The effect of topical Voltaren use on initial patient satisfaction and overall success with rigid gas permeable lenses

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Abstract
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Subjects/Methods: Ten subjects were enrolled, all of whom were new rigid lens wearers and free of contraindicating corneal disease. Two randomly selected groups were chosen for either the placebo or Voltaren drops. Each subject was evaluated using currently accepted fitting techniques, and at the dispense were given a manila envelope containing the masked bottle marked "A" or "B". Each subject filled out two questionnaires based on their perception of, and adaptation to, rigid lenses at four intervals: pre-fitting, after fifteen minutes post-fit, at one week and one month. Each subject was re-evaluated at these sessions as well to ensure their lenses were fitting appropriately.

Results: Statistics were run using unpaired tests for each questionnaire and significance was found, albeit in favor of the placebo group, in five categories: Long Term Wear, Comfort, Tearing, Lens Awareness and Blinking.

Discussion: Results from this study indicate that there is no statistical significance in favor of using Voltaren versus the placebo. This may have been due to a preexisting bias of those in the placebo group even though each subject was randomly assigned, as there was significance found in the Pre-Fit answers to the questions of Long Term Wear and Lens Awareness. This factor may have negatively impacted the results. Further study needs to be undertaken on this subject, using Voltaren at least three times prior to lens insertion at dispense.

Degree Type
Thesis

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The Effect of Topical Voltaren Use on Initial Patient Satisfaction and Overall Success with Rigid Gas Permeable Lenses

By

Kerri Carr
Patricia Bleckinger

A thesis submitted to the faculty of the College of Optometry Pacific University Forest Grove, Oregon for the degree of Doctor of Optometry

December, 2000

Advisors:

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Kerri Carr

Kerri Carr was born in Newberg, Oregon. In 1995 she received her Bachelor of Science degree in Psychology from Pacific University. She is currently a fourth year optometry student. Upon graduating with a Doctor of Optometry degree in May, 2001 she plans to practice primary care optometry with an emphasis in vision training.

Patricia Bleckinger

Patricia Ann Bleckinger is originally from Buffalo, NY. She received her Bachelors Degree in Biology from Portland State University and will be residing in Eugene, Oregon upon graduating Pacific University College of Optometry with honors. Her main area of focus in optometry will be in the realm of pediatrics and/or retinal co-management. Her other areas of interest outside optometry include sea kayaking and hiking in the beautiful Northwest.
Acknowledgments

We would like to extend our sincere thanks to our faculty advisors, Dr. Jennifer Smythe and Patrick Caroline for consultation and guidance on this project.
Abstract

Introduction: Rigid gas permeable lenses have many advantages over soft contact lenses yet due to ocular discomfort and associated period of adaptation required with this modality, many practitioners neglect to consider this option. Topical anti-inflammatory drugs (NSAIDs), including diclofenac sodium or Voltaren, have become popular among practitioners for its analgesic, anti-inflammatory and anti-puretic effects. It has also been demonstrated that Voltaren decreases corneal sensitivity and has an anesthetic effect in healthy, unoperated human corneas, and that pretreatment with diclofenac before cataract surgery decreases post-operative inflammation. Our proposal is that the use of Voltaren post RGP dispense for one week will provide increased comfort, better tolerance and improve adaptability to RGP use.

Subjects/Methods: Ten subjects were enrolled, all of whom were new rigid lens wearers and free of contraindicating corneal disease. Two randomly selected groups were chosen for either the placebo or Voltaren drops. Each subject was evaluated using currently accepted fitting techniques, and at the dispense were given a manila envelope containing the masked bottle marked "A" or "B". Each subject filled out two questionnaires based on their perception of, and adaptation to, rigid lenses at four intervals: pre-fitting, after fifteen minutes post-fit, at one week and one month. Each subject was re-evaluated at these sessions as well to ensure their lenses were fitting appropriately. Results: Statistics were run using unpaired t-tests for each questionnaire and significance was found, albeit in favor of the placebo group, in five categories: Long Term Wear, Comfort, Tearing, Lens Awareness and Blinking. Discussion: Results from this study indicate that there is no statistical significance in favor of using Voltaren versus the placebo. This may have been due to a preexisting bias of those in the placebo group even though each subject was randomly assigned, as there was significance found in the Pre-Fit answers to the questions of Long Term Wear and Lens Awareness. This factor may have negatively impacted the results. Further study needs to be undertaken on this subject, using Voltaren at least three times prior to lens insertion at dispense.
Introduction

