bausch and Lomb, has attempted to set itself apart from ClearCare by claiming it cleans better in less time. While both have FDA approval for use with soft contact lenses, there is little information on the differences between the solutions. Both use 3% hydrogen peroxide neutralized by a platinum catalytic disc within the lens case. (See Figure 1 and Figure 2)² According to the studies performed by Bausch and Lomb, when compared to ClearCare, PeroxiClear offered “superior all day comfort, longer-lasting moisture, and a longer-lasting clean.”³ The only objective information available is that PeroxiClear’s solution is neutralized within four hours, while ClearCare recommends six hours. This study aims to determine which peroxide based contact lens solution, if either, is preferred by patients. The researchers hope to use this information to help practitioners make informed decisions on solution recommendations as well as suggestions to the manufacturers on alterations to their product.



Figure 1. PeroxiClear Lens Case



Figure 2. ClearCare Lens Case

CHAPTER 2: METHODS

Six adults aged 18 years or older were selected from the University Eye Center at Michigan College of Optometry patient database. Each subject was a current soft silicone hydrogel contact lens wearer that was able to follow instructions and maintain the study appointment schedule. Also, each participant had a comprehensive eye examination within the last six months. Participants were excluded if he or she was not over the age of 18, if he or she was not a prior soft contact lens wearer, if he or she wore a soft contact lens with a replacement schedule of daily, biweekly, or conventional wear, or if he or she wore a soft hydrogel contact lens. Participants were excluded if he or she had anterior segment disease, such as dry eye, keratoconus, blepharitis, anterior basement membrane dystrophy, corneal uclers, or infections. Pregnant and nursing women were also excluded.

Six established soft silicone hydrogel contact lens wearers on a monthly disposable schedule were selected to participate. Three participants began using Alcon ClearCare®, and the other three participants began using Bausch and Lomb PeroxiClear®. Each participant used the dispensed solution for a one-month duration. Once the participant had consented to participate and all questions were answered, he or she was dispensed a Peroxide Solution Instructions Kit (Appendix B). A sample of the solution was dispensed in the Peroxide Solution Instructions Kit. The participants were required to use the solution following the manufacturer's guidelines. The solution was used daily to clean and disinfect the current soft silicone hydrogel lens of a monthly replacement schedule. At the end of the month, each of the six participants was e-mailed a link to the online survey provided on the

instructions sheet. The online survey (Appendix C) was provided using a link to the website SurveyMonkey. The survey asked various questions regarding comfort of the lenses and ease of use of the solution and case. A detailed analysis and comparison of the two solutions was then conducted.

CHAPTER 3 RESULTS

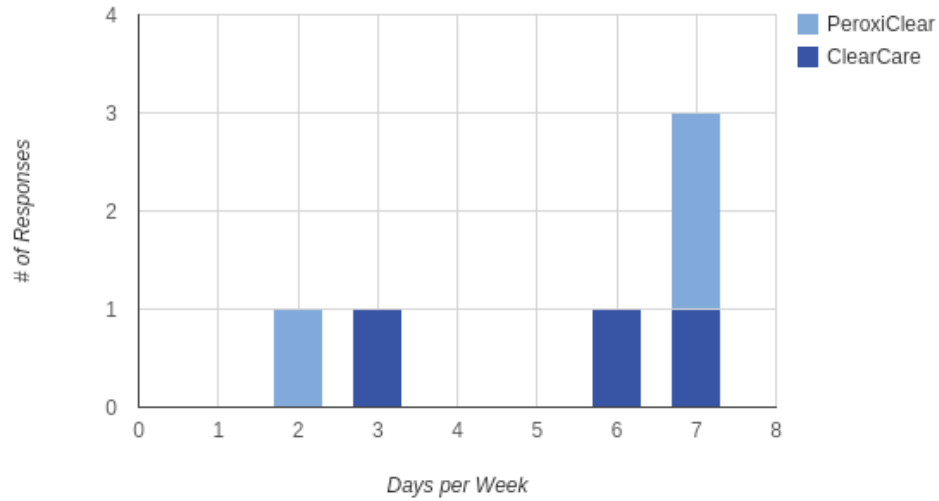
The six surveys were closely analyzed, and the following outlines the results of the comparison of PeroxiClear® and ClearCare®. Although not statistically significant, this study provides a starting foundation for future comparative analyses between the two leading hydrogen peroxide disinfecting multipurpose contact lens solutions.

