The S.H.A.D.E. STUDY

ThermoEyes System Holistic Approach to Dry Eye Study

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"Sherman set the Wayback Machine to the year 1981. Today we visit Dr. Rob Gerowitz. He's just graduated optometry school and entered into private practice. If you look closely his patient has told him about their dry eyes and now he's handing them some artificial tears to use."

"Now, Sherman let's move forward in time to 1996. Dr. Gerowitz has just completed his TPA course work and now that same patient is back still complaining of dry eye. See what he's doing now? Yes, that's right; he's putting in silicon punctal plugs into the lower eyelids."

Sound familiar? It should, because that's exactly what most of us have been doing all these years and unfortunately will continue to do as long as we look at our patients as just a pair of eyeballs and nothing more.

A Breakthrough of Sorts

My personal epiphany occurred two years ago at a lecture given by Dr. Paul Karpecki who among other things runs an ocular surface disease clinic in Kansas City, Missouri. It was at this meeting that Dr. Karpecki outlined his very straightforward and systematic approach to dry eye treatment including the most logical patient questionnaire I'd yet seen. The key to this "dry eye survey" is to elicit not only patient symptoms but also information about home and work environments, diet, water consumption, medications and systemic health history, artificial tear use, and personal habits. In this way, the dry eye specialist can get a complete picture of the patient from a holistic point of view. With his permission, I incorporated Dr. Karpecki's questionnaire into my dry eye program.

The next step in my paradigm change was to go from a "drop and plug" treatment approach to a "Holistic Dry Eye Program". This requires the patient fully understand that while you can guide their treatment, they must be *active participants* in their care as well. Further they need to understand that there is "no magic bullet" as relates to dry eye remediation. Since they've already tried almost every drop on the store shelves (with and without your oversight) this isn't really so difficult to get across. Finally, your patient needs to be aware of the fact that there are just some things beyond your and their control. These are contributing factors to dry eye such as age, sex, medicine that can not be changes or stopped, and even their career. Just get them to deal with those factors that are in their control (*see sidebar #1: "Dry Eye Recommendations"*).

I often will include with these early environmental and habitual changes treatment for the inflammatory components of ocular surface disease. Typically, I prescribe Lotemax (Loteprednol Etabonate ophthalmic suspension, Bausch and Lomb) q.i.d. x 14 days and then reduce to b.i.d. x 14 days. Concurrently, if the patient's dry eye has an aspect of tear insufficiency as indicated by Zone-Quick phenol red string test and decreased tear meniscus, we will start them on Restasis (Cyclosporin A ophthalmic suspension, Allergan) b.i.d. x 26 weeks. According to Stephen C. Pflugfeld, M.D., Professor of Ophthalmology at Bascom Palmer Eye Institute as submitted to the F.D.A. (www.fda.gov/OHRMS/DOCKETS/AC/99/slides/3533/3533s1c/sld160.htm) Restasis showed decreased ocular irritation as a patient symptom of dry eye and rose bengal staining at six weeks with an increase in TBUT by eight weeks. The thinking

behind this concurrent therapy is that right about the time that the Lotemax is being discontinued; the Restasis is starting to create its desired effect (*see sidebar #2: "Dry Eye Protocols"*).

Which Brings Us to Vegetable Oil

I met a corneal specialist once who told me that he didn't have one dry eye patient he didn't put on hot compresses for the eyelids. Now this seemed to make a lot of sense particularly if the patient has "tear evaporative-type" dry eye (*see sidebar #3: In the Blink of an Eye"*).

The approximately 60 meibomian glands of each upper and lower lid pair produce lipids that are excreted from orifices on the lid margins. Internal changes to the health of these glands or extrinsic agents such as bacteria, makeup, dirt and particulates can alter the composition of these lipids to the extent that normally free flowing meibum solidifies forming a "toothpaste-like" substance that stagnates and further plugs the glandular openings. Think of it like putting your vegetable oil in the refrigerator. The oil gets hard, cloudy, and won't pour from the bottle. Only bringing the oil back to room temperature allows it to become free flowing once more.

Over the years, numerous methods have been described to warm the lids. These techniques range from cooked rice in cheese cloth applied to the lids, hard-boiled eggs place over the closed eye, and of course the commonly prescribed hot compress. The trick here is getting a consistently hot medium in contact with the lids that is both hygienic and safe without burning the epidermis.

Enter THERMOEYES and S.H.A.D.E.

One afternoon while perusing a magazine, I came upon an ad for a facial mask with a self-heating insert. I was immediately intrigued. Thermoeyes masks are made from medical grade, flexible rubber material that is FDA approved. As part of the kit that I originally tried on myself were two sets of self-heating gel pads that activate rapidly and are reusable by boiling them in water. Next, I asked a few dry eye patients who were using hot compresses for Meibomian Gland Disease (MGD) to try them out. With favorable responses, I then contacted the manufacturer, *Eye Eco (*www.eyeeco.com*)*; and presented the idea of a short term study to compare the effectiveness and quality of life with Thermoeyes versus hot compresses for a group of previously untreated dry eye patients. The "Thermoeyes System Holistic Approach to Dry Eye Study" was born.