Rigid gas permeable (RGP) contact lenses have many advantages over soft contact lenses, yet practitioners often neglect consideration of this option due to a number of factors. RGP lenses are more difficult to accurately fit than soft lenses, however a more common problem encountered by eye-care professionals and their patients is the ocular discomfort and associated period of adaptation on initiation of lens wear. Due to the smaller diameter and thicker, less flexible composition of RGP lenses, lens-wearers often describe ocular foreign body sensation, increased blinking frequency, pruritus, lacrimation, movement of the lens, photophobia, blurred vision and redness. These symptoms are caused by the sensitivity of the cornea and lid margin to the repetitive mechanical trauma from blinking against the lens edge. In an effort to reduce these symptoms, alterations to the lens architecture have been made with limited success.' During the fitting process topical anesthetic drops such as proparacaine are often used,' however long-term use is contraindicated due to risk of corneal toxicity and the problems with adaptation persist. This frequently leads to discontinuation of contact lens wear and dissatisfaction of patient and provider alike.

Topical nonsteroidal anti-inflammatory drugs (NSAIDs) have gained widespread popularity among eyecare professionals for their versatility in providing relief of ocular discomfort. NSAIDs produce potent analgesic, antipyretic and anti-inflammatory effects. Diclofenac sodium is a member of the phenylacetic acid group of NSAIDs. It is thought to act as an inhibitor of the cyclooxygenase arm of the arachidonic acid metabolic pathway. This causes shunting of arachidonic acid to the triglyceride pool
and reduces its availability for prostacyclin, prostaglandin, thromboxane and leukotriene synthesis, which are involved in the inflammatory cascade and pain pathways. This explains in part both its anti-inflammatory effect and its ability to induce corneal anesthesia. The complete mechanism of action remains controversial, and other proposed mechanisms include increased levels of beta-endorphins and depressed corneal nerve conduction. Side effects are minimal, with a transient burning and stinging sensation of varying intensity most commonly reported immediately after instillation of drops; those with allergy to systemic NSAIDs should avoid topical use as well due to risk of reaction.

Studies have shown significant benefits with use of topical diclofenac in reducing corneal surface pain following excimer laser corneal refractive surgery, traumatic abrasions and removal of corneal rust ring. Diclofenac treated patients rarely experience the early peak in pain after photorefractive keratectomy, and experience less pain overall. In addition, such patients have significantly less post-laser photophobia, burning and stinging symptoms. Diclofenac is also effective in treating symptoms of allergic conjunctivitis, including episcleritis, hay fever conjunctivitis, phlyctenular conjunctivitis, and corneal limbal ulcers. It has also been demonstrated that diclofenac decreases corneal sensitivity and has an anesthetic effect in healthy, unoperated human corneas, and that pretreatment with diclofenac before cataract surgery decreases postoperative inflammation. With these documented benefits and tolerance for diclofenac, we have proposed that use of topical diclofenac prior to application of RGP contact lenses and regular use during wear may
provide increased comfort, better tolerance and improve adaptability to RGP use.
Methods

Ten subjects (n=10) were randomly selected to participate in this one month study, two female and eight male. All were new rigid lens wearers with an average age of 24, an average refractive error of: OD -3.18, OS -.2.53, and an average flat K reading of: OD 43.49, OS 43.35. All subjects had 20/20 acuity or better and each were examined to rule out corneal disease or contraindications. Study requirements for patient eligibility were:

1. All participants must be over 18 years of age, or have release signed by parent or guardian, and
2. All participants must be free of systemic or ocular disease, as it relates to standard of care for rigid gas permeable contact lens wear, and
3. All participants must be non-rigid gas permeable lens wearers, which includes those who have worn soft contact lenses or never worn contact lenses, and
4. No two subjects can live in the same house, to ensure the masked nature of the study.

Patients who were non-compliant with the prescribed regimen for using the assigned drops were removed from the study. As well, any subject was free to remove themselves from the study for any reason without prejudice. Informed consent was obtained from each subject using a consent form approved by the Institutional Review Board at Pacific University College of Optometry.
Paragon HDS CAD lenses were chosen for the study, along with (A) 10mL GenTeal and (B) 2.5mL 0.1% Voltaren drops. Subjects were randomly assigned a manila envelope containing a bottle of drops marked "A" or "B". Both subject and examiner were masked as to the contents of the package. The examiner did not see the bottles as they were put in the envelopes nor handled the envelopes to ensure the masked nature of the study. Subjects were asked not to bring their bottles back to the follow-up visits.

