

Physical Properties of OTC Dry Eye Products in the US Market

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Introduction

Lubrication to human eyes is typically obtained naturally from a tear film, formed over the outer exposed surface of the eye (Scheme 1). A breakdown in this precorneal tear film results in dehydration of the exposed ocular outer surface. This condition is commonly referred to as "dry eye (DE) syndrome", and it affects millions of people.

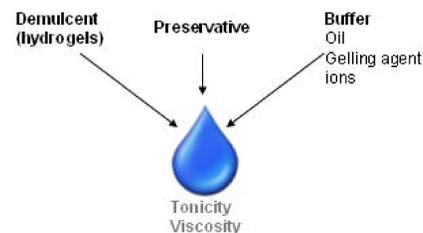
A dry eye patient may experience dry, itchy, gritty inflamed eyes. It can be attributed to an aging population, in which the lacrimal glands produce less moisture¹. It is also commonly attributed to computer use, contact lens use, decreased levels of hormones in women, flying in commercial airlines, and environments of low humidity².

The tear fluid is referred to as "Non-Newtonian" (increasing shear rate → decreasing viscosity), has an ion composition of potassium, and a sodium bicarbonate buffering system. A layer of mucus underlies the tear film and is thought to provide "wetting" for a continuous tear film. Most dry eye products (OTC) are intended to dilute hypertonic tears, increase tear volume, stabilize or correct the tear film imbalance, and/or provide nutrients to the tear film. It is important to consider viscosity, ion composition, mucus properties, nature and concentration of additives in artificial tears when treating DE³.

There are currently many products on the market that claim to be effective in providing relief, treatment, or prevention of DE. These products vary in their compositions. Some products are marketed as artificial tears, and consist of buffered, isotonic saline solutions +/- aqueous polymers that promote longer retention on the ocular surface¹. Other products contain lipid components that claim to offer greater relief of DE by stabilizing the tear film and reducing evaporation of fluid.

To date, not much data is available regarding the physical properties of these formulations. In this study, the pH, viscosity, osmolality and surface tension of current OTC products was investigated.

Important Artificial Tear Components



Scheme 1. Components in Artificial Tear

Method

The pH, osmolality, viscosity, and surface tension of twenty-four OTC dry eye drops sold in the US market were measured at room temperature. Histograms of each parameters were plotted to show the range and distribution.

Results

Table 1. OTC dry eye products that were examined for physical properties.

Brand Name (Company)	pH	Osmolality mOsmo/kg	Viscosity cps**	Surf Tension mN/m
Advanced Eye Relief (B&L)	7.183	311	1.31	30.767
ReNu Multiplus (B&L) *	6.988	300	1.31	70.105
B&L Soothe	6.887	249	9.16	69.858
Alimera Soothe XP (B&L)	7.512	283	1.31	45.998
Tears Naturale II (Alcon)	7.476	299	8.50	50.472
Systane (Alcon)	7.067	283	8.50	62.074
Refresh Liquigel (Allergan)	7.277	286	30.1	74.344
Endura (Dry Eye Therapy) (Allergan)	7.393	230	22.9	46.736
Optive (Allergan)	7.306	351	9.16	71.005
Gentle Mild (Novartis)	6.858	216	1.31	50.737
Gentle Moderate (Novartis)	6.879	218	6.54	56.772
Gentle Gel Drops (Novartis)	6.854	223	24.9	51.606
Visine (Pfizer)	7.408	294	1.31	35.780
Visine Lasting Relief (Pfizer)	7.393	294	8.50	36.546
Clear Eye (Medtech)	5.712	277	17.7	35.518
Thera Tears (Advanced Vision Res.)	8.269	191	6.54	73.041
Dry Eye Relief (Similasan)	7.682	287	-	73.922
Murine Tears (Prestige)	7.025	261	1.31	36.752
Aquify Comfort (CIBA) *	6.915	305	7.19	72.051
Blink Tears (AMO)	7.347	176	11.1	70.767
Complete Blink-N-Clean (AMO) *	7.618	292	2.62	39.979
OptiZen (Innozen)	7.075	292	1.31	38.832

* Product is primarily used as lens care solution or rewetting drops, but has been used off-label for mild to moderate dry eye syndrome.
** Measured at 25 °C, 5 rpm.