Using the same patient symptom survey and testing methodology as I normally utilized, I selected 15 patient volunteers (one was subsequently lost to follow-up; 10 female and 4 male; ages 7 to 72 years old) to try Thermoeyes on the Right eye and hot compresses concurrently on the Left. This was in addition to any other life style-dietary-pharmaceutical treatment that I would normally employ. As I readily admit to not being a pure researcher but a clinician, my goal in testing out these side by side treatments was not only to see which performed better but also to improve my patient's conditions. This statement is expressed to hold off complaints that my study was not conducted using strictly one dry eye treatment modality only. Worded another way, as an Optometrist in the trenches, I wanted to find out which was better, number one or number two!

Each patient was evaluated initially, a determination of what type of dry eye syndrome they had was made, and a follow-up consult outlining their treatment was scheduled as well as two progress checks at four week intervals.

The Results (or Made in The S.H.A.D.E.)

Overall improvement from the start of the study to its completion showed an average increase of Tear Break-up Time (TBUT) of +3.30 seconds with eyes treated with Thermoeyes masks compared with only +2.10 seconds for those patients treated with hot compresses.

Both eyes that were treated with Thermoeyes and hot compresses showed an increase for the Zone Quick (red string) measurement of tear quantity. In this case, +6mm for Thermoeyes and +9mm for hot compresses.

Next, using the Meibomian Gland Dysfunction (MGD) grading scale (see sidebar #4), Thermoeyes treated Right Upper Lids improved +1.54 units compared with hot compress treated Left Upper Lids which changed by just +.69 units; or by 2.23 times. As well, Right Lower Lids improved by +1.46 units versus Left Lower Lids at +1.08 units; or 1.35 times improvement of scale.

In order to establish how well Thermoeyes was received by my patients and how well it compared to hot compress therapy, I asked each patient to fill out a "Quality of Life" survey. Sidebar #5 shows the survey along with the average score for each question at the four and eight week visits. For every question, a rating of "good" to "very good" was given to the Thermoeyes mask in each category.

Lastly, as an evaluation of the entire treatment from a holistic point of view, we surveyed our test patients for change in original subjective problems. In every case, patient symptoms decreased or were alleviated altogether (*see sidebar #6: Symptom Change Chart).*

In Conclusion (or It's Cooler in The S.H.A.D.E.)

The three factors we most wished to enhance for the alleviation of Tear Evaporative Dry Eye, was an increase of TBUT, a decrease of MGD, and a lessening of patient subjective complaints. At the same time we wished to determine if we could "build a better mousetrap" by not only going to a holistic dry eye treatment but also make a part of it more convenient and comfortable.

The following are just a few of the patient comments regarding the use of Thermoeyes:

- "it's comfortable and easy to wear"
- "my eyes look more moist"
- "definite improvement"
- "my daughter says my eyes look better"
- "my eyes are feeling better"
- "it is pretty convenient and effective"
- "a microwave version of the gel pad would be great"

In answer to that last comment, *Eye Eco* has recently released a microwaveable disc as an alternative to the self heating gel pad.

Did absolutely everyone on the study love Thermoeyes? The answer to that is, no. But I've found in practice that not every treatment approach or device is universally loved by every patient. Thermoeyes gives my practice a very effective and more modern weapon for an age-old problem, Dry Eye Syndrome.

SIDEBAR #1: DRY EYE RECOMMENDATIONS

- ❑ Practice correct blinking technique every day until deep blinking is a habit
- ❑ Reduce contact lens wearing time to a maximum of _____ hours per day
- ❑ Use the Thermoeyes mask or hot compresses every night for 5-10 min.
- ❑ Do lid scrubs every night for _____ weeks and then at least 3 times per week thereafter
- ❑ Increase fish meals to 3 or more per week
  -or-
- ❑ Take Omega-3 (OM3) an organic fish/flaxseed combination 500mg/day for 7 days *then* 1000mg/day for 7 days *then* 2000mg per day
- ❑ Increase water consumption to more than 3 glasses per day
- ❑ Limit caffeinated (coffee, tea, cola) drinks to no more than 3 per day
- ❑ Avoid direct air currents that blow into your eyes
- ❑ Replace air filters at home, clean air ducts, use clean air machines
- ❑ Every 20 minutes, look 20 feet away, for 20 seconds when doing close work (reading, computer, etc.)
- ❑ Use 1 drop of _____ in each eye _____ times per day for _____weeks
- ❑ Use 1 drop of _____ in each eye _____ times per day for _____weeks
- ❑ Use 1 drop of _____ in each eye _____ times per day for _____weeks
- ❑ Report any increase of symptoms or adverse effects of this treatment immediately to this office
- ❑ Return for Dry Eye Follow-up in _____ weeks