Before the initial lens fitting, each patient filled out two questionnaires: (see Appendix A) about their perceptions/expectations and adaptation to rigid contact lenses. Adaptation questions pertained to comfort, dryness, itching, adaptation and satisfaction and were rated from 0 (very negative) to 10 (very positive). Perception questions asked about motivation, comfort, sensitivity, blink rate, tearing and overall success. Current contact lens fitting techniques were used to fit each patient and the criteria for an acceptable fit was: good lid interaction, 3' and 9' bite, unimpeded vertical movement and good edge lift.

Fifteen minutes after the subject's lenses were dispensed, the same two questionnaires were filled out regarding perception/expectation and adaptation. Afterward each subject individually picked out their given manila envelope containing: instructions, a statement about rigid gas permeable lenses and their benefits (see Appendix B) and a bottle of drops. Each was instructed to begin using the drops four times a day (breakfast, lunch, dinner, bedtime) for five days. All subjects were provided Boston Original Comfort Formula care regimen (PolymerTechnology Corporation).
Follow-up visits were at one week and one month. Lenses were re-evaluated to ensure a proper fit and each subject filled out the two questionnaires again.
Results

Ten out of ten subjects completed the one-month study. In all six categories of the "Adaptation" questionnaire no statistically significant differences were found between the placebo and Voltaren groups, using an unpaired t-test (See Figures 12-17, Appendix A). The average responses were: Overall Comfort: placebo=6.6, Voltaren=6.0; Dryness: placebo=6.8, Voltaren=6.4; Itching: placebo=6.2, Voltaren=6.7; Adaptation: placebo=7.0, Voltaren=5.6; Overall Satisfaction: placebo=7.3, Voltaren=6.1; Average Wear Time: placebo=10.6, Voltaren=8.3.

Again using an unpaired t-test for the 'Perception' questionnaire, five areas were shown to have statistical significance albeit in favor of the placebo group (See Figures 1-11, Appendix A). The first was "Long Term Wear" (Pre-Fit: p=0.035; Fifteen minutes: p=0.020) with average responses of: Pre-Fit, placebo=8.2 vs. Voltaren=5.2; Fifteen minutes, placebo=8.2 vs. Voltaren=5.8. The question of "Comfort" had significance only at Fifteen minutes (p=0.008), with averages of: placebo=7.7 vs. Voltaren=5.0, as did "Tearing" (p=0.009) at Fifteen minutes, average of: placebo=6.8 vs. Voltaren=4.6. There was a significant difference at the Pre-Fit (p=0.005) for "Lens Awareness" with averages of: placebo=6.6 vs. Voltaren=4.0 as well as at Fifteen minutes (p=0.001), averages of placebo=7.2 vs. Voltaren=3.6. The last category with significance was "Blinking" at Fifteen minutes (p=0.003), averages of placebo=6.6 vs. Voltaren=3.6 and at One Week (p=0.010), averages of placebo=7.2 vs. Voltaren=2.0. This
last question had the only statistical significance found at the One Week mark
Discussion

It is common to have rigid lens patients drop out during the initial stages of adaptation, yet all ten of our subjects completed the study. This finding is in direct correlation with the results, as it accurately reflects how little difference there was between the two group's responses. None of the six questions posed on the "Adaptation Questionnaire" showed a significant difference between the Voltaren and placebo groups in their averages, \( p=0.533 \), while on the "Perception Questionnaire" four areas showed significant differences including: Long Term Wear (Pre-Fit: \( p=0.035 \); Fifteen minutes: \( p=0.020 \)), Comfort (Fifteen minutes: \( p=0.008 \); One week: \( p=0.057 \)), Tearing (Fifteen minutes: \( p=0.009 \)), and Lens Awareness (Pre-Fit: \( p=0.005 \); Fifteen minutes: \( p=0.001 \)). All four of these areas were significantly different in that the placebo group had higher average scores than the Voltaren group.