To get an idea of the surveyed participants' contact lens habits, the first several questions of the survey were aimed at determining patient compliance regarding contact lens use. We began by determining how often and how long each participant was wearing his or her soft lenses. We also wanted to determine if he or she was non-compliant by sleeping, swimming, or showering while wearing the contact lenses. Finally, we wanted to know the average age of the participant's lenses and if he or she rubbed the contact lenses while cleaning them. Since a majority this study was focused around comfort, it was important to determine if other factors, besides the solutions, would contribute to discomfort. We wanted to determine if the factors identified as causing discomfort could be overcome by using the peroxide based solutions. The following outlines the survey questions and the corresponding answers.

Question 1: How many days per week are you wearing your soft contact lenses?

Two of the three participants using PeroxiClear® reported wearing his or her lenses 7 days a week. The third participant reported wearing lenses for 2 days a week. One of the three participants using ClearCare® reported wearing his or her lenses 7 days a week, another reported wearing lenses for 6 days a week, and the third reported wearing lenses for 3 days a week. (Table 1: Wearing Schedule).

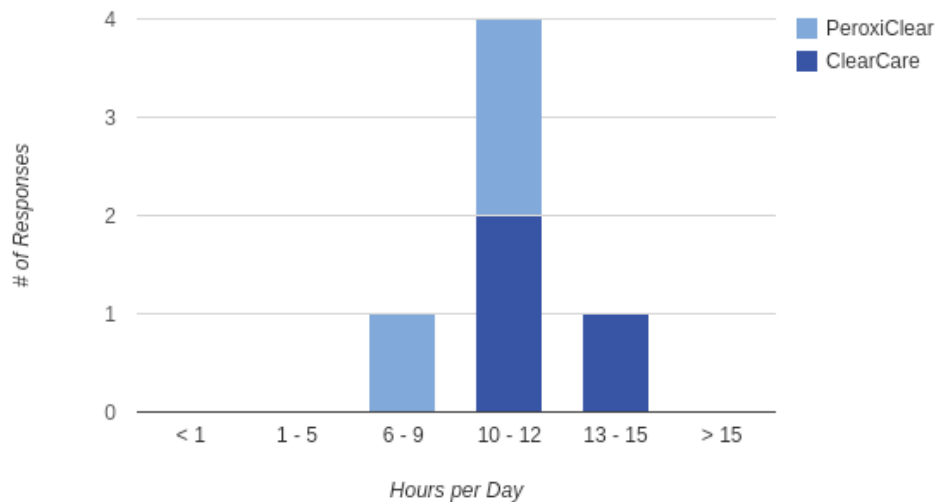
Table 1: Wearing Schedule in Days



Question 2: How many hours per day are you wearing your soft contact lenses?

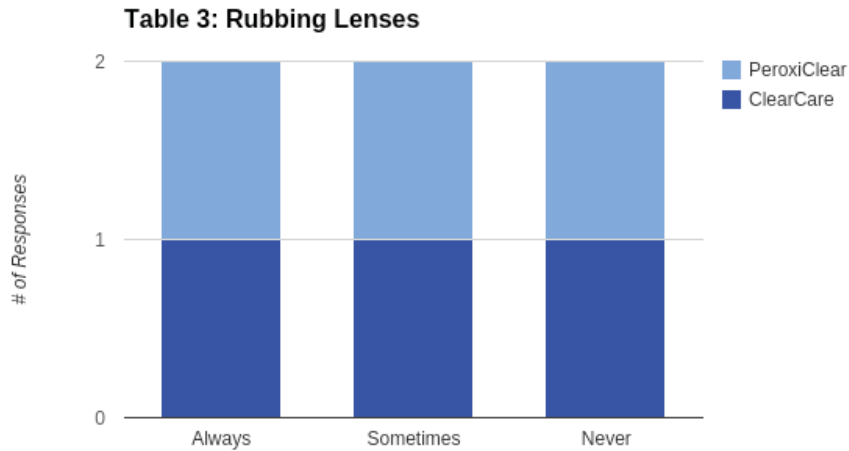
Two of the three participants using PeroxiClear® reported an average wear time of 10-12 hours per day, while the third participant reported only an average wear time of 6-9 hours. Two of the three participants using ClearCare® reported an average wear time of 10-12 hours per day, while the third participant reported an average wear time of 13-15 hours per day. (Table 2: Wearing Schedule).

