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Comparative clinical evaluation of rub vs. no rub lens care regimens for a silicone hydrogel soft contact lens

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Abstract

Purpose. Although no-rub cleaning regimens have proven effective with traditional HEMA based lenses, there has been little reported on the impact of deleting the rubbing step for silicone hydrogel lenses. This study investigated the impact of a rub vs. no-rub cleaning regimen on the comfort of a silicone hydrogel contact lens.

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Results: Mean comfortable wearing time for the rubbed lenses (R) was 10 hours (95% CI 7.9, 12.0) compared to the non-rubbed (NR) at 8.35 hours (95% Cl6.1, 10.6). P = 0.1064. Comfort as recorded on a visual analogue scale had a mean of75.1 for the Rand 66.4 for the NR. P = 0.3708. The R group scored higher for overall comfort, end of day comfort and dryness. Forced choice results indicated that subjects preferred the R regimen over the NR. P = 0.0847. There were no differences in slit lamp examination findings.

Conclusions: A cleaning regimen consisting of a 10 second rub showed a trend towards improved comfort and wear time in a pilot study of silicone hydrogel lens wearers. Practitioners may wish to consider this when prescribing lens care for these patients, however, further research with a larger sample size would be warranted to confirm the results of this study.

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Keywords

silicone hydrogel, rub cleaning regimen, no rub cleaning regimen, comfort, lipid deposits

Subject Categories

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COMPARATIVE CLINICAL EVALUATION OF RUB VS. NO RUB LENS CARE REGIMENS FOR A SILICONE HYDROGEL SOFT CONTACT LENS

BY: TRACY JACOBSEN AND

MARK MARAMAN

A THESIS SUBMITTED TO THE FACULTY OF THE COLLEGE OF OPTOMETRY PACIFIC UNIVERSITY FOREST GROVE, OREGON FOR THE DEGREE OF DOCTOR OF OPTOMETRY MAY 2007

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Mark is the recipient of the Peg Gilbert Award for Excellence in Basic Visual Sciences. He is also a member of Beta Sigma Kappa National Honors Society. He plans to complete a residency in ocular disease after graduation.

Abstract

Purpose. Although no-rub cleaning regimens have proven effective with traditional HEMA based lenses, there has been little reported on the impact of deleting the rubbing step for silicone hydrogel lenses. This study investigated the impact of a rub vs. no-rub cleaning regimen on the comfort of a silicone hydrogel contact lens.

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Conclusions: A cleaning regimen consisting of a 10 second rub showed a trend towards improved comfort and wear time in a pilot study of silicone hydrogel lens wearers. Practitioners may wish to consider this when prescribing lens care for these patients, however, further research with a larger sample size would be warranted to confirm the results of this study.

Key Words: silicone hydrogel, rub cleaning regimen, no rub cleaning regimen, comfort, lipid deposits

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Introduction:

It is estimated that 80% of contact lens complications can be attributed to poor compliance with recommended lens care guidelines.[1] Therefore, practitioners have an obligation to the public to make the adequate recommendations offering patients the newest technology and the best choice for their particular lifestyle. It is also imperative that the patient is educated about proper lens care, wearing schedule and cleaning regimen. With the advent of new materials, new issues arise which must be addressed, however, the consumer's safety and desires must not be overlooked when patient education is communicated.

With the advent of silicone hydrogel contact lenses, new problems have arisen concerning the type of lens deposits they accumulate compared to traditional-based HEMA lenses. Traditional lenses have problems with protein deposition which was addressed with new solutions and enzyme cleaners. Silicone hydrogel lenses have incorporated siloxane groups into the base hydrogel material.[2,3] This has greatly improved the oxygen transmission of the lens, however, it has resulted in the production of an extremely hydrophobic surface.[2,3,4] The hydrophobic surface of the lenses attracts and binds lipids forcing the need for surface treatments of the lens to reduce the deposition and increase the wettability of the lens.[2,3,4] Regardless of the attempts to surface coat the lenses, studies have found that the surface remains relatively hydrophobic when compared to conventional hydrogels.[2,4] The lipid deposition does create a problem for some patients and the logical question then becomes, are the cleaning regimens that are available for the traditional lenses now adequate for providing patients with the comfort and safety in new silicone hydrogel contact lenses?

Traditional solutions have been forced to undergo rigorous trials dealing with their safety and efficacy. If the solutions are not effective at removing harmful pathogens, then the patient is put at risk of serious ocular infection.[5] Therefore, the stand-alone procedure was developed which involves mixing a standard inoculum of a representative range of microorganisms with the disinfecting product to ensure that the number of microorganisms is decreased by 3.0 logs if the solution is used as a disinfecting solution.[5] In addition, the solution should reduce the number of yeast or mold by 1.0 log within a set amount of time to be considered as disinfecting solutions.[5] Clinical trials have resulted in no-rub products that work well to remove large amounts of loosely bound, non-denatured protein that is found on many conventional lenses as well as meeting the standards of disinfection.[6] Many traditional solutions contain components such as citric acid and hydroxyalkylphosphonate that adequately remove the protein from the lens and solution.[7] The new silicone hydrogel lenses deposit very small amounts of denatured proteins, and as mentioned previously, deposit larger amounts of lipids when compared to traditional HEMA-based materials.[6]

Another significant difference between the traditional HEMA-based lenses and the new silicone hydrogel lenses that must be considered when taking into account solutions is the reduced wettability of the silicone hydrogel lenses secondary to exposure of silicon groups at the material surface.[7] The decrease in wettability, in addition to the lipid contamination, for most, results in symptoms of dryness and visual dissatisfaction,

predominantly at the end of the day.[4, 7] Patient comfort is a very important factor to consider when suggesting a particular solution to a patient. Up to 50% of contact lens wearers will complain about dryness and discomfort, particularly at the end of the day, and this remains one of the most common reasons that people choose to abort contact lens wear.[7] The new solution OPTI-FREE RepleniSH™ (Alcon, Fort Worth, Texas) has attempted to address this issue of wettability by adding Tetronic 1304 and C9-ED3A.[6] These agents form a network over the surface of the lens to decrease the amount of protein deposition as well as enhance the wettability in an attempt to increase the lens comfort for the wearer.[6] OPTI-FREE RepleniSH™ (Alcon, Fort Worth, Texas) was the solution that was used in this study. The purpose of the study was to investigate the comfort of a silicone hydrogel contact lens using two different cleaning regimens – a no rub cleaning regimen and a rub cleaning regimen.

Materials and Methods:

All materials used were within the expiration date and were obtained from the University where the study was performed. Sixteen subjects were enrolled in the study with fifteen completing the study. All subjects had ≤ 1.00 diopter of astigmatism and a refractive error between -11.00 and +10.00 in each eye. All of the subjects had worn lenses for at least four weeks, without complications, prior to commencement in the study. All subjects were screened to ensure that they complied with the inclusion criteria outlined in Appendix A. If the participants were found to be eligible, the process and aim of the study were explained and an informed consent was signed. The demographics are included in Table 1 in Appenndix B.