One factor to consider in light of this is that even initially, on the "Perception" questionnaire, there was a statistically significant difference on the "Pre-Fit" answers for "Long Term Wear" and "Lens Awareness". This may be important in showing that the perceptions of those subjects in the placebo group started out at a more positive level at than those of the Voltaren group, irregardless of the fact that both groups were treated identically in their fitting and dispensing visits. Also, each group was given the same statement regarding rigid gas permeable lenses and as such should not have been subject to any bias. This finding however, may have effected the entire study simply because the initial perception of one group far outweighed the other, that group being the placebo group, and
their responses reflected their attitude. To better determine if this was the case, a larger sample size in any forthcoming study would reduce the likelihood of such bias.

Initial lens comfort plays a critical role in patients becoming successful wearers of rigid lenses. Although the results from this study would not seem to indicate that the continued use of anti-inflammatory agents post-dispense directly influences patient success, the above mentioned variables need to be addressed. Subsequent investigations may want to consider beginning Voltaren use thirty minutes before lens insertion by instilling one drop in each eye at thirty minutes, fifteen minutes and finally just prior to lens insertion. Voltaren's analgesic effect increases significantly only after three or more drops have been instilled, which may have been a confounding factor in the current study. Using a larger sample size would also prove to be helpful to rule out any preconceived bias the subjects might bring into the study. This study sought to determine if continued use of anti-inflammatory agents after contact lens dispense had any significant effect on patient overall satisfaction with their rigid gas permeable lenses. The idea that anti-inflammatory agents used post-dispense to reduce patient irritation would seem to be a logical off-labeled use of the products. Further investigation into this and the analgesic effect of these drugs needs to be done, so that another barrier to successful patient outcomes with rigid gas permeable lenses is overcome.
Bibliography

Appendix A

Figures 1-17

Perception Questionnaire

Adaptation Questionnaire

Patient RGP Information
Figure 2
Figure 11
Figure 14

- Itching
- Placebo
- Voltarol

15 min.
1 wk
1 mo
Perception Questionnaire

Name: ____________________  Date: ________

Scale 0 – 10

0 1 2 3 4 5 6 7 8 9 10

Strongly Disagree  Neither  Strongly Agree

Please use the scale above to rate the following statements:

1. I am very motivated to wear contact lenses. ______
2. I will adapt to RGP’s very easily. ______
3. I will be a long term wearer of RGP’s. ______
4. RGP’s will be very comfortable. ______
5. My eyes are not very sensitive. ______
6. My eyes will not tear excessively when wearing RGP’s. ______
7. I will not be very aware of the lens moving on my eye. ______
8. I will not be very aware of blinking excessively. ______
9. I feel I will adapt to RGP’s in a short amount of time. ______
10. My head posture will not change when wearing RGP’s. ______
11. I expect my RGP fitting experience to be comfortable and pleasant. ______
Adaptation Questionnaire

(To be completed 30 minutes after dispense, after one week and one month)

Name: ______________________    Date: ______

Please rate the comfort of the contact lenses using the scales below. The scales are numbered 0-10. Higher numbers indicate greater comfort. Rate the comfort by drawing a short vertical line through the scale corresponding to the comfort rating. The vertical line may be placed anywhere along the scale. **Above** the vertical line print R for the right eye, L for the left eye, or BOTH if each eye is experiencing identical comfort.

1. Please rate the overall comfort of the contact lenses.

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<td>Severe Discomfort</td>
<td>Moderate Discomfort</td>
<td>Mild Discomfort</td>
<td>Moderate Awareness</td>
<td>slight Awareness</td>
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2. Please rate the sensation of dryness associated with lens wear.

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3. Please rate the sensation of itching with lens wear.

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4. Please rate your overall adaptation to the lenses.

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5. Please rate your overall satisfaction with the lenses.

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6. Please estimate the average number of hours you have worn the lenses per day.

__________________________

7. Please list any other symptoms you are experiencing.
Rigid gas permeable lenses have the benefits of increased oxygen transmission, improved visual clarity, durability, and ease of care. It is important, however, that you understand there is a difference in adaptation versus soft contact lenses. It is not uncommon for you to be aware of the lenses when you are first adapting to them only because they are small and you are feeling the lids coming in contact with the lens when you blink. If you lift up the lids the lenses are very comfortable, just as they typically will be after your eyes adapt to rigid lens wear. Due to this increased awareness, you will be provided with a wearing schedule that is important to adhere to in order for comfortable wear to be achieved. The process of adaptation can take a few days to 2 weeks so keep this in mind.