Table 2: Wearing Schedule in Hours



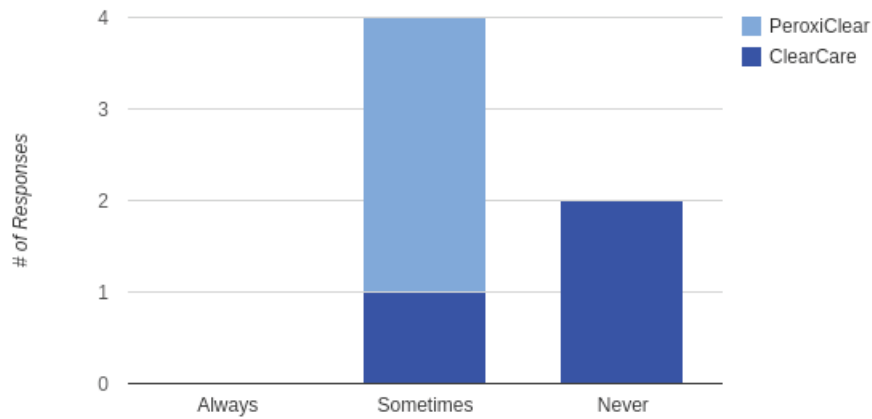
Question 3: How many nights per week are you sleeping in your soft contact lenses? All participants in this study reported that he or she does not sleep in the lenses any night per week.

Question 4: Do you rub your soft contact lenses when cleaning them? For both solutions, PeroxiClear® and ClearCare®, one participant reported that he or she always rubs the lenses while cleaning, one reported that he or she sometimes rubs the lenses while cleaning, and one reported that he or she never rubs the lenses while cleaning. (Table 3: Rubbing Lenses).



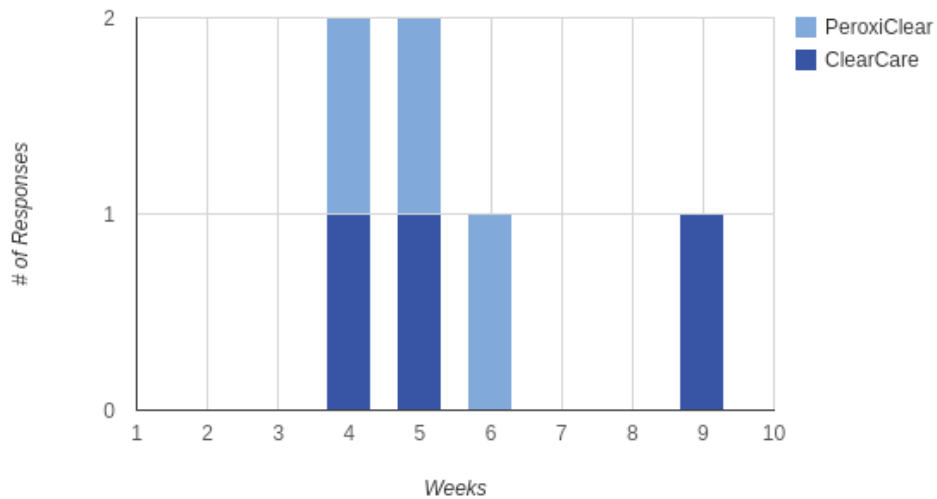
Question 5: Do you shower or swim while wearing your soft contact lenses? All three of the participants using PeroxiClear® reported that he or she sometimes showers or swims while wearing the lenses. Two of the three participants using ClearCare® reported that he or she never showers or swims while wearing the lenses, and the third participant reported sometimes showering or swimming while wearing the lenses. (Table 4: Swim or Shower in Lenses).