The subjects were fit with Ciba Vision O_2 Optix lenses (CIBA Vision, Duluth, GA). Each subject was randomly assigned to either a rub or no rub cleaning regimen. The participants were given a printed copy with instructions on how to clean the lenses including how long to rinse and rub the lenses. A copy of the instructions is included in Appendix A. Participants were instructed not to wear the lenses through the night while sleeping. OPTI-FREE RepleniSH™ (Alcon, Fort Worth, Texas) cleaning solution was used during the study.

Each subject was randomly assigned to a group by flipping a coin. The exact purpose of the study was unknown to the subjects. The subjects were told that they would be evaluating the comfort of two different contact lenses after two weeks of wearing each lens. The subjects wore the O_2 Optix lens (CIBA Vision, Duluth, GA) for two weeks while either rubbing and rinsing or rinsing the lenses without rubbing. They then were told that they would be fit with a different lens requiring a different cleaning regimen. After two weeks, the participants returned and were given a new O_2 Optix lens (CIBA Vision, Duluth, GA) and new printed cleaning instructions. At this visit they were then crossed over to the other subject group – those that had been rinsing and rubbing were switched to a rubbing with no rinsing cleaning regimen.

At the baseline visit the best refraction and keratometry readings were obtained on all subjects. A full slit lamp evaluation was performed noting the location and extent of any conjunctival hyperemia and corneal staining. The O_2 Optix lenses (CIBA Vision, Duluth, GA) were inserted by the investigator and an over refraction was performed. The

fit was assessed by the investigator and the lenses were dispensed if found acceptable. The subjects were asked to assess the initial vision quality of the O_2 Optix lenses (CIBA Vision, Duluth, GA) as a percentage with 0% being poor vision quality and 100% being great vision quality. The subjects were then instructed about the correct way to clean the lenses and they were given contact information for each of the investigators if problems arose.

At the subsequent two week visit, the subjects were asked questions about the lens comfort by the investigators. They were asked to rate the lenses in the areas such as overall comfort, initial comfort, end of day comfort, dryness, and vision quality. Examples of grading scales and subject questionnaires are included in Appendix A. The lenses were evaluated by the investigator and then removed. A refraction was performed on each subject. A slit lamp evaluation with emphasis on location and extent of hyperemia and corneal staining was also performed. A new O_2 Optix lens (CIBA Vision, Duluth, GA) was fit and written and verbal instructions were given to each subject about the correct cleaning regimen.

The final visit included the subjects, once again, evaluating the lenses for overall comfort, initial comfort, end of day comfort, dryness, and vision quality. They were also asked if they preferred the first pair, second pair or if they had no preference in the areas of overall comfort, initial comfort, end of day comfort, dryness, vision and comfortable wearing time. The lenses were evaluated by the investigators and then removed. After the lens was removed, keratometry was performed and a full refraction and slit lamp evaluation was performed. The slit lamp evaluation again focused on extent and location of hyperemia and corneal staining.

Results:

Of the 16 subjects initially enrolled in the study, 15 (93.8%) completed the one month double cross-over study. One subject (6.2%) had to discontinue the study due to lens intolerance. None of the subjects were eliminated from the final outcome data analysis due to non-compliance (defined as > 3 days of missed or improper adherence to the cleaning regimen). Average patient age was 23.6 with 11 female and 5 male participants in the study.

As per study protocol all subjects were current soft contact lens wearers prior to entrance into the study and there were no significant differences between groups in baseline findings of primary or secondary outcome measurements (including: refractive error, best corrected visual acuity, anterior segment examination, subjective questionnaire comfort scale, symptom questionnaire, visual analogue comfort scale, average contact lens daily wearing time, and average comfortable daily wearing time). There were also no significant differences between groups in visual acuity or soft contact lens fit acceptance throughout the duration of the study or at the end of the study.

Primary outcome measurements in our analysis included subjective patient comfort analysis as well as anterior segment evaluation of the cornea and conjunctiva. Anterior segment evaluation showed no statistical or clinical differences between the rub (R) and no-rub (NR) groups (see Table 2, Appendix B). Comfort assessed by visual analogue scale (0—100) had a mean value of 75.1 for the R group and 66.4 for the NR

group, with a paired t-test value of 0.9270 (degrees of freedom = 13, two-tailed p = 0.3708) (see Figure 1, Appendix B). Other subjective symptoms assessed were: overall discomfort, excess tearing, photophobia, itching, burning/stinging, blurred vision, variable vision, dryness, and redness. These symptoms were evaluated based on a 0 to 5 scale, with 0 indicating no symptoms and 5 indicating severe symptoms. There was a trend for less dryness and discomfort for the rub group vs. the no-rub group, with the Wilcoxon Matched-Pairs Signed-Ranks Test showing a statistically significant difference in symptoms of dryness between the groups (dryness: p = 0.02441, Discomfort: p = 0.09424). No other significant differences were apparent between the groups upon analysis of all other symptoms (see Table 3, Appendix B). Other symptoms that presented in the no-rub group included a foreign body sensation, which occurred in 2 of the 16 patients. No additional symptoms were present in the rub group. A patient comfort questionnaire was used to subjectively assess overall comfort, beginning of the day comfort, end of the day comfort, dryness, and vision. As expected, vision and initial comfort were nearly the same in both groups. As shown in Table 4 (Appendix B) there was no statistical difference among the other comfort outcomes, however, overall comfort, end of day comfort, and dryness trended towards the rub group in subjectively feeling better to the patients (Friedman's ANOVA was also performed with similar statistical outcomes showing no significant difference between groups).

Secondary outcomes included: forced choice of lens care regimen (patient blinded), mean contact lens deposition, and average comfortable wear time. Forced choice results found in Table 5 (Appendix B) show a strong trend towards preference of the rub group, however, a Chi-square test for independence did not reach statistical significance (chi-square: 13.889, Degrees of Freedom: 8, p-value: 0.0847). Figure 2 (Appendix B) results show that the majority of patients preferred the rub cleaning regimen to the no-rub regimen for overall comfort, end of day comfort, symptoms of dryness and comfortable wear time. There was no preference for vision or initial comfort for either cleaning regimen. There was no difference in contact lens deposits between groups. Lens deposition was subjectively scored by examiners during slit lamp examination using a scale of 0 to 4 to evaluate the amount of deposit on each lens, as determined at the end of each trial period. The average total group values for lens deposition were as follows: rub-group = 0.27, no-rub group = 0.34. Average comfortable contact lens wearing time was assessed by patient report. Mean comfortable wear time was 10.13 hours/day (95% CI 7.9, 12.00) for the rub group, 8.5 hours/day (95%CI 6.1, 10.6) for the no-rub group. The two-tailed p-value is 0.1064, paired t test = 1.735 with 13 degrees of freedom. Results indicate no statistical difference, but showed a slight advantage for the rub cleaning regimen vs. the no-rub regimen with an increased comfortable wearing time in the rub group (Figure 3, Appendix B).

Although there wasn't a statistically significant difference between the rub and no-rub groups for the majority of the primary or secondary endpoints, all subjective data assessing patient comfort, symptoms and forced choice preference trended towards the rub group. The patient population size was small with an n of 16 for the no-rub group and 15 for the rub group, thereby showing the need for a larger scaled study in order to reach statistical significance for the outcomes measured in this clinical pilot study.

