EVALUATION OF CORNEAL STAINING AND COMFORT ASSOCIATED WITH OPTI-FREE VERSUS BIOTRUE MULTIPURPOSE CONTACT LENS SOLUTIONS

by

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ABSTRACT

The purpose of this research study is to evaluate the amount and distribution of corneal staining due to multipurpose contact lens solution (MPS) exposure. The two solutions that were compared are Opti-Free Replenish (Alcon) and Biotrue (Bausch & Lomb). Staining was evaluated after thirty minutes of contact lens wear, instead of a two hour time interval that has been utilized in prior studies. Recent research has shown that different components of MPS are released for the same contact lens at different rates and the manufacturer states that this is the reason for some MPS having excessive staining at two hours. It has also been stated that the different MPS would cause equal staining amounts if the cornea were to be evaluated at a shorter time period. In this study several subjects wore two contact lenses made of the same material, with one lens being presoaked in Opti-Free for 24 hours and the other lens presoaked in Biotrue solution for 24 hours. After thirty minutes of wear time, the contacts were removed and the amount of corneal staining was objectively evaluated. After this initial visit the subjects continued to store the contact lenses in the two solutions for two additional weeks. At the conclusion of the two week time period, a survey was completed to evaluate how comfort differed between the two lenses based on the solutions used. At the conclusion of this study it was found that the amount of corneal staining at thirty minutes is significantly different than the staining observed at two hours.

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Introduction

There have been several studies on the subject of corneal staining with contact lenses and their many different multipurpose solutions (MPS). This topic has been under great debate since the staining grid was created. The staining grid is a collaboration of numerous studies which exhibits various amounts of staining found with many combinations of soft contact lenses and MPS. Several studies have since been completed with the goal of uncovering what might truly be occurring in order to result in the difference in staining that is observed on the staining grid. The most popular belief is that the staining is caused by the actual components in the MPS. These components are possibly toxic to the cornea. Certain preservatives that are biguanide-based, of which Biotrue is an example, were shown to have a higher rate of corneal staining than other preservatives such as polyquaternium, as found in Opti-Free Replenish, after two hours of wear.[1] This data was alarming for those companies that use a biguanide-based preservative in their MPS. Consequently, some doctors have moved away from using such products to better insure the health of their patients. The question of whether or not the increase in staining noted on the staining grid is in fact significant remains to be answered.

New research is suggesting that biguanide-based products might not be as bad as the staining grid suggests. According to new research, it has been shown that polyhexamethylene biguanide or better known as PHMB does not affect the cell membrane of a corneal epithelial cell.[2] The same research project also found that

fluorescein has a fifty times greater affinity for PHMB as compared to polyquaternium.[2] These two new developments along with the discovery that PHMB is absorbed more readily into an ionic non-silicon hydrogel lens, thus being released at a slower rate, might be the reason for the increased staining seen on the staining grid.[3] Defenders of PHMB say that there is no true staining that is occurring, rather it is a hyperfluorescence that is completely benign.[4] Therefore the patient would not be at any higher risk of pathology. The companies that use PHMB have become quite adamant that if staining was evaluated at a shorter time period than two hours, as used in the staining grid studies, hyperfluorescence would also be seen in MPS that use polyquaterinum.[4] It is our goal to test this theory and to see how the staining compares between a MPS that contains PHMB and one that contains polyquaternium when measured at 30 minutes.