Table 4: Swim or Shower in Lenses



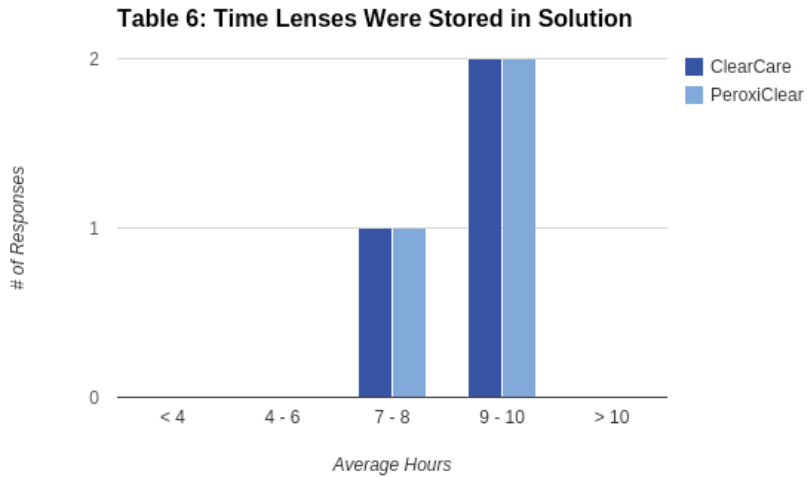
Question 6: How many weeks do you wear one pair of lenses for? When asked this question, one participant using PeroxiClear® reported wearing the lenses for 4 weeks, another reported 5 weeks, and the third reported 6 weeks. One participant using ClearCare® reported wearing the lenses for 4 weeks, another reported 5 weeks, and the third reported 9 weeks. (Table 5: Replacement Schedule).

Table 5: Replacement Schedule

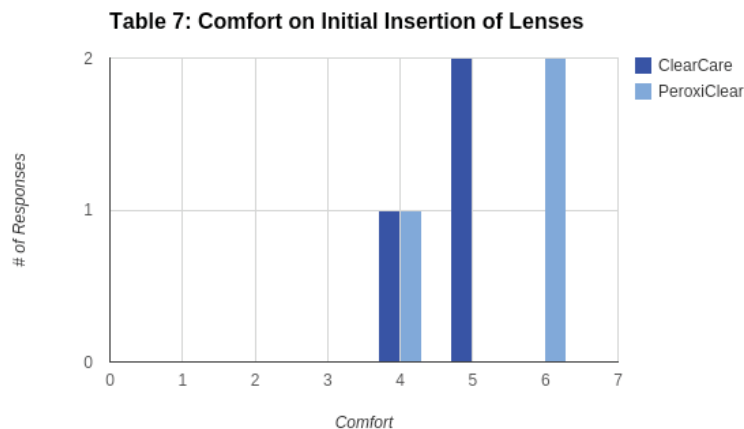


Question 7: How long are your study lenses typically stored in solution each night? Two participants using PeroxiClear® and two using ClearCare® reported storing

lenses in the solution 9-10 hours per night, while the third participant of each group reported storing the lenses for 7-8 hours per night. (Table 6: Time Lenses Were Stored in Solution).

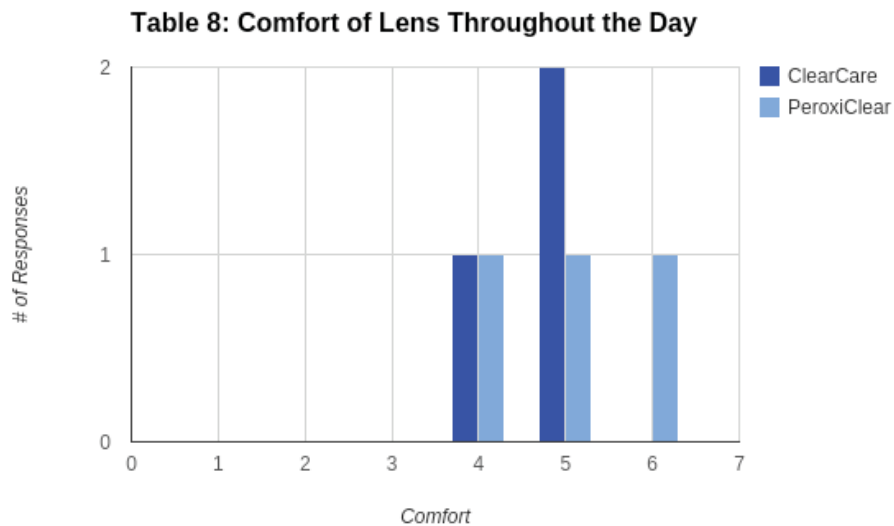


Question 8: On a scale of one to six, how comfortable are your lenses when you initially insert them? 1 being extremely uncomfortable and 6 being extremely comfortable. Two of the three participants using PeroxiClear® reported the initial comfort as a six, while the third reported initial comfort as a four. Two of the three participants using ClearCare® reported the initial comfort as a five, while the third reported initial comfort as a four. (Table Comfort on Initial Insertion of Lenses.)