Discussion:

To date, there have been no clinical studies performed to assess the comfort of silicon hydrogel soft contact lenses with the use of standard no-rub cleaning regimens compared to a rub cleaning regimen which has been recommended by many practitioners. This study appears to be the first of it's kind in evaluating the comfort of silicon hydrogel lenses comparing two common cleaning regimens; a no-rub regimen which is the most commonly used regimen among contact lens patients today, and a rub regimen which is being implemented by a growing number of practitioners based on their anecdotal experience with the silicone hydrogel lenses.

For the past several years the contact lens care industry has spent an enormous amount of time, energy, and cost into marketing no-rub multipurpose solutions which provides the contact lens patient a more convenient cleaning, storing, and disinfecting protocol. There is no doubt these solutions have made it easier for contact lens wearers to care for their lenses on a daily basis, while at the same time providing equivalent safety and efficacy rates of other disinfectant/cleaning regimens.[8, 9] All no-rub, multi-purpose solutions use a thorough rinsing procedure in their cleaning regimen instructions, which is used to replace the old standard of rubbing the lenses to remove or loosen any protein or lens deposits which commonly adhere to soft contact lenses.[10] While these multipurpose no-rub solutions have been shown to be very effective in removing protein with traditional HEMA-based lenses there has been some evidence that the silicone hydrogel lenses have a greater affinity for lipid deposition, rather than protein.[6, 7, 11] There is very little evidence on how well these solutions perform in removing or preventing the deposition of lipids[12, 13] and therefore the question remains what effect, if any, these differences will have on the comfort and safety of using the no-rub multipurpose solutions in patients wearing the silicone hydrogel lenses. Is there a reduction in overall lens comfort, comfortable wearing time, or an increase in symptoms of contact lens induced irritation? If the answer is yes to any of these, what is the cause of this decreased comfort or increased irritation – decreased lens wettability, which has been indicated by some to be more prevalent in silicone hydrogel lenses? Increased lipid deposition causing a mechanical irritation or local immune response?

The results in this study have attempted to answer the first question in assessing subjective comfort and irritation criteria. There is some preliminary proof from these results that shows a difference between a rub cleaning regimen and a no-rub cleaning regimen indicating that patients who used the standard no-rub protocol are more prone to an overall decrease in lens comfort, with reduced daily wearing time and increased dryness. Subjective questionnaire results shown in Table 3 (Appendix B) indicate a higher rate of discomfort and dryness in the no-rub cleaning regimen, with all other subjective questions assessing comfort showing a trend in favor of the rub group. These results along with the other subjective findings in this study show a preference for a rub cleaning regimen over a no-rub cleaning regimen using a standard multipurpose solution, Opti-Free RepleniSH™ (Alcon, Fort Worth, Texas). Although these findings represent a small sample size and therefore don't hold statistical significance for most outcomes, the data does support continual trending towards significance in almost every subjective category tested.

Due to cost and the need for specialized equipment we did not attempt to objectively quantify surface properties in order to analyze differences in lens deposition and assess the composition of surface contaminants between the groups. Based on these early findings we feel that further research is warranted in this area to assess lens surface contaminants/deposits which might help to explain the comfort differences seen in this study. Without this information we are left to hypothesize a possible mechanism for why we might see a difference in comfort within these two cleaning protocol regimens. Many studies have shown that the deposition of lipid, protein, cellular debris, or microorganisms on soft contact lenses can lead to irritation and dryness with a decrease in comfort.[14] There has also been evidence as mentioned earlier that silicone hydrogel lenses have a higher tendency to bind lipids to there surface, instead of protein.[6, 13] We hypothesize that the rub cleaning regimen with the multipurpose solution is more effective at removing lens deposits, specifically lipids, than using a no-rub (rinse only) cleaning procedure. This decrease in lipid deposition provides for a cleaner, smoother contact lens surface which results in less contact and irritation with the upper lid and a decreased amount of tear film debris, resulting in reduced overall ocular irritation. In comparison, the no-rub regimen leads to increased lipid deposition on the lens which also allows for other deposits and debris to attach to the lens as well. These deposits not only provide an irregular surface for the upper lid to pass over, but they also have the potential for acting as a reservoir for the attachment of other microorganisms and debris which can accumulate in the tear film causing a greater increase in ocular irritation and symptoms of dryness. It is worth mentioning that not all silicone hydrogel lenses are the same. Our results hold true for the O_2Optix lens (CIBA Vision, Duluth, GA) used in this study, however, results may be different for the other lenses in this class. The basic structure of this class of lenses is the same, but there are differences in the surface properties of the various silicone hydrogels which may affect the lipid binding properties to varying degrees and as a result the comfort outcomes as well.[13]

Decreased vision could have an impact on the patient's perception of comfort and, therefore, affect the other subjective endpoints. There were no differences between groups when assessing vision by subjective patient report. No difference between groups in SCL fit, movement and visual acuity, combined with the patient's perception of equal vision, allows for greater confidence in the outcome measurements and indicates a high validity of the results, free of influence by non-tested parameters. Any differences in environmental or pre-study factors that might influence comfort assessment have been controlled by performing the study in a double cross-over design (some examples may include: climate, lifestyle differences, and anatomical/physiological patient variation such as tear film composition or a predisposition for greater protein/lipid accumulation). Although the cross-over design was very beneficial in controlling variable factors which could not be eliminated or isolated, we would recommend that a wash-out period be performed in any future studies of this kind to help reduce any residual effects from the first cleaning regimen to the next which may influence the outcome results.

As per the instructions of the manufacturer we instructed the patients to thoroughly rinse the lenses before storing them each night in the no-rub group protocol. We wanted to be as realistic as possible as patients do not typically rinse their lenses for five to ten seconds, but are much more likely to simply place the lenses into their case with the multi-purpose solution.[15, 17] This study required the rinsing step, which is most

likely not adhered to by many patients in real life and, therefore, represents a better than expected compliance of the manufacturer's cleaning instructions, giving us the best potential efficacy that these no-rub multipurpose cleaning regimens have to offer. Also, although the O_2Optix lens (CIBA Vision, Duluth, GA) is a two-week replacement lens, it is more realistic that patients will wear a two-week lens an average of three to four weeks or longer.[18] Average length of wear for a pair of replacement lenses in this study was 19.6 days for the no-rub group and 20.1 days for the rub group.

The study was designed to simulate a realistic patient compliance rate as what would be expected in a private practice setting for the maintenance, care, and replacement frequency of the average contact lens wearer. As with any study, controls and the implicit nature of the study itself bias the results towards greater compliance than what is seen in a standard clinical practice. Therefore, it might be expected that these findings indicating a trend towards greater comfort with a rub cleaning regimen might actually be even more dramatic in the standard clinical setting.