Methods

Twenty optometry students volunteered for this study. They were required to attend two visits to the clinic. The purpose of the first visit was to fit volunteers with a Soflens 66 spherical contact lens. The base curve selected for all contact lenses used in the study was 8.60. The overall diameter selected for all contact lenses in the study was 14.0 mm. The power for the contacts used was determined by the volunteers current distance prescription. This lens was selected because of the large difference in staining seen with this lens on the staining grid in combination with Biotrue and Replenish MPS. After the initial fitting the right lens was stored in Replenish and the left lens was stored in Biotrue. After a twenty four hour period the volunteers inserted the lenses and waited for a half an hour. After a half an hour the lenses where removed and sodium florescein was instilled in the inferior bulbar conjunctiva of both eyes. The amount of staining was then evaluated using a cobalt filter in combination with a Wratten #12 filter. The cornea was divided into five areas; superior, inferior, nasal, temporal, and central cornea. The amount of staining was quantified from 0 to 100 percent for each separate area of the cornea. When all of the staining data was collected the average of each individual area was calculated. These five areas were then averaged to give a more broad sense as to the amount of staining that was found in each eye.

At the conclusion of the second visit the volunteers were instructed to wear the contact lenses on a daily basis. They were also instructed to continue storing the right lens in Replenish and the left lens in Biotrue. At the end of one week of wear the

volunteers were asked to complete a comfort survey. In the survey the subjects were asked to rate the overall comfort of the contact lenses on a scale of one to ten. A score of one represents extreme discomfort, while a score of ten represents extreme comfort. The subjects were also asked to report the average wear time of the contact lenses per day, and the comfort throughout the day, again using the one to ten scale. Finally, they were asked if they had any other additional comments regarding their experience with the contact lenses and multipurpose solutions. The data was then compiled and converted into a percentage in order to easily observe the overall opinion of the volunteers.

Data Analysis

Twenty subjects participated in this study. All subjects were previous contact lens wearers. Subjects were fit with a spherical Soflens 66 (Bausch & Lomb) contact lens. The base curve selected for all contact lenses used in the study was 8.60. The overall diameter selected for all contact lenses in the study was 14.0 mm. The mean dioptric power of the contact lenses selected for wear in the right eye was -2.93. The mode dioptric power selected for wear in the right eye was -1.50. The mean dioptric power of contact lenses selected for wear in the left eye was -3.34. The mode dioptric power selected for wear in the right eye was -3.50.

After the preselected lenses were soaked for 24 hours in Opti-Free Replenish and Biotrue multipurpose solutions, staining was evaluated with fluorescein and a wratten filter. The cornea was divided into five areas and staining was evaluated then graded as a percentage of each area from 0 to 100 percent. The average percentage of staining for the entire cornea for the right eye was 3.68% while the average percentage of staining for the entire cornea for the left eye was 1.79%. The right eye, which had a lens that was soaked in Opti-Free replenish showed more staining at 30 minutes than the left eye, which had a lens that was soaked in Biotrue. Figure 1 (see below) represents the percentage of volunteers that exhibited staining in each sector of the right eye as well as the average percentage of staining exhibited in each sector. More volunteers showed staining in the inferior sector, while a greater average percent stained was shown in the central sector.

Figure 2 (see below) represents the percentage of volunteers that exhibited staining in each sector of the left eye as well as the average percentage of staining exhibited in each sector. Similar to results found in the right eye, a greater amount of volunteers showed staining in the inferior sector, while a greater average percentage of staining was shown in the central sector of the left eye.

After one week of wearing the contact lenses selected for the trial and soaking them in the preselected solutions, a comfort survey was completed. Twelve of 20 participants completed surveys. The contact lens in the right eye was soaked in Opti-Free Replenish and the contact lens in the left eye was soaked with Biotrue. Overall comfort was ranked on a scale of one to ten for each eye. A score of one represents extreme discomfort, while a score of ten represents extreme comfort.

Figure 3 (see below) and Figure 4 (see below) represent the results of the overall comfort survey for the right eye and left eye respectively. The sections represent a percentage of the twelve survey participants that rated each value on a scale of one to ten for each eye, as explained above. The overall comfort rating in the right eye was 6.75, while the overall comfort rating in the left eye was 6.67.