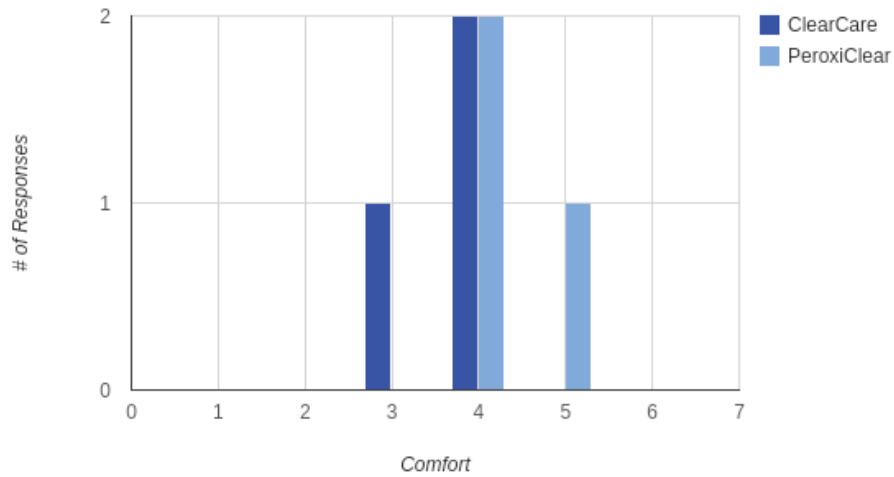
Question 9. On a scale of one to six, how comfortable are your lenses throughout the day? 1 being extremely uncomfortable and 6 being extremely comfortable.

One of the three participants using PeroxiClear® reported initial comfort as a four, one reported a five, and one reported a six. Two of the three participants using ClearCare® reported initial comfort as a five, while the third reported a four. (Table 8: Comfort of Lenses Throughout the Day).



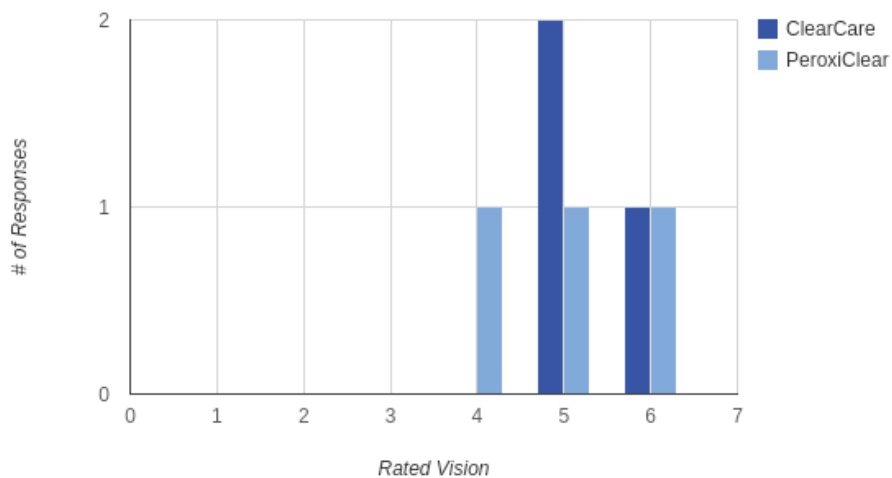
Question10: On a scale of one to six, how comfortable are your lenses at the end of the day? 1 being extremely uncomfortable and 6 being extremely comfortable. Two participants using PeroxiClear® and two participants using ClearCare® reported that the comfort at the end of the day was a four, while the third using PeroxiClear® reported a five, but the third using ClearCare® only reported a three. (Table 9: Comfort of Lenses at the End of the Day).