In conclusion, our pilot study results indicated a trend based on subjective patient responses of comfort for a preference towards a rub cleaning regimen in the use of silicon hydrogel lenses with multipurpose solutions. Although we were unable to show statistical significance for most of the comfort outcomes, all primary and secondary endpoints showed a strong trend towards the rub group in the areas of improved comfort, decreased symptoms of irritation and dryness, and increased comfortable wearing time. Further research is warranted to confirm the results of this study with the need for a larger sample size to show statistical significance. Studies containing objective data, such as lens deposition analysis, would be very beneficial in assessing the difference between these two cleaning regimens. Likewise, longer range studies assessing comfort over a greater period of time would also help in determining the best lens care regimen for the silicon hydrogel lenses. Based on these early findings, practitioners may want to consider implementing instructions of a rub cleaning regimen when prescribing silicon hydrogel lenses to improve comfort, compliance, and most importantly satisfaction in their contact lens patients. A five second rub of the lenses is a simple and effective cleaning protocol that requires little extra lens care maintenance, with benefits of a cleaner, more comfortable lens for the patient; improving the overall satisfaction with their contact lenses and ultimately their satisfaction with their eye care provider.

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Appendix A (Study Materials)

Lens Care Instructions To Patients:

No-rub Regimen
Contact Lens Care:
Remember to wash hands before inserting and removing lenses.
These lenses are not designed to be worn overnight, but are intended for daily wear only.
It's important with these lenses to follow cleaning and storage procedures precisely as instructed below.
After removing lenses for storage at night:
1. **Thoroughly rinse each side of the lens with the Renu Multi-Purpose Solution provided. (Do not** rinse or store with habitual solution your currently using at home)(if you run out of the solution provided, please contact us and will provide more)

2. Place cleaned contact lens in the lens case and fill with fresh Renu Multi-Purpose Solution. **Soak at least four (4) hours**.

3. Your lenses are now ready to wear. No saline rinse is necessary. If any debris remains on contact lenses, rinse with Renu Multi-Purpose Solution prior to insertion.

Rub Regimen
Contact Lens Care:
Remember to wash hands before inserting and removing lenses.
These lenses are not designed to be worn overnight, but are intended for daily wear only.
It's important with these lenses to follow cleaning and storage procedures precisely as instructed below.
After removing lenses for storage at night:
1. Place small amount of Renu Multi-Purpose Solution on the lens, holding the lens in the palm of your hand. **Next, use the index finger of your other hand to gently message the lens against the palm of your hand for 10 seconds** as demonstrated when you received the lenses.

2. **Thoroughly rinse each side of the lens with the Renu Multi-Purpose Solution provided. (Do not** rinse or store with habitual solution your currently using at home)(if you run out of the solution provided, please contact us and will provide more)

3. Place cleaned contact lens in the lens case and fill with fresh Renu Multi-Purpose Solution. **Soak at least four (4) hours**.

4. Your lenses are now ready to wear. No saline rinse is necessary. If any debris remains on contact lenses, rinse with Renu Multi-Purpose Solution prior to insertion.

ID: **Baseline:Visit 1**

VISIT DATE: (MM/DD/YY) ☐☐ ☐☐ ☐☐ Sex: M ☐ F ☐ Age: ☐☐

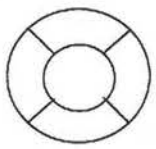
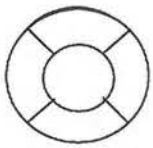
Completed Informed Consent? Yes ☐ No ☐ Current Lens Brand: _____

Average daily wearing time with current contact lenses: ☐☐ (hours per day)

Average comfortable daily wearing time with current contact lenses: ☐☐ (hours per day)

	RE	LE
Spectacle refraction	±☐☐.☐☐-☐.☐☐ x ☐☐☐	±☐☐.☐☐-☐.☐☐ x ☐☐☐
Distance VA (with spec Rx)	20 / ☐☐.☐	20 / ☐☐.☐
Best Vision Sphere	±☐☐.☐☐ D	±☐☐☐☐ D
Distance VA (with BVS)	20 / ☐☐.☐	20 / ☐☐.☐
Keratometry Fl	☐☐.☐☐ @ ☐☐☐	☐☐.☐☐ @ ☐☐☐
Keratometry St	☐☐.☐☐ @ ☐☐☐	☐☐.☐☐ @ ☐☐☐

SLIT LAMP EXAMINATION

	RE	LE
Bulbar Conjunctiva	0 ½ 1 ½ 2 ½ 3 ½ 4	0 ½ 1 ½ 2 ½ 3 ½ 4
Limbal Hyperaemia	☐☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐☐
Bulbar Hyperaemia	☐☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐☐
Palpebral Conjunctiva		
Upper Palp. Hyperaemia	☐☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐☐
Lower Palp. Hyperaemia	☐☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐☐
Corneal Staining		
Extent	☐☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐☐
Region	S I N T C	S I N T C
		
Conj. staining	☐☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐☐
Region	S I N T	S I N T
	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐
Other Slit Lamp Findings (please grade & describe)	☐☐☐☐☐☐☐☐☐ _____	☐☐☐☐☐☐☐☐☐ _____

Comments on Baseline:

Sub ID: ☐☐–☐☐☐ **Dispensing Visit 1 / Visit 2** ☐ ☐

Insert Lenses according to Enrolment Log

	RE	LE
Lens Type:	O2 Optix	O2 Optix
Cleaning Regimen	Rub/No Rub ☐ ☐	Rub/No Rub ☐ ☐
Base Curve:	☐☐.☐ mm	☐☐.☐ mm
Power	±☐☐.☐☐ D	±☐☐.☐☐ D
Lot #:	_____	_____

Assess if lenses are suitable to dispense

	RE	LE
Distance VA (with CLs) (Without over-refraction)	20 / ☐☐.☐	20 / ☐☐.☐
BVS over-refraction	±☐☐.☐☐ D	±☐☐.☐☐ D
Distance VA (with CLs) (With over-refraction)	20 / ☐☐.☐	20 / ☐☐.☐
Vision quality	☐☐☐ %	☐☐☐ %

	RE	LE
Centration:	Horizontal ±☐☐.☐ mm Vertical ±☐☐.☐ mm	Horizontal ±☐☐.☐ mm Vertical ±☐☐.☐ mm
	plus – nasal/superior minus – temporal/inferior	
Corneal Coverage	Yes ☐ No ☐	Yes ☐ No ☐
Post-Blink Movement	☐.☐ mm	☐.☐ mm
Push-up Test	☐☐☐ %	☐☐☐ %
Fit Acceptance	0 ½ 1 ½ 2 ½ 3 ½ 4 ☐☐☐☐☐☐☐☐☐	0 ½ 1 ½ 2 ½ 3 ½ 4 ☐☐☐☐☐☐☐☐☐
Reason if ≤2	_____	_____
Lens OK to dispense	Yes ☐ No ☐	Yes ☐ No ☐
Reason if no	_____	_____

Subject was provided with Renu Moistureloc Multipurpose Solution and schedule next visit

Comments on dispensing:

Sub ID: ☐☐ – ☐☐☐

Visit ID	Visit 1	Visit 2	Visit 3	Unsched	Unsched
		Baseline	Rub	No Rub	
	☐	☐	☐	☐	☐