On average the participants who completed the survey found the comfort in the left eye to be greater in the morning, afternoon and evening than the comfort in the right eye. Five of the twelve participants or 41.67% who completed the survey were using Opti-Free Replenish multipurpose contact lens solution prior to the study. Two of the twelve participants who completed the survey, or 16.67%, were using ClearCare contact lens solution prior to the study. One participant of the twelve was previously using

Biotrue, Renu and Rexall multipurpose solutions respectively, prior to the study. The rest of the participants were wearing daily contact lenses and therefore did not require a cleaning solution. The majority of subjects that responded to the survey wore the contact lenses for 12 to 14 hours per day. Several comments given by participants mentioned less comfort; sometimes described as a 'burning sensation' in the left eye initially, but equal comfort with long term wear time.

In conclusion, the corneas fit with a contact lens pre-soaked in Opti-Free multipurpose solution exhibited greater overall staining after thirty minutes of wear time than the corneas fit with a contact lens pre-soaked in Biotrue multipurpose solution. Participants rated the overall comfort of the two lenses after one week of wear time to be approximately equal.

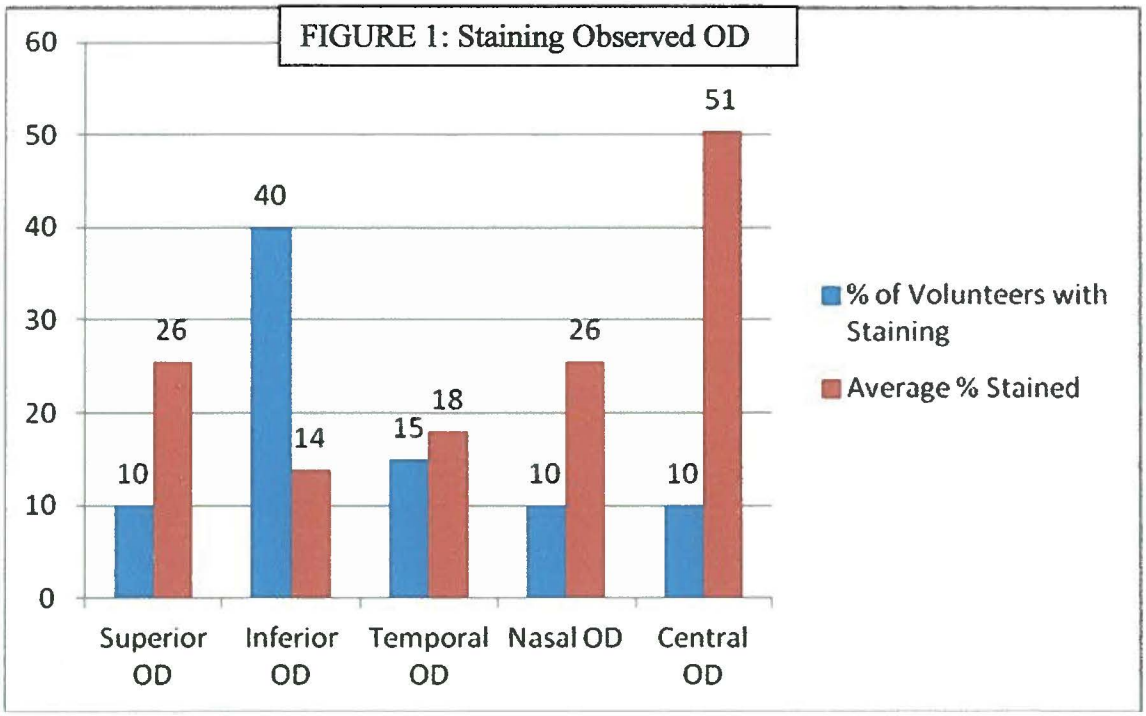


FIGURE 1: Staining Observed OD
60
50
40
30
20
10
0
10
26
40
14
15
18
10
26
10
51
Superior OD
Inferior OD
Temporal OD
Nasal OD
Central OD
% of Volunteers with Staining
Average % Stained