Table 9: Comfort of Lenses at the End of the Day

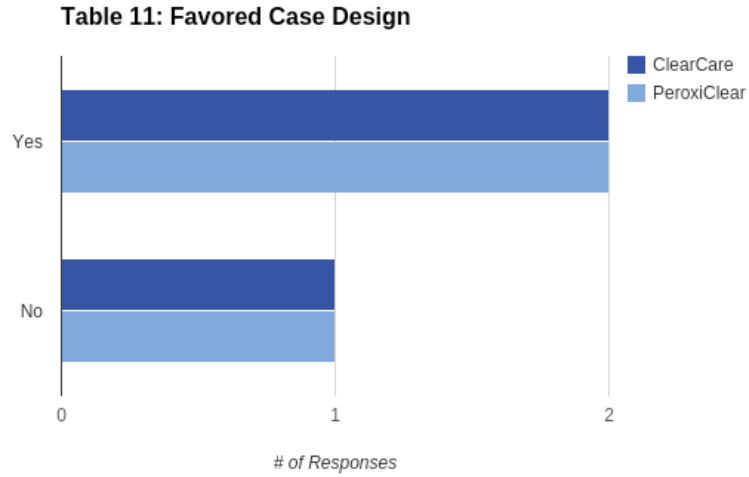


Question 11: On a scale of one to six, how would you rate your vision with your lenses? 1 being very poor and 6 being very good. One participant using PeroxiClear® reported the vision with the lenses as a four, one reported a five, and one reported a six. One participant using ClearCare® reported the vision with the lenses as a six, while the other two participants reported a five. (Table 10: Vision with Contact Lenses).

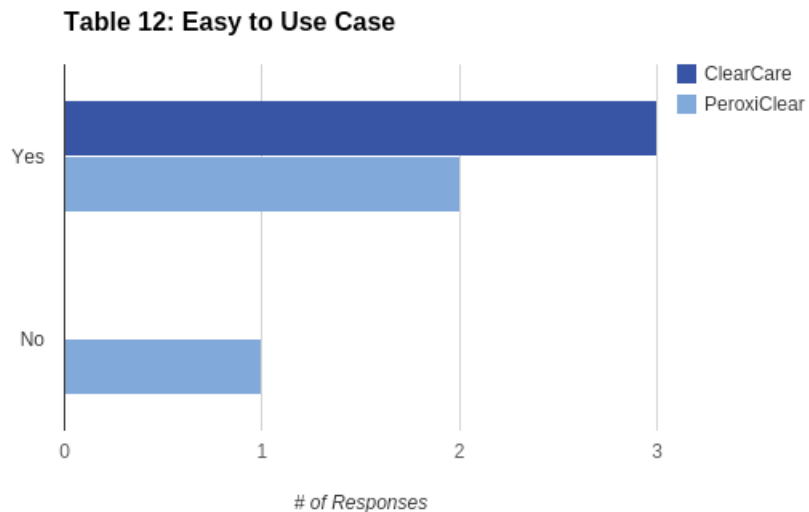
Table 10: Vision with Contact Lenses



Question 12. Do you like the design of the case you used for the past month? Two participants from each group reported that he or she liked the design of the case. The third participant of each group reported that he or she did not like the design of the case. (Table 11: Favored Case Design).



Question 13. Was the case easy to use? All participants using ClearCare® reported that the case was easy to use, while only two participants using PeroxiClear® reported that the case was easy to use. The third participant reported that the case was not easy to use. (Table 12: Easy to Use Case).



Question 14. Did you damage any of your lenses while using this solution and case?

None of the participants damaged any of the lenses while using either PeroxiClear® or ClearCare®.

CHAPTER 4 DISCUSSION

The goal of the study was to measure the patients' assessments of comfort, average wear time, ease of use of the solution and case, and portability of the system. Since PeroxiClear® is new to the market, many practitioners do not have experience prescribing it. However, nearly all practitioners are familiar with ClearCare®. This study serves as a clinical review of what patients prefer and helps guide practitioners in prescribing the most appropriate solution on an individual basis.

Although the number of responses to the survey and study are not of statistical significance, we believe that the information provided is still valuable. It is our hope that this study will continue and participation will increase, especially as the availability and popularity of PeroxiClear® becomes more widespread. Currently, our data shows neither ClearCare® or PeroxiClear® as having an appreciable margin of comfort difference over its competitor. However, this study does not claim to be an accurate representation of the population. For initial insertion comfort, PeroxiClear® users reported an average comfort level of 5.33 out of a six point scale, while ClearCare® users were not far behind with an average comfort level of 4.66. For comfort throughout the day, PeroxiClear® averaged a 5.00 out of a six point scale and ClearCare® averaged 4.66. Finally, for end of the day comfort PeroxiClear® averaged 4.33 and ClearCare® averaged 3.66. Minimal difference exists in terms of vision as PeroxiClear® users rated their vision an average of 5.00 out of a six point scale, and ClearCare® users averaged 5.33. While the majority of participants were compliant with their contact lens hygiene regimen by rarely sleeping, showering, or swimming in the lenses, one of the ClearCare® users reportedly only replacing his or her lenses every 9 weeks. This fact, and not the ClearCare® solution