Visit date (MM/DD/YY): ☐☐/☐☐/☐☐

Wearing time today ☐☐

Number of days worn since last visit: ☐☐

Number of Noncompliant cleaning regimen days: _____

	RE	LE
Symptoms & Problems:	None----------Severe	None----------Severe
Discomfort	0 1 2 3 4 5	0 1 2 3 4 5
Excess tearing	0 1 2 3 4 5	0 1 2 3 4 5
Photophobia	0 1 2 3 4 5	0 1 2 3 4 5
Haloes	0 1 2 3 4 5	0 1 2 3 4 5
Itching	0 1 2 3 4 5	0 1 2 3 4 5
Burning/stinging	0 1 2 3 4 5	0 1 2 3 4 5
Blurred vision	0 1 2 3 4 5	0 1 2 3 4 5
Variable vision	0 1 2 3 4 5	0 1 2 3 4 5
Dryness	0 1 2 3 4 5	0 1 2 3 4 5
Redness	0 1 2 3 4 5	0 1 2 3 4 5
Other (describe below)	0 1 2 3 4 5	0 1 2 3 4 5
	----------	----------

***Please** ask subject to complete Comfort at Visit (10cm VAS)*

	RE	LE
Distance VA (with CLs) (Without over-refraction)	20 / ☐☐.☐	20 / ☐☐.☐
Vision quality (0 to 100)	☐☐ ☐%	☐☐ ☐%

	RE	LE
Centration:	Horizontal ±☐☐.☐ mm Vertical ±☐☐.☐ mm	Horizontal ±☐☐.☐ mm Vertical ±☐☐.☐ mm
	plus – nasal/superior minus – temporal/inferior	
Corneal Coverage	Yes ☐ No ☐	Yes ☐ No ☐
Post-Blink Movement	☐☐ mm	☐.☐ mm
Push-up Test	☐☐☐ %	☐☐☐ %
Fit Acceptance	0 ½ 1 ½ 2 ½ 3 ½ 4 ☐☐☐☐☐☐☐☐☐	0 ½ 1 ½ 2 ½ 3 ½ 4 ☐☐☐☐☐☐☐☐☐
Reason if <3	_____	_____

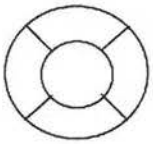
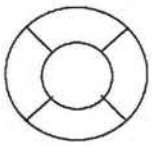
Comments

Baseline Rub No Rub

Sub ID: ☐☐-☐☐☐ **Visit ID** Visit 1 ☐ Visit 2 ☐ Visit 3 ☐ Visit 4 ☐ Unsched ☐

Please remove lenses and place in a lens case with saline. If this is Visit 3 or Visit 5, please ensure these lenses are labelled and stored in preparation for return.

SLIT LAMP EXAMINATION

	RE	LE
Bulbar Conjunctiva	0 ½ 1 ½ 2 ½ 3 ½ 4	0 ½ 1 ½ 2 ½ 3 ½ 4
Limbal Hyperaemia	☐☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐☐
Bulbar Hyperaemia	☐☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐☐
Palpebral Conjunctiva		
Upper Palp. Hyperaemia	☐☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐☐
Lower Palp. Hyperaemia	☐☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐☐
Corneal Staining		
Extent	☐☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐☐
Region	S ☐ I ☐ N ☐ T ☐ C ☐	S ☐ I ☐ N ☐ T ☐ C ☐
		
Conj. staining	☐☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐☐
Region	S ☐ I ☐ N ☐ T ☐	S ☐ I ☐ N ☐ T ☐
Amount of Lens Deposit	☐☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐☐
Other SLF	☐☐☐☐☐☐☐☐☐	☐☐☐☐☐☐☐☐☐
(please grade & describe)	_____	_____

SUBJECTIVE QUESTIONNAIRE

Please ask the subject the following questions using the wording provided

'On a scale of 'Excellent', 'Very good', 'Good', 'Fair' & 'Poor', how would you rate the performance of the lenses you are currently wearing, for the following?'

	Poor	Fair	Good	Very Good	Excellent
Overall comfort	1	2	3	4	5
Initial comfort	1	2	3	4	5
End of day comfort	1	2	3	4	5
Dryness	1	2	3	4	5
Vision	1	2	3	4	5

'What is your average comfortable daily wearing time?' ☐☐ *(hours per day)*

- ***If this is Visit 2 please continue to dispense the second pair of lenses on the Visit 2 Dispensing form.***
- ***If this is Visit 3 please complete the Preference Questionnaire & Exit Form***

Comments:

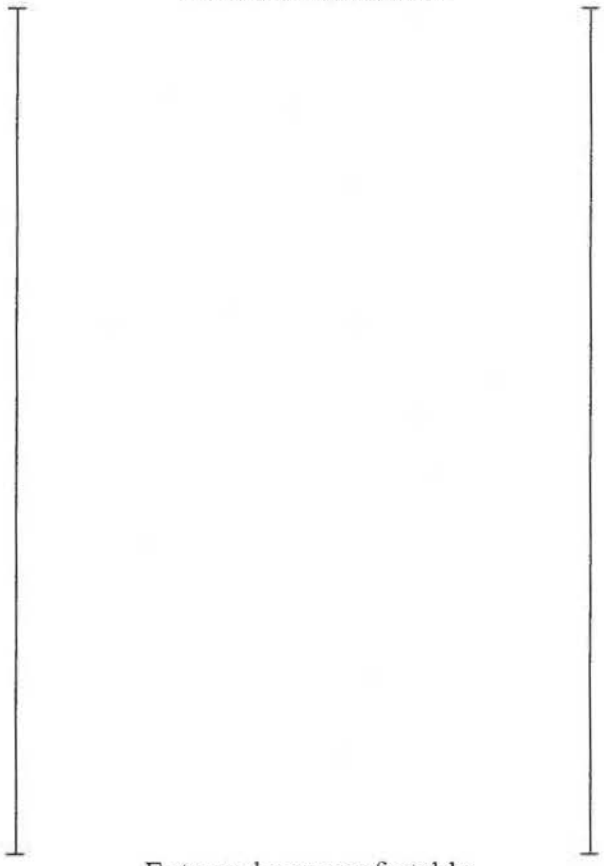
Sub ID: ☐☐ – ☐☐☐	Visit ID	Baseline: Visit 2	Visit 3	Rub: Visit 4	No Rub: Visit 5	Unsched
		☐	☐	☐	☐	☐

Visual Analogue Scale: Comfort at Visit

Please indicate how comfortable your eyes feel:

LEFT **RIGHT**

Extremely comfortable,
Lenses unnoticeable



Extremely uncomfortable
Impossible to wear the lenses

Sub ID ☐☐ – ☐☐☐ VISIT DATE (DD/MM/YY) ☐☐ ☐☐ ☐☐ **Study Exit**

Was the subject compliant with both cleaning regimens (miss < 7 days)? ☐ YES ☐ NO

If YES please complete the Preference Questionnaire. If NO please go to section 3

PREFERENCE QUESTIONNAIRE ***(Please ask the subject the following questions using the wording provided)***

'Did you prefer the first pair of lenses or the second pair of lenses, which you wore on this study, for the following? (you may choose no preference if this is the case).''