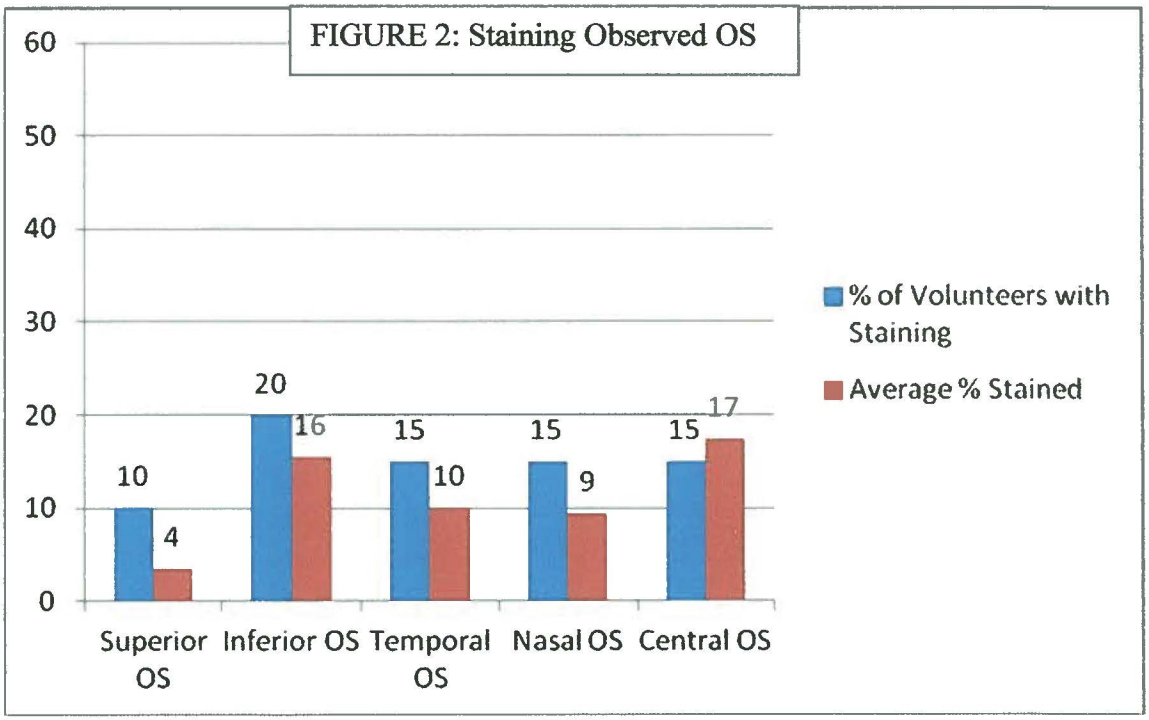


FIGURE 2: Staining Observed OS
60
50
40
30
20
10
0
10
4
20
16
15
10
15
9
15
17
Superior OS
Inferior OS
Temporal OS
Nasal OS
Central OS
% of Volunteers with Staining
Average % Stained

