

Nature's Tears®: Comfort for Patients with Ocular Irritation

OPPORTUNITIES

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A mist of sterile, hypotonic water provides comfort for patients with dry or irritated eyes.

Nature's Tears® (Figure 1) is a very simple product. It is nothing more than sterile, hypotonic spring water that is gently misted on the eyes. Patients with a variety of dryness symptoms find it highly soothing. Since it contains only sterile water with traces of mineral solute, Nature's Tears is absolutely safe to use. In fact, the water used for Nature's Tears is so gentle to cells that it is also sold for tissue culture.

How It Was Developed

Nature's Tears grew out of a cosmetic product called Nature's Mist that was marketed for some years by Rogue Valley Natural Springs, Inc. to refresh the skin around

one in their region with ocular surface expertise. They wanted my input because customer reactions to Nature's Mist, the cosmetic product, made it seem as if the product might be useful for the eyes directly. I was initially skeptical—the idea that one could simply put water back on the eye seemed too good to be true.

Having never had a commercial attachment in the past, I agreed to look into the product only because I didn't like the idea of rejecting an hypothesis solely on the basis of my own prejudices. I began by trying the product on a small number of patients. I realized quickly that patients liked it. It was soothing for their dry eyes. I then became seriously interested in the product and why it provided relief.

PATIENTS FOR WHOM NATURE'S TEARS MAY BE INDICATED

- ✓ Dry eye patients, including patients with severe dry eye conditions
- ✓ Patients who have difficulty using artificial tears
- ✓ Computer users
- ✓ Patients in dry or dusty environments



FIGURE 1 Nature's Tears® all-natural moisturizing mist from Bio-Logic Aqua™ Technologies.

the face. While meant to refresh the eyes as well as the skin, Nature's Mist wasn't aimed at the eyecare market.

About 4 years ago, the owners sought me out as some-

First Steps

The basic concept, replacing water, is quite simple. But in Nature's Tears both the water itself and the means by which it is applied are quite different from traditional rewetting technologies, such as artificial tears. Nature's Tears was a new way of thinking about an old problem. Unlike artificial tears, a sterile mist has no preservatives, is easy to apply, allows patients to titrate their dose, and makes very small doses possible. Both in its formulation and its delivery, Nature's Tears was quantitatively and qualitatively different from previous attempts to rewet the eye.

At my insistence, the product was made sterile, because any product to be used on a compromised cornea or by a patient in contact lenses has to be germ free. Although the water comes out of the ground sterile, it could become contaminated in the process of packaging it for application. So after the water is sealed in its pressurized canister, there is a sterilization step to ensure there are no live organisms.

The Water

The water used comes from a natural spring in southern Oregon. Water reaches the spring by an aquifer whose source is Crater Lake, 80 miles away. Passage through the aquifer results in a pure water with an extremely low solute concentration. Unlike most water, which is quite alkaline, Nature's Tears is very slightly acidic, a pH that is excellent for biocompatibility. There are no detectable

EDITOR'S NOTE: This article is part of a series called "Opportunities," in which we feature novel ideas, typically from new and/or small companies. Since many of these opportunities are in the early stages of commercial development, we go directly to the source, the company, for information, which is presented from the company's perspective. All of the normal caveats—and excitement—that pertain to new ideas and new companies apply. In a field driven by ever-changing ideas and technology, our aim is to help readers stay on the cutting edge of practice and technology.

organic compounds in the water. In the 15 years over which it has been repeatedly tested, the water has not varied in composition.

When sold to the consumer, the water comes in a pressurized canister that produces a fine mist about the eyes. Inside the canister, the water is held in a bladder made of

a material that doesn't leach into the water. Containing the water within a bladder ensures there is no propellant contamination.

NATURE'S TEARS

✓	Sterile
✓	Hypotonic (extremely low concentration of inorganic solutes)
✓	Slight acidic pH
✓	No organic molecules detectable
✓	Highly biocompatible
✓	Non-drying on skin

Use by Patients

When I started using the product on patients, they reported that it felt good and wanted to continue using it. In addition to a wealth of anecdotal material, we have now have

clinical study results to support patient acceptance. (In a pilot study with 39 patients, for example, we found that 72% thought the mist more effective and 84% found it more convenient than the tear products they had been using.)

Nature's Tears can be used by itself or in conjunction with artificial tears and topical medication. Although it doesn't necessarily replace other eye drops, it does add water. But, unlike drops, which add a massive volume of water (and solutes) all at once, the dose is small, and patients can control their dose. With the canister held at 14 cm, the eyes receive approximately 1 $\mu\text{L}/\text{cm}^2/\text{second}$. So for a second or two, the patient is gently adjusting the water content of his or her tears. Nothing is washed away; there's no osmotic shock; and it feels good.

Non-drying on the Skin

Testing by an independent laboratory found that the mist wasn't drying to the skin. This was quite unexpected, since all water is thought to be drying. The lack of drying effect in Nature's Tears may be due to the pH and the extremely low osmolarity. Typically, when water dries on the skin, it leaves a residue of solute that exerts an osmotic effect on water within the skin, causing drying. It appears that the water in Nature's Tears has such an infinitesimal solute load that the osmotic effect is undetectable.

In other testing, a cell biologist at the Oregon Health and Sciences University tried using the water for cell culture. Julia Oxford, PhD, tested the water in tissue cultures and actually found out it superior to the filtered and distilled water typically used for tissue culture. This bolstered our conviction that the water would have no toxic effects and be good for the cells of the ocular surface.