Sidebar #2:
DRY EYE PROTOCOLS

Phase 1
- Eliminate environmental factors
- Add in 4 – 6 glasses Water per day
- Start Lid Hygiene procedures: Thermoeyes Mask or hot compress
  baby shampoo scrubs
  Zylet (lotemax + tobrex)
- Liquigel, Optive, Theratears Gel, etc. if cornea shows staining
- Omega 3: Organic Fish + Flaxseed combination
  500mg per day x 7d -> 1000mg per day x 7d -> 2000mg per day
  Contraindicated w/ Coumidin / Plavix / Heparin

Phase 2
- Lotemax 1gtt OU qid x 14d -> bid x 14d
- Restasis 1gtt OU bid x 6 mo

Phase 3
- Silicone Plugs: > 6 wks if no improvement through Phases 1- 2
  or Immediately if A.Rosacea present

Sidebar #3:
In the Blink of an Eye

With each blink, a new refractile surface is formed; indeed the tear film is the very first of many refractive surfaces that incoming light passes through on its way to the retina.

Overlying the hydrophobic cornea is a layer of mucous produced by goblet cells of the conjunctiva. This mucin creates a more favorable surface for the aqueous layer (produced by the supraorbital lacrimal gland and the accessory lacrimal glands) to float above and actually combines within the aqueous layer to allow for greater stability of the tear film. Above it all is the "oil slick" known as the lipid layer which when properly functioning prevents rapid evaporation of the aqueous.

Dry Eye Syndrome can be linked to:
- Tear Insufficiency (low tear volume)
- Tear Evaporation (poor tear quality)
- Related to Blepharitis
- As a byproduct of Meibomianitis
- A multifactorial combination of all of the above

Sidebar #4:
MGD Grading Scale

0+ (NONE)= lids without inflammation / gland orifices clear / clear oil droplets
1+ (TRACE)= minimal inflammation / subtle and inconsistent gland obstruction / clear meibum
2+ (MILD)= mild inflammation / more diffuse and pronounced gland obstruction / translucent meibum
3+ (MODERATE)= significant marginal inflammation / gland obstruction and blockage / thick, cloudy meibum that is expressed with palpation
4+ (SEVERE)= severe gland obstruction / toothpaste-like meibum that is expressed with forceful palpation

Note: the status of the meibum was the determining factor used in this study's grading of patients.

Sidebar #5:
Thermoeyes Quality of Life Survey

Directions: Please rate the following aspects based on your experiences with the Thermoeyes mask using this scale:

0 = never, not at all, poor
1 = rarely, almost poor
2 = sometimes, fair
3 = often, good
4 = all the time, very good
5 = excellent in all aspects

		RESULTS at WEEK 4	RESULTS at WEEK 8
A)	How easy was it to **understand** the usage of your ThermoEyes mask? _____0 _____1 _____2 _____3 _____4 _____5	**4.00**	**4.21**
B)	How easy was it to **use** your ThermoEyes mask / How convenient? _____0 _____1 _____2 _____3 _____4 _____5	**3.36**	**3.64**
C)	How comfortable was it to **wear** your ThermoEyes mask? _____0 _____1 _____2 _____3 _____4 _____5	**4.14**	**4.00**
D)	How would you **compare** ThermoEyes to hot compresses? _____0 _____1 _____2 _____3 _____4 _____5	**3.64**	**3.93**
E)	Do you feel your **dry eye symptoms** have changed since starting treatment? _____0 _____1 _____2 _____3 _____4 _____5	**3.36**	**3.86**
F)	Would you **recommend** ThermoEyes to others? _____0 _____1 _____2 _____3 _____4 _____5	**3.36**	**4.00**

Comments:

Sidebar #6:
Symptom Change Chart

SYMPTOM	# of CASES of IMPROVEMENT	# of CASES of ALLEVIATION
Redness	2	
Tearing	2	2
Contact Lens Discomfort	1	4
Sandy-Gritty Feeling	3	1
Blurry or Fluctuating Vision	3	3
Dryness	7	3
Burning		1
Lid Crusts	4	
Difficulty with Night Driving	2	4
Stinging	1	1
Itching	3	3
Photophobia	1	2
Irritation	3	2

Dr. Robert Gerowitz is in private practice in Palatine, Illinois. He specializes in Dry Eye Treatment and Orthokeratology. Dr. Gerowitz has no financial interest in any of the products or companies mentioned in this article. *He wishes to acknowledge the work of Drs. Paul Karpecki, Scot Morris, Trisha Rogers, Stephen Pflugfeld; and Ms. Suzanne Paulson, Founder of Eye Eco for their tireless efforts to help those with dry eye.*