FIGURE 3: Comfort Survey OD

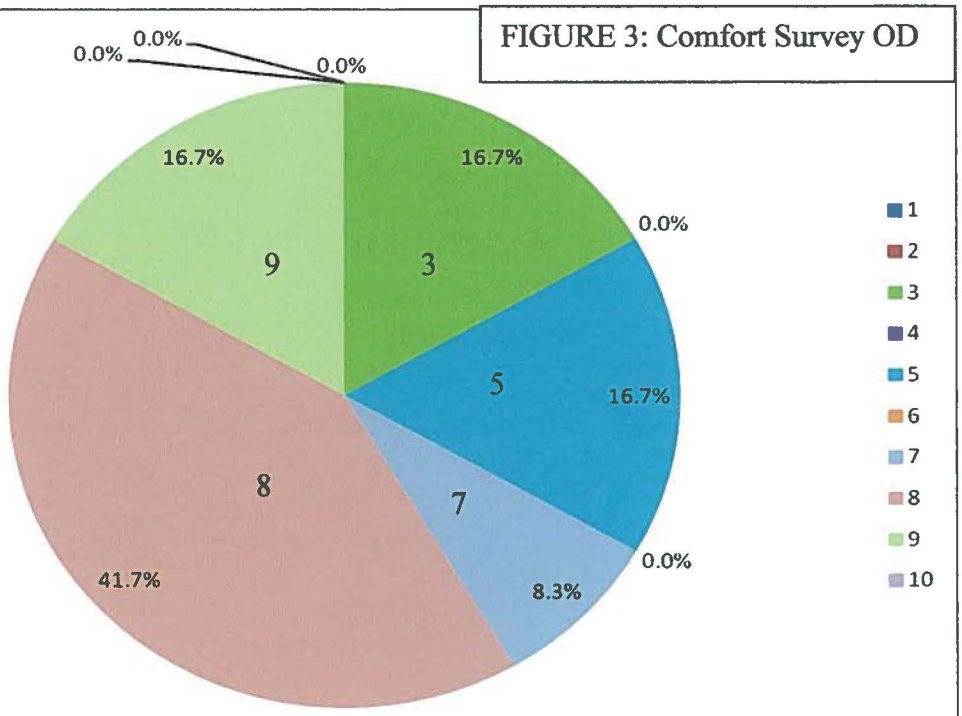
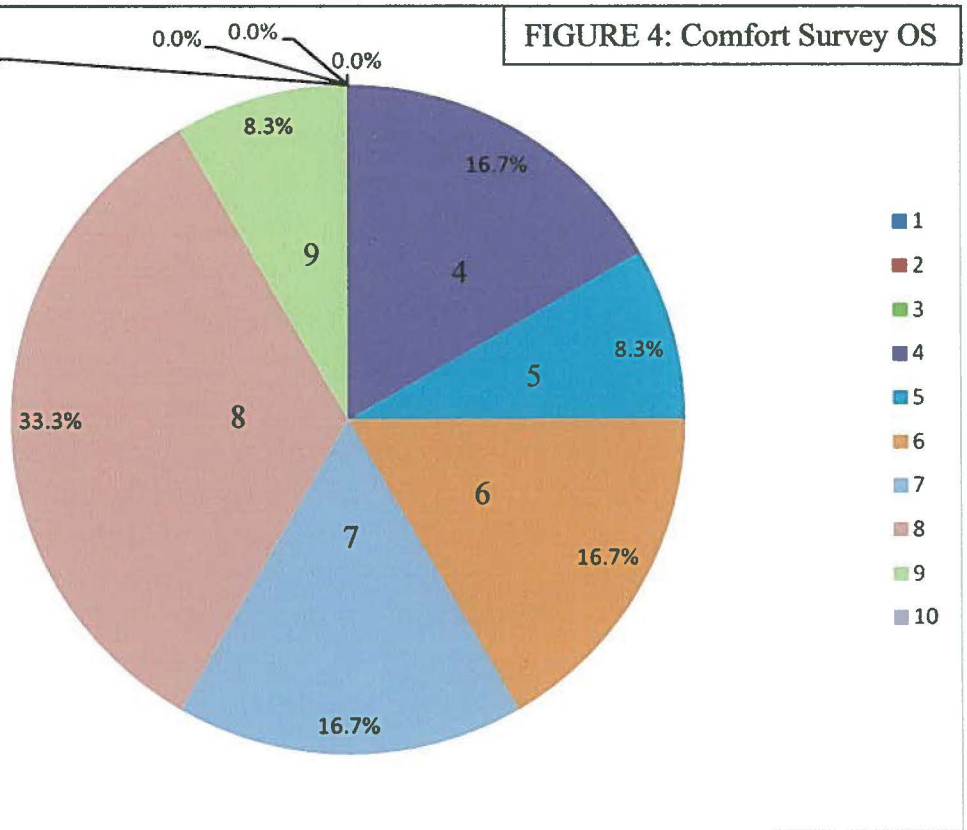