Since sterile spring water isn't a medication, Nature's Tears

doesn't require FDA approval. (The FDA treats it like other natural products.) On the other side of the coin, the company does not claim that Nature's Tears treats or cures dry eye or any other condition. Nature's Tears isn't a medical treatment. Rather, it is an eye refresher. It floats contact lenses, and it makes eyes, especially dry eyes, feel better.

How it Works

Using Nature's Tears has several effects: it lowers tear osmolarity, and it increases the flushing action of the natural tears. Since the amount that reaches the ocular surface is very small, it does not wash away proteins, antibodies, lysozyme, or other useful elements of the tear film. The tear film retains its integrity, but its natural washing action is enhanced.

Nature's Tears also makes the skin around the eyes feel better. The refreshing, pleasant feeling adds to the sense of decreased irritation. The key, however, is that the dose is titratable and the water itself is highly biocompatible, allowing the user to gently shift the osmotic balance of the tear film. With artificial tears or other drops, the sheer volume can create osmotic shock, and applying the drop triggers the sensitive nerve fibers in the eye, causing it to blink. (Many people find it challenging to instill drops.) The Nature's Tears product doesn't create osmotic shock, nor is it difficult to apply. It is simply sprayed in a mist for 1 or 2 seconds in front of the face.

There are two significant factors that make the product effective: the water and the delivery system. It is the synergistic combination of these two that makes the product unique. Either one alone wouldn't be as effective.

Who Will Benefit?

Patients who are sensitive to compounds in eyedrops and ocular medications will enjoy this because it is completely nonsensitizing. Patients who have difficulty instilling eyedrops or artificial tears in their eyes will find this much easier. Arthritic patients and patients whose blink reflex is strong can obtain some symptomatic relief without hassle. The mist also provides a sense of refreshment for people with ocular surface irritation from blepharitis or dry eye.

Nature's Tears works for contact lens patients whose lenses feel as if they are sticking. Adding a little more volume to the tear film gently refloats the lenses; and the mist can be used as often as needed.

Patients don't have to have clinically significant problem benefit from the mist. It's a great product for temporarily dry environments, such as airplanes. Computer

The water used for Nature's Tears is so pure that it is also sold for tissue culture

users can give themselves a quick spritz to feel better. Nature's Tears is also very helpful for washing airborne chemical or particulate irritants out of the eye. For example, a quantity was given to New York City fire fighters, who use it wash out their eyes after exposure to smoke or solvents. Cooks use it when chopping onions, because a quick misting washes the chemical irritants out of the eye, allowing onions to be chopped without tearing. As humble an application as this is, it's a nice demonstration of the product's effectiveness.

Presenting Nature's Tears to Patients

When offering Nature's Tears to patients, I tell them it is a new product, an ultrapure water that is applied by misting the eyes and face. I let patients know that they can use it safely and freely, with or without other medications. Its purpose is to help them feel better, and that if they find it refreshing, they can keep using it. And they can use it as often as they like.

So far, the product has been very well received. Still a new product, Nature's Tears is being rolled out slowly, with drug stores and other retailers beginning to carry it. Nature's Tears can also be marketed through eyecare practices, and it is available directly via an "800 number" and the World Wide Web. Consumer advertising will begin soon, increasing product recognition. At the same time, I and others are pursuing the scientific aspects, with further clinical trials and laboratory studies.

Bucking the Trend

The pharmaceutical therapies now being planned or tested for dry eye are highly sophisticated, and some will no

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doubt prove extremely useful. But they should not preclude the adjunctive use of effective but less complex remedies. For example, I use anti-inflammatory medication to quiet ocular inflammation in some dry eye patients. I've found that using Nature's Tears in conjunction with the anti-inflammatory help in providing relief of symptoms and

lower the dose of drug needed.

There's even a theoretical basis for this effect. Patients with aqueoustear-deficient dry eye often have a relatively normal lacrimal gland that is quite capable of functioning. The gland, however, has been shut down.

What appears to be happening in those patients is that the feedback loop between the gland and the ocular surface is disrupted. With ineffective stimulation from the ocular surface, the gland produces fewer tears. This interference with the signaling system and (the consequent

curtailment of aqueous tear production) can happen as a result of a variety of ocular surface conditions, such as high osmolarity, irritation, inflammation, etc.

Restoration of the ocular surface, through drugs and/or simple palliatives, can, over time, restore the feedback loop, improving the health of the entire system. When the feedback loop begins to recover, the eye can start to make its own tears again. Thus, artificial tears and products like Nature's Tears that we think of as palliatives may do more than just relieve symptoms; they may support the process of restoring function.

Nature's Tears in Practice

Nature's Tears are as gentle a way to refresh the irritated eye as we possess. But this is a new product, and patients need to try it. It will do no harm, and there is compelling logic for why it should work. (I've never heard a dry eye patient say his or her eyes didn't feel better in the shower.)

Patients with severe drying, including Sjogrens syndrome patients, can use the mist frequently. In these cases, the mist is used as an adjunct to their other medications. Patients who like viscous tears but can't apply the viscous tears continually, can use Nature's Tears mist to extend the time they are comfortable between applications. Comfort is the key to Nature's Tears. It simply makes life better for many patients with ocular irritation.

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THE BOTTOM LINE

Nature's Tears is a sterile hypotonic spring water product that is misted on the eyes, providing relief for a variety of dry eye conditions. Completely safe, it can be used as often as patients like, with or without artificial tears or pharmaceuticals. A mist, it is the only ocular surface rewetting preparation that patients can titrate themselves. Also, because it is a mist, it is easy to apply and doesn't create osmotic shock when applied. Nature's Tears may provide a feeling of relief for a wide variety of conditions, including dry eye, contact lens irritation, computer use, and dry or dusty environments.

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