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Interlot, intralot, and time variations in pH of commercially available artificial tears

Abstract

This study examines the stability and range of pH in several commercially available artificial tear preparations. pH immediately upon opening varies between 6.4 and 8.5 among the preparations. pH fluctuation was not found to occur in five of the seven preparations. The pH of one lot of a multiple use artificial tear decreased 0.4 units during the first week and then remained stable for the following 21 days. pH was found to vary by 0.5 units between lots in one brand of a single use artificial tear preparation. These results allow for informed selection of artificial tears in the treatment of dry eye.

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INTERLOT, INTRALOT AND TIME VARIATIONS IN pH OF COMMERCIALY
AVAILABLE ARTIFICIAL TEARS

By

JULIE A. BROWN, Ph.D.

and

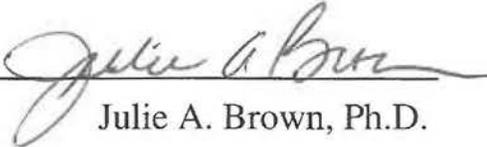
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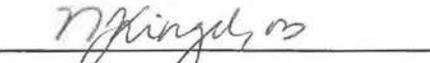
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Biographical Information

Julie A. Brown received her B.S. degree in biology and chemistry from Metropolitan State College, Denver Colorado where she graduated magna cum laude. She received her Ph.D. degree in biochemistry from Oregon Graduate Institute, Beaverton, Oregon. Julie is currently a fourth year optometry student at Pacific University. Following graduation from Pacific University Julie plans to practice optometry in the Portland metropolitan area.

Brian C Hatch received his B.S. degree in microbiology from Brigham Young University, Provo, Utah. Currently he is a fourth year optometry student at Pacific University. He is a four year Navy HPSP scholarship recipient and one of twelve students nation wide to be named on the Dell Dean's List of Notebook All-Americans. Upon graduating from Pacific University Brian plans to begin his optometric career as an officer in the United States Navy Medical Service Corps.

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Abstract

This study examines the stability and range of pH in several commercially available artificial tear preparations. pH immediately upon opening varies between 6.4 and 8.5 among the preparations. pH fluctuation was not found to occur in five of the seven preparations. The pH of one lot of a multiple use artificial tear decreased 0.4 units during the first week and then remained stable for the following 21 days. pH was found to vary by 0.5 units between lots in one brand of a single use artificial tear preparation. These results allow for informed selection of artificial tears in the treatment of dry eye.

Key Words

pH, artificial tears, lubricating drops, dry eye

Introduction

Dry Eye Syndrome (Keratoconjunctivitis sicca) is a common problem for which many people seek treatment. A major component in the treatment of mild to moderate cases of dry eye is the instillation of artificial tears to increase lubrication and stabilize production of the patient's natural tears. Many brands of tear supplements are currently available.

As practitioners, our choice of which tear to prescribe is based on efficacy, patient compliance and cost. While most artificial tears are effective in relieving discomfort, restoring a smooth optical surface and protecting the cornea, our experience has been that some patients complain that artificial tears burn or sting upon instillation. A recent study indicates that 37% of patients for whom artificial tears had been prescribed discontinued usage and that experiences of burning or blurry vision accounted for 5% of the reported discontinuation (1).

Stinging or burning following instillation of an artificial tear solution could be due to either the corneal epithelial damage integral to dry eye or irritation due to a component of the artificial tears. Preservatives and surfactants, common components of artificial tears can be ocular irritants. Changes in pH from physiological values could also contribute to irritation. Normal human tear pH has been determined to range between pH 6.5 to 7.6 with a mean of 7.0 (2).

One study found that patients tolerated a slightly alkaline preparation of pH 8.0 better than preparations closer to physiological pH (3), another found the pH of the most preferred artificial tear to be 6.8, significantly more acidic than physiological pH (4). Interestingly, this study could not identify a single factor that accounted for patient preference.

Another study examined the relationship between pH and osmolarity of artificial tears and patient preference. Neutral hypotonic tear preparations and near-isotonic alkaline preparations were equally preferred (5). Previous work has also indicated that pH is among the factors that determine patients tolerance of artificial tears (3, 4, 5).

We questioned whether the pH of individual bottles of artificial tears change after opening a bottle of artificial tears, making a preparation that was initially comfortable become irritating. In addition, variation between lots of a single preparation might

contribute to increased patient noncompliance with prescribed usage. This study examines pH stability of seven commercially available artificial tear preparations.