FIGURE 4: Comfort Survey OS



Discussion

Staining was evaluated at two hours when collecting data to create the staining grid. The staining grid shows that the multipurpose contact lens solution Biotrue exhibits more corneal staining than Replenish.[1] Biotrue uses a biguanide-based preservative known as PHMB, while Replenish uses a polyquaternium based preservative. Recent research has shown that fluorescein has a greater affinity to PHMB than polyquaternium.[2] This research has also shown PHMB is absorbed into certain contact lens materials more readily than polyquaternium.[3] Due to this new research it has been suggested that if staining were to be checked at a shorter time period than two hours the staining would be more similar.[4] For this study two lenses were chosen from the staining grid that demonstrated a large difference in staining. The goal of this study was to determine the amount of staining found with Replenish and Biotrue when measured at 30 minutes and compare the results to those on the staining grid.

This study proves that as suggested, the staining found at thirty minutes is very similar for Biotrue and Replenish. Biotrue had significantly less staining at thirty minutes than at two hours. Biotrue exhibited staining of 1.79% of the cornea after thirty minutes, compared to 52% of the cornea reported by the staining grid. Replenish exhibited staining of 3.68% of the cornea after thirty minutes, compared to 1% reported by the staining grid. The staining measured at thirty minutes and at two hours is significantly different. The reason for this difference in staining seen at thirty minutes

compared to two hours still remains unproven.

Although there was a larger amount of staining found at thirty minutes compared to the staining grid for Replenish, the color it would be assigned on the grid would still be green.[1] This could support the theory that true corneal staining is not occurring. If actual epithelial damage occurred then the amount of staining found at thirty minutes compared to that found at two hours would not be expected to be decrease. The rate of corneal repair required to occur in order to result in these findings is far more rapid than what the cornea is capable of.[4] One possible explanation for this decrease in perceived staining from thirty minutes to two hours is that hyperfluorescence is occurring. The data gathered in this study supports the theory that PHMB is held in the lens longer than polyquaternium, thus resulting in greater perceived staining for Biotrue compared to Replenish when measured at two hours. It is possible that true corneal staining is not occurring, in reality it may be hyperfluorescence that is being observed.

One critique of this study is that baseline data regarding corneal staining of subjects prior to the study was not gathered. If one individual had corneal staining greater in one eye than the other prior to the study it could negatively affect the data. One subject did exhibit large amounts of staining in both eyes compared to other subjects. If this staining was due to a preexisting condition then the amounts of staining would be erroneously high. Baseline staining data may have been helpful in determining if the staining observed was pre-existing or from the contact lens wear. Another critique of this study is that the results of the comfort survey are inconsistent. The average overall comfort was approximately equal for both eyes. However, the comfort throughout the day

was rated higher for the left eye than the right eye. Even though the survey responders rated the comfort equal overall between the two eyes and more comfortable throughout the day in the left eye, they also reported many complaints of the left eye causing a stinging sensation. The responses to the survey do not seem to correlate with each other. Historically, comfort surveys are not very consistent and the data collected must be taken with caution.[5]

The results of this study are significantly different than the data reported on the staining grid. It is obvious that the perceived staining or possible hyperfluroescence observed is time sensitive. At thirty minutes more staining is found with Replenish than Biotrue, while on the staining grid the opposite is true. This puts into question the validity of the staining grid, or any staining comparisons made at a certain time interval. More studies should be conducted to determine if other contact lens and MPS combinations give similar results as those found in this study. If MPS related staining is time sensitive, then a new way of evaluating contact lens and MPS compatibility needs to be established. Until this topic is further investigated clinicians should question whether or not the staining grid should impact which MPS they recommend.

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