system, could be the cause of the mild discrepancy between the average comfort of ClearCare® versus PeroxiClear®. It would have been ideal to get a survey regarding both ClearCare® and PeroxiClear® from each individual participant, but limits on the study would not allow for that data to be collected. It would be beneficial to this study to obtain that information in the future.

Bausch and Lomb's claim that PeroxiClear® has a more convenient four hour neutralizing time over the recommended six hours for ClearCare® also did not affect the participants of this study. For either solution, the participants reported a minimum soaking time of 7-8 hours. Perhaps the only appreciable difference is what the participants thought of the case designs. While the majority of both PeroxiClear® and ClearCare® users both liked the case and found it easy to use, several comments regarding the cases did arise. A ClearCare® user reported "having to fill it (the case) below the line" to avoid solution spilling upon capping it. A PeroxiClear® user stated, "I thought the case was flimsy. (It) Seemed like a cheap product." While another participant simply said, "I did not like the style of the case" in regards to the PeroxiClear® case. This study did not find a single peroxide based solution that provided better comfort, vision, or ease of use over its competitor. More information and increased numbers of participants are needed to make any definitive decisions on which solution, if either, is superior.

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2. Gromacki S, New hydrogen peroxide lens care system enters U.S. market. *Contact Lens Spectrum*, 29, 23, May 2014.
3. PeroxiClear. Bausch & Lomb Incorporated US/OCD/14/0022. Available at:
<http://www.peroxiclearsolution.com/>

APPENDIX A
IRB FORM APPROVAL

Ferris State University

Institutional Review Board (FSU - IRB)

Office of Academic Research
Ferris State University
1201 S. State Street-CSS 310 H
Big Rapids, MI 49307
(231) 591-2553
IRB@ferris.edu

To: Dr. Josh Lotoczky, Dr. Chad Rosen, Hannah Woodke and Sara Nonhof
From: Dr. Stephanie Thomson, IRB Chair
Re: IRB Application #140708 (Title: *Short-term Clinical Comparison of Two Peroxide Based Disinfecting Contact Lens Solutions*)
Date: October 7, 2015

The Ferris State University Institutional Review Board (IRB) has reviewed your application for using human subjects in the study, "*Short-term Clinical Comparison of Two Peroxide Based Disinfecting Contact Lens Solutions*" (#140708) 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 October 7, 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 (#140708), 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,



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

APPENDIX B

PEROXIDE SOLUTIONS INSTRUCTION KIT

Peroxide Solution Instructions Kit

Kit includes the following:

1. 2 sample bottles of Alcon ClearCare® -OR-
2. 2 sample bottles of Bausch and Lomb PeroxiClear®
3. Instruction Sheet for Alcon ClearCare® and link to online survey -OR-
4. Instruction Sheet for Bausch and Lomb PeroxiClear® and link to online survey
5. 2 informed consent sheets that will be signed and returned to the clinic prior to survey completion

Instructions Sheet for Alcon ClearCare®

Use ClearCare® to clean and disinfect your lenses by following the directions below for 1 month. At the end of the month, discontinue use. An e-mail will be sent to the e-mail account that you provided with a link to an on-line survey that will ask questions regarding your experience..

Instructions for ClearCare® use as dictated by the manufacturer and approved by the FDA Regulations:

Step 1: One of the most important steps to follow for healthy contact lens wear is to wash and dry your hands before touching your contact lenses.

- Start by washing your hands
- Use a soap that's free of oils or lotions
- Dry your hands with a lint-free towel

Once your hands are washed and dry, you're ready to start cleaning your contact lenses.

Step 2: Each ClearCare® solution comes with a special lens case that must be used in order for the solution to work properly.

- *Contains a platinum-coated disc
- *Essential to proper neutralization
- *Converts peroxide into gentle saline solution after 6 hours

The solution and special lens case work together to kill germs and remove protein, bacteria, dirt and buildup that may be on the lenses.