	1st Pair	2nd Pair	No preference
Overall comfort	☐	☐	☐
Initial comfort	☐	☐	☐
End of day comfort	☐	☐	☐
Dryness	☐	☐	☐
Vision	☐	☐	☐
Comfortable wearing time	☐	☐	☐

	RE	**LE**
Spectacle refraction	±☐☐.☐☐ - ☐.☐☐ x ☐☐☐	±☐☐.☐☐ - ☐.☐☐ x ☐☐☐
Distance VA (with spec Rx)	20 / ☐☐.☐	20 / ☐☐.☐
Best Vision Sphere	±☐☐.☐☐ D	±☐☐☐☐ D
Distance VA (with BVS)	20 / ☐☐.☐	20 / ☐☐.☐
4 Keratometry Fl	☐☐.☐☐ @ ☐☐☐	☐☐.☐☐ @ ☐☐☐
St	☐☐.☐☐ @ ☐☐☐	☐☐.☐☐ @ ☐☐☐

5 Did the subject complete the study successfully? ☐ YES ☐ NO

If YES stop here. If NO continue below.

Please indicate the main reason for discontinuation (one reason only and indicate which eye, if applicable)

Investigator Dissatisfied	Subject Dissatisfied	Other
☐ Visual Acuity	☐ Visual Acuity	☐ Lost to Follow-up
☐ Slit Lamp Findings	☐ Discomfort	☐ Disinterest
☐ Adverse Reaction	☐ Handling	☐ Unable to Attend Appoints
☐ Unacceptable Lens Fit		☐ Unrelated Medical Problem
.....		☐ Protocol Deviation
.....		☐ Inclusion / Exclusion Criteria
..... ←		☐ Other (please explain to the left)

Which eye did this problem relate to? N/A☐ Left☐ Right☐ Both☐

Does subject require a post study follow-up visit? NO☐ YES☐ → ..... (Reason if YES)

I have reviewed all data IN THESE CASE REPORT FORMS and found THEM to be complete and accurate.

_____ ____/____/____

Principal Investigator's Signature **Date**

Eligibility Checklist

Please indicate whether the following statements are true or false:

		True	False
1.	The subject is of legal age (i.e. 18 years or over)	☐	☐
2.	Subject has signed Written Informed Consent.	☐	☐
3.	The subject is an existing soft contact lens wearer and has worn lenses at least 4 weeks prior to study commencement	☐	☐
4.	The subject has not worn RGP or PMMA lenses within the last 4 weeks	☐	☐
5.	Please ask subject the following comfort question & ensure that approximately half the subjects enrolled have a typical maximum comfortable wearing time of 10 hours per day: *'What is your typical maximum comfortable wearing time in hours per day?'*	☐☐ (Hours per day)	
6.	The subject has normal, healthy eyes (see protocol section 5.3)	☐	☐
7.	The subject requires a visual correction in both eyes	☐	☐
8.	The subject requires a spherical distance contact lens correction in the range: -1.00 to -10.00D or less then +10.00D in each eye	☐	☐
9.	The subject has astigmatism less than or equal to1.00D in both eyes	☐	☐
10.	The subject is spherically correctable to a visual acuity of 20/30 or better	☐	☐
11.	The subject is not taking any ocular medication	☐	☐
12.	The subject has no systemic illness affecting contact lens wear or the medical treatment of which would affect vision or successful lens wear	☐	☐
13.	The subject has not had eye surgery or injury in last eight weeks	☐	☐
14.	The subject has no abnormal lacrimal secretions	☐	☐
15.	The subject has no pre-existing ocular irritation that would preclude contact lens fitting	☐	☐
16.	The subject is not an existing extended/continuous wearer (i.e. overnight wear)	☐	☐
17.	The subject does not have keratoconus or other corneal irregularity	☐	☐
18.	The subject is not pregnant, lactating or planning a pregnancy	☐	☐
19.	The subject is not participating in any concurrent clinical trial	☐	☐
20.	The subject does not have known hypersensitivities to any SCL solutions	☐	☐

If ALL statements are 'True', this patient is eligible to be enrolled. Please assign the next available subject ID in the Enrolment Log, indicate this below and continue with Baseline Visit

Subject ID Number: Subject # ☐☐ Initials ☐☐☐

If ANY statement is 'False', this patient is not eligible to be enrolled. They must not take a subject number and may not be enrolled in the study.

Appendix B (Tables & Graphs)

Table 1 Study Demographics

	Mean ± SD	Range
Age	23.6 +/- 2.4	21 to 31
Sphere	-4.45 ± 2.99	-0.75 to -11.00
Cylinder	-0.125 ± 0.224	0 to -0.75
Flat Keratometry Reading	43.64 ± 1.62	40.25 to 46.00
Steep Keratometry Reading	44.31 ± 1.56	41.25 to 46.50

Table 1.
Patient demographics showing mean age, refractive status, and corneal curvature by keratometry. The sphere, cylinder, and keratometry values were all calculated based on the measurements of the right eye. No subject in the study had anisometropia of greater than 1.50 diopters.

Table 2 Summary of anterior segment findings (scale: 0—none to 4--extreme)					
No-rub (N = 16)	Limbal Hyperemia	Bulbar Hyperemia	Palpebral Hyperemia	Corneal Staining	Conjunctival Staining
Mean	0.41	0.47	0.25	0.44	0.13
SD	0.38	0.39	0.26	0.48	0.22
Rub (N =15)	Limbal Hyperemia	Bulbar Hyperemia	Palpebral Hyperemia	Corneal Staining	Conjunctival Staining
Mean	0.23	0.40	0.10	0.40	0.20
SD	0.25	0.27	0.20	0.66	0.31
p-value (two-tailed)	0.1251	0.5652	0.0788	0.8443	0.4682

Table 2.
Anterior segment slit lamp examination findings. Showing mean differences between the Rub cleaning regimen group vs. the No-rub cleaning regimen group. Conjunctival hyperemia, corneal staining, and conjunctival staining was assessed subjectively by the examiner using a scale from 0 to 4, with a score of 0 indicating no hyperemia/staining and 4 indicating severe hyperemia/staining.