Methods

The pH of seven brands of artificial tears were tested. Three types of pH indicator strips were utilized. This was necessary to cover smaller unit increments over the desired pH ranges. Two types of pH indicator strips, one of pH 5.1 to 7.2 with 0.3 pH unit intervals and another of pH 6.0 to 7.7 with 0.4 pH unit intervals were obtained from Baxter Scientific Products, catalogue numbers P1119-23 and P1119-24 respectively. The third pH indicator strip of pH 7 to 10 with 0.5 pH unit intervals was obtained from EM Science, catalogue number 9588. Accuracy of pH measurement was limited by the pH unit intervals of the test strips. No attempt was made to interpolate pH value between the color-coded keys provided with each product. To reduce intraobserver variations the same person performed all testing.

Four brands of the artificial tears tested are available in multiple use 15ml bottles. They are: GenTeal (CIBA Vision), Tears Naturale II (Alcon), Viva-Drops (Vision Pharmaceuticals) and Moisture Drops (Bausch and Lomb). Three bottles each of three different lots were tested on days 1, 8, 15, 22 and 29. This was done to simulate a one month shelf life after opening.

The remaining three brands of artificial tears that were also tested are available in single use vials. These are: Tears Naturale Free (Alcon), Refresh Plus (Allergan) and Thera Tears (Advanced Vision Research). For the artificial tears available as single use vials, three vials each of three different lots were tested once immediately upon opening. Repeated measurements were not performed for single use vials.

When evaluating multiple use preparations the bottles were shaken five times before dispensing two drops on a pH indicator strip. To simulate patient usage of five times per day, three more drops from each sample were dispensed and discarded. To simulate the same patient usage, the bottles were shaken five times and five drops were dispensed and discarded on interim days.

Single use vials were opened and two drops were dispensed on a pH indicator strip with the remainder discarded. All artificial tears were stored at room temperature.

Results

Initial pH ranged from 6.4 to 8.5. pH was found to be stable between lot numbers and over time in the multiple use preparations with the exception of one lot of Tears Naturale II in which the pH of all three bottles of lot 2 decreased from 7.7 to 7.3 during the first week. The pH of each bottle of lot 2 then remained stable at pH 7.3 for the following 21 days (see table 1).

The pH of single use tears, Refresh Plus and Tears Naturale Free were also consistent within and among lots. Variation was identified in the pH of Thera Tears where the pH of two lots (three vials) was 8.0 while the pH of the third lot tested (three vials) was 8.5 (see table 2).

Discussion

Although pH is stable among most of the commercially available artificial tears tested in this study, the range of pH values (6.4 to 8.5) leads us to suggest that pH is a factor to consider when prescribing a particular brand of artificial tears to treat Dry Eye Syndrome. Given the mixed results of previous studies of patient preference and pH, it seems that a single pH may not be best for all patients.

Patient follow up is critical to determine comfort of the prescribed artificial tears. If burning or stinging is reported, a change in prescription may increase compliance with the therapeutic regime. pH data from this study allows for better informed selection of artificial tears in the continuing treatment of dry eye.

This study was conducted in an extremely controlled laboratory environment. Patients do not, however, use artificial tears in a temperature-controlled environment or in a sterile setting. Further phases of this study will evaluate pH fluctuation as a result of temperature and actual patient usage.

TABLE 1: Multiple Use Bottles

PRODUCT NAME	pH on opening	pH on days 8, 15, 22, 29
Genteal Lot 1	6.7	6.7
Genteal Lot 2	6.7	6.7
Genteal Lot 3	6.7	6.7
Moisture Drops Lot 1	6.4	6.4
Moisture Drops Lot 2	6.4	6.4
Moisture Drops Lot 3	6.4	6.4
Tears Naturale II Lot 1	7.7	7.7
Tears Naturale II Lot 2	7.7	7.3
Tears Naturale II Lot 3	7.7	7.7
Viva Drops Lot 1	6.7	6.7
Viva Drops Lot 2	6.7	6.7
Viva Drops Lot 3	6.7	6.7

TABLE 2: Single Use Vials

PRODUCT NAME	pH on opening
Refresh Plus Lot 1	6.6
Refresh Plus Lot 2	6.6
Refresh Plus Lot 3	6.6
Thera Tears Lot 1	8.0
Thera Tears Lot 2	8.0
Thera Tears Lot 3	8.5
Tears Naturale Free Lot 1	7.3
Tears Naturale Free Lot 2	7.3
Tears Naturale Free Lot 3	7.3

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