Step 3: Once you're ready, remove and place each soft contact lens into the specially designed lens holders on the unique ClearCare® solution lens case. Do not put ClearCare® solution on your contact lenses and insert them directly into the eye or a burning and stinging or redness will result.

- *Remove and place each contact lens into the appropriately marked L/R domed lens holder. Rinse with ClearCare® solution for 5 seconds.
- *Fill the lens case to fill line with ClearCare® solution and place the lens holder in the case.
- *Tighten the cap and store the lenses for at least 6 hours or overnight. This time is required to allow for complete neutralization of the hydrogen peroxide.
- *Do NOT shake the case.

Instructions Sheet for Bausch and Lomb PeroxiClear®

Use PeroxiClear® to clean and disinfect your lenses by following the directions below for 1 month. At the end of the month, discontinue use. An e-mail will be sent to the e-mail account that you provided with a link to an on-line survey that will ask questions regarding your experience.

Instructions for PeroxiClear® use as dictated by the manufacturer and approved by the FDA Regulations:

Step 1: Always wash, rinse, and thoroughly dry your hands before handling your lenses.

Step 2: Place lenses in special lens case baskets. Only use the lens case provided.

Step 3: Rinse each lens for 5 seconds with the PeroxiClear® solution over a sink or basin.

Step 4: Fill lens case to line with solution and secure lid. Do not invert or shake case.

Step 5: Leave soaking in lens case for at least 4 hours to allow for proper neutralization.

Step 6: Lenses are ready to use.

The red tip means DO NOT put peroxide solution directly in the eye. Failure to follow directions for use will result in burning and stinging. DO NOT place your lens into the eye until complete neutralization of the solution has occurred (minimum 4 hours). Do not rinse lenses with PeroxiClear® solution prior to inserting lenses into your eyes. If you want to rinse your lenses, use a sterile saline solution.

APPENDIX C
PEROXIDE SOLUTION SURVEY

Clinical Evaluation of Alcon ClearCare® and Bausch and Lomb PeroxiClear®

This survey has been developed by investigators in order to gain a better understanding of the subject's contact lens use, contact lens solution use, and impressions of their contact lens solution experiences.

The investigators do not anticipate any risks of harm to the subject as a result of the Contact Lens Information Questionnaire (CLIQ). The Information and Consent Form specifically notes that the subject is not required to answer questions that he/she is uncomfortable with. All tests and reports will be strictly confidential as was explained in the IRB application. No identifying information will be recorded in this survey.

The online questionnaire, as it will be given to subjects in this study, is as follows:

Subject Identification Number: _____

INSTRUCTIONS

This questionnaire is designed to survey your contact lens wearing habits and experiences with the solution you have been using for the past month.

Please complete this online survey by answering the questions as they pertain to your habits and to the solutions being used in this study.

1. How many days per week are you wearing your soft contact lenses?

1 2 3 4 5 6 7

2. How many hours per day are you wearing your soft contact lenses?

<10 10-12 13-15 >15

3. How many nights per week are you sleeping in your soft contact lenses?

1 2 3 4 5 6 7

4. Do you rub your soft contact lenses when cleaning them?

Yes No

5. Do you shower or swim while wearing your soft contact lenses?

Yes No

6. How many weeks do you wear one pair of lenses for?

2 3 4 5 6 7 8 >8

7. How long are your study lenses typically stored in solution each night?

< 4 4-6 7-8 9-10 >10

8. On a scale of one to six, how comfortable are your lenses when you initially insert them? 1 being extremely uncomfortable and 6 being extremely comfortable.

1 2 3 4 5 6

9. On a scale of one to six, how comfortable are your lenses throughout the day? 1 being extremely uncomfortable and 6 being extremely comfortable.

1 2 3 4 5 6

10. On a scale of one to six, how comfortable are your lenses at the end of the day? 1 being extremely uncomfortable and 6 being extremely comfortable.

1 2 3 4 5 6

11. On a scale of one to six, how would you rate your vision with your lenses? 1 being very poor and 6 being very good.

12. Do you like the design of the case you used for the past month?
Yes No
13. Was the case easy to use?
Yes No
14. Did you damage any of your lenses while using this solution and case?
Yes No
15. If yes to question 14, how many lenses did you damage?
16. If yes to question 14, describe how the lens or lenses became damaged?