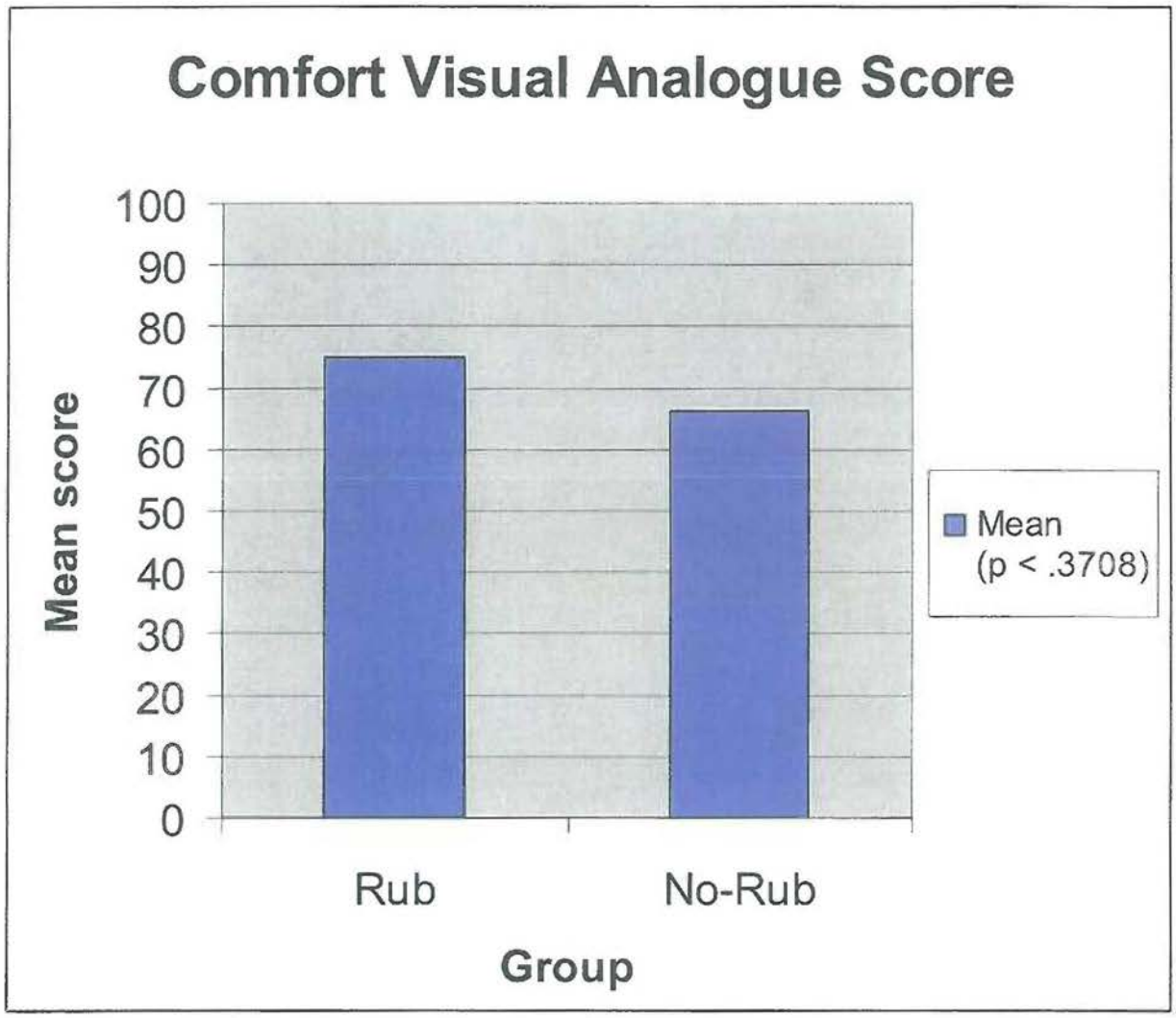


Figure 1.
Subjective comfort scale is shown above, comparing the rub group vs. the no-rub group. Comfort was assessed using the visual analogue scale from 0 to 100 (as shown in Appendix A). N = 15 for the Rub group and N = 16 for the No-Rub group.

Table 3
Summary of symptoms (scale: 0—none to 5--extreme)

No-rub (N = 16)	Discomfort	Excess tearing	Photophobia	Itching	Burning/Stinging	Blurred Vision	Variable vision	Dryness	Redness
Mean	2.19	0.44	0.31	0.75	0.88	0.5	0.38	2	0.5
SD	0.98	0.89	0.6	1.24	1.15	0.73	0.62	1.26	0.89
Rub (N=15)	Discomfort	Excess tearing	Photophobia	Itching	Burning/Stinging	Blurred Vision	Variable vision	Dryness	Redness
Mean	1.37	0.07	0.13	0.27	0.8	0.27	0.47	0.87	0.07
SD	1.04	0.26	0.35	0.59	0.86	0.46	0.74	0.99	0.26
W+	70	8.5	8	13	19	8.5	20.5	58	6
W-	21	1.5	2	2	17	1.5	24.5	8	0
p-value	0.09424	0.25	0.375	0.1875	0.9453	0.25	0.8203	0.02441	0.25

Table 3.
Subjective symptoms as reported by the patient, showing mean differences between the Rub cleaning regimen group vs. the No-rub cleaning regimen group. Patients rated their symptoms from 0 to 4, with a score of 0 indicating no symptoms and 4 indicating severe symptoms. Statistical analysis was performed using the Wilcoxon Matched-Pairs Signed-Ranks Test. (W+ indicates the sum of all positive ranks, W- indicates the sum of all negative ranks)

Table 4 Summary of subjective comfort questionnaire (scale: 1--poor to 5--excellent)					
No-rub (N = 16)	Overall comfort	Initial comfort	End of day comfort	Dryness	Vision
Mean	3.31	4.00	2.75	3.44	4.44
SD	0.946	0.966	0.774	1.153	0.629
Rub (N = 15)	Overall comfort	Initial comfort	End of day comfort	Dryness	Vision
Mean	3.8	4.2	3.33	3.93	4.47
SD	0.862	0.775	0.976	0.799	0.516
W+	27	15	35.5	31.5	10.5
W-	9	6	9.5	13.5	10.5
p-value	0.25	0.4375	0.1289	0.3008	1.000

Table 4.
Subjective comfort rating as reported by the patient, showing mean differences between the Rub cleaning regimen group vs. the No-rub cleaning regimen group. Patients rated their symptoms from 1 to 5, with a score of 1 indicating extreme discomfort and 5 indicating a high level of comfort. Statistical analysis was performed using the Wilcoxon Matched-Pairs Signed-Ranks Test. (W+ indicates the sum of all positive ranks, W- indicates the sum of all negative ranks)

Table 5 Summary of forced choice results						
	Overall Comfort	Initial Comfort	End of Day Comfort	Dryness	Vision	Comfortable Wearing Time
Rub	8 (53.33%)	2 (13.33%)	8 (53.33%)	8 (53.33%)	5 (33.33%)	10 (66.67%)
No Rub	5 (33.33%)	3 (20.00%)	4 (26.67%)	3 (20.00%)	2 (13.33%)	3 (20.00%)
No Preference	2 (13.33%)	10 (66.67%)	3 (20.00%)	4 (26.67%)	8 (53.33%)	2 (13.33%)
Chi-square for independence: 13.889, DOF: 8, p-value: 0.0847						

Table 5.
Forced choice analysis. The table above shows the results of the patient responses given to which cleaning regimen they preferred based on comfort, dryness and vision. Results were statistically analyzed using the Chi-square test for independence. (DOF = Degrees of Freedom)