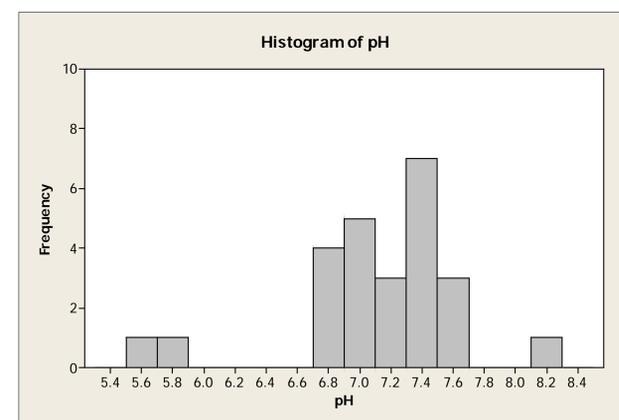


Figure 1. Histogram of pH for US OTC dry eye products

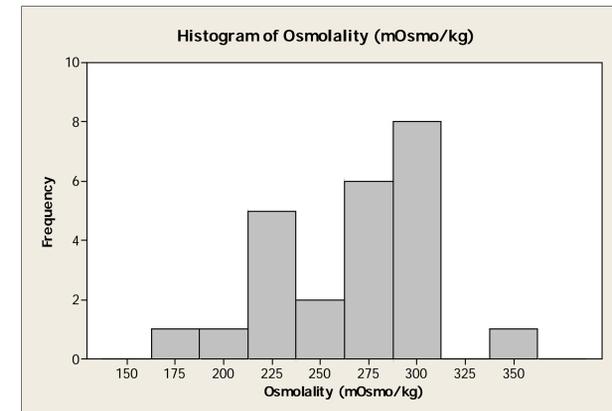


Figure 2. Histogram of Osmolality for US OTC dry eye products

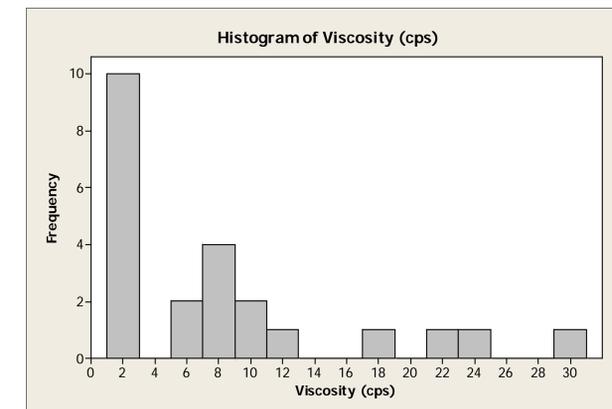


Figure 3. Histogram of Viscosity for US OTC dry eye products

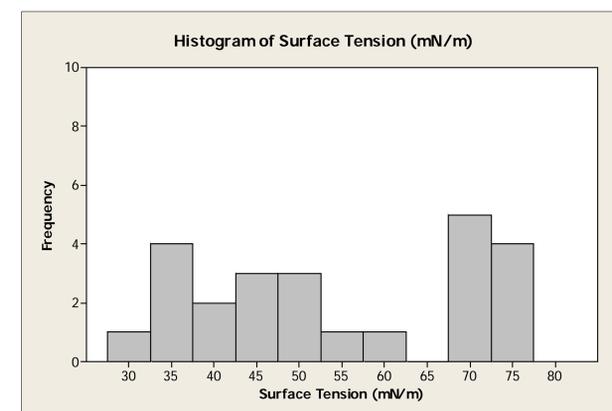


Figure 4. Histogram of Surface Tension for US OTC dry eye products

Conclusion

- All the solutions, sold in US OTC market for DE syndrome, had pH values that fell within the tolerable pH range for ophthalmic products, and many had pH values that were very close to neutral (6.8 to 7.8). Only Thera Tears demonstrated significantly higher pH value at 8.2.

- Osmolality of OTC DE products demonstrated two major distributions: one around 280-300 mOsmo/kg which is from isotonic to slight hypotonic range, and another around 225 mOsmo/kg which hypotonic is believed to balance tear hyperosmolarity in severe dry eyes.

- It showed in the histogram of viscosity that nearly half of the tested OTC DE products had formulation viscosity close to natural tear (3 mPa·s). Another fifty percent of the tested formulations were with "medium" viscosity at which the ocular residence time is improved without causing significant side effects such as blurry vision. Very few fell into "high" viscosity range. It was noted that one of the best selling products, Systane, was medium viscosity.

- The distribution of surface tension for OTC DE products were over a wide range. About forty percent of the tested products had surface tension close to that of pure water (74 mN/m). A small higher distribution, but not obvious, was noted at the surface tension of natural tear (44 mN/m).

- This is the first time that the critical physical characteristics were investigated for US marketed DE products. Based on this study, most of the commercial OTC DE products had a pH close to physiological pH, an osmolality at iso- to hypotonic, a viscosity preferably from low to medium (1 – 12 cps), and a surface tension widely distributed (30 – 75 mN/m).

Reference

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