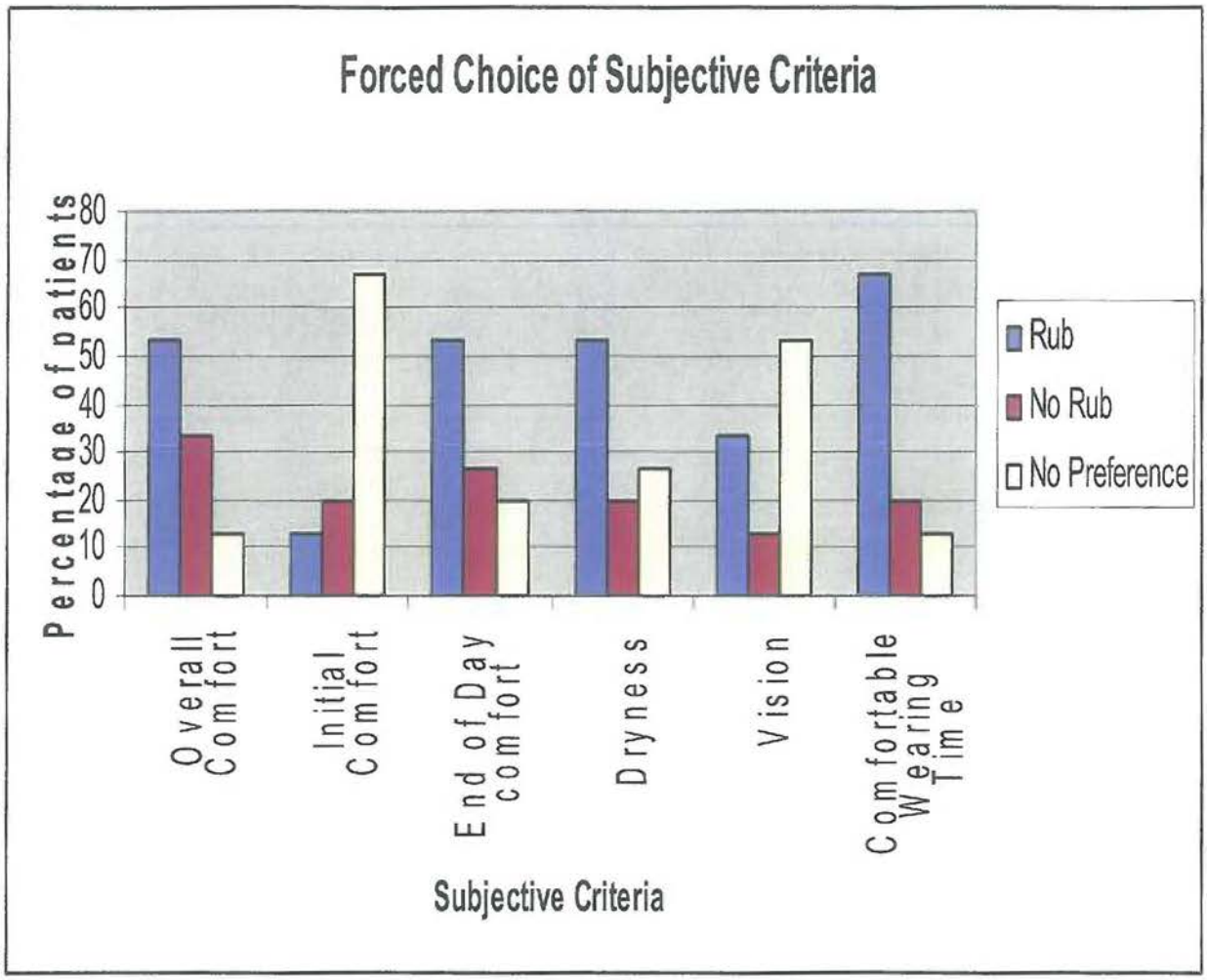


Figure 2.
Graph of forced choice results. Overall comfort, end of day comfort, dryness, and comfortable wearing time shows patient preference for the rub cleaning regimen. Vision and initial comfort criteria show that patients did not have a preference for either treatment group. Statistical significance was not reached for any of the criteria.

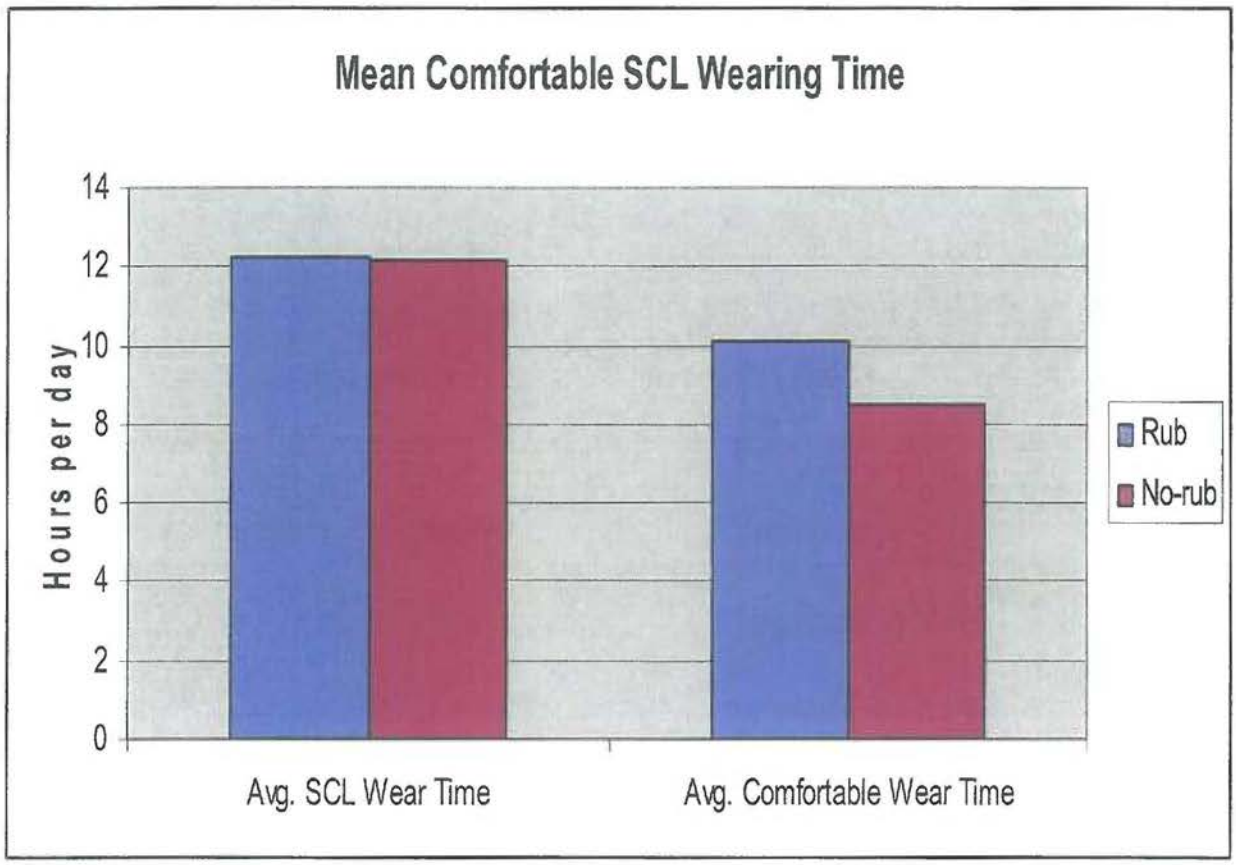


Figure 3.
Graph of mean comfortable wear time comparing rub cleaning regimen to no-rub cleaning regimen. There were no statistically significant differences between groups.