CONQUERING OCULAR SURFACE DISEASE

With Next Generation Hygiene Therapy

> *Optometrists are not strangers to wellness, hygiene and preventive care—yet we shy away from pushing such principles in practice. Why is this the case?*

Blepharitis affects 80 million patients in the United States each year, with *Demodex* being the culprit much of the time.[1] Because *Demodex* mites can cause ocular inflammation and exacerbate many pre-existing ocular surface conditions—such as dry eye, chalazion, meibomian gland dysfunction, and pterygium—effective treatment is needed or a snowball effect will almost certainly follow.[2-4] This flies in the face of our true calling, as optometrists, to deliver preventative care.

Though the changes are gradual, there is no doubt that some segment of eye care can, and should, be moving in the direction of an ocular hygiene model in which optometrists position themselves as dentists do. Hygiene and ongoing wellness are the hallmark of dentistry and are the primary drivers of that profession's success. Optometrists, likewise, are not strangers to wellness, hygiene and preventive care—yet we shy away from pushing such principles in practice. Why is this the case?

Until recently, we could easily justify our reluctance. We lacked the diagnostic tools to recognize and fully understand ocular surface and lid disease. Plus, there really was not enough evidence and research to support using treatments that, in many cases, also lacked sufficient evidence to support regular use. But much has changed in the past several years. The mysteries of the ocular surface are now well known, and the treatments are safe, scientifically tested, and proven to be effective.

This is a new era for optometry. We are armed with knowledge and it is incumbent upon us to use it. At this roundtable event, a panel of experts joined

PAUL M. KARPECKI, OD, FAAO
Koffler Vision Group
Lexington, Kentucky

ALAN G. KABAT, OD, FAAO
Southern College of Optometry
Memphis, Tennessee

SCOTT G. HAUSWIRTH, OD, FAAO
Minnesota Eye Consultants
Minneapolis, Minnesota

SCOTT E. SCHACHTER, OD
Vision Source
Pismo Beach, California

MICHAEL S. COOPER, OD,
Windham Eye Group
Willimantic, Connecticut

to discuss a significant piece of the ocular hygiene puzzle. As an instigator of ocular surface and lid disease, *Demodex* blepharitis has plagued both doctors and patients as they hesitantly concocted lid scrubs from drug store shampoos and online essential oil retailers.

But with the introduction of a new scientifically-tested, preservative-free lash, eyelid and facial cleanser called Cliradex®, optometrists now have a uniform, professional treatment that is safe for everyday use.

This panel will examine the challenges of *Demodex* blepharitis and detail how we can help patients improve their overall health by taking care of their eyes each day, in much the same way as they take care of their teeth.

EARLY EXPERIENCE WITH TEA TREE OIL

DR. KARPECKI: *Tea tree oil for managing skin and ocular conditions has been documented in research around the world. Have you used or recommended it prior to commercialization and what was your experience?*

DR. SCHACHTER: I jumped in several years ago with a homemade 50/50 macadamia nut/tea tree oil. We would treat in the practice and sometimes send patients home with a lower concentration, which worked pretty well.

DR. KABAT: The thing that concerned me with old-school tea tree oil is that it lacked uniformity. Should we use pure tea tree oil as Dr. Schachter described, or a tea tree oil shampoo? Should it be diluted, and if so, to what concentration? There are too many variables. It's no wonder some patients had good responses, while others had very negative responses.

DR. HAUSWIRTH: The College of Optometry, the chief scientific and professional body in the UK, recently came out with an advisory against having practitioners and patients mix up their own tea tree oil. I've never been comfortable with having patients mix it on their own at home, but we really had no standardized alternatives for at-home treatment before Cliradex. Even in the office, I was not really a fan of mixing it up myself.

DR. KARPECKI: I have never been a proponent of having patients make it themselves. In our clinic, we've seen a number of patients who have tried and later presented with significant toxicity, SPK and other issues.

DR. COOPER: I agree. Using 100% pure Melaleuca alternifolia extract around the eye can be irritating. Sooner or later, if you condone at-home mixing, you will see toxicity reactions.

DR. SCHACHTER: There is also the concern of contamination with tea tree oil blending. Cliradex was developed by scientists and is commercially prepared, which gives me more peace of mind and appears more professional in the patient's view.

DR. COOPER: Cliradex has been an immense addition to my practice. BioTissue's scientists have researched and examined all the major chemical constituents that make up tea tree oil. Their findings led them to a key constituent called 4-Terpineol, which is the active ingredient found in Cliradex. This organic compound safely and effectively cleans and soothes the skin.

DR. HAUSWIRTH: You also can feel confident knowing that you get the same thing in

every package. It's contained in a small wipe that's easy for patients to use and apply.

THE 4-TERPINEOL DIFFERENCE

DR. KARPECKI: *How have companies improved the efficacy and minimized the issue of toxicity with commercial versions of tea-tree oil and why is 4-Terpineol isolation so important?*

DR. KABAT: When you look at the literature, it's clear that 4-Terpineol—a key constituent of Melaleuca alternifolia—is an ideal lid margin cleaner for a number of reasons. Obviously, it kills the *Demodex* mites. But peer-reviewed studies also suggest that it is anti-fungal, anti-microbial, and an anti-inflammatory.[5-8]

DR. KARPECKI: *Is it more effective than tea tree oil?*

DR. COOPER: At a concentration of 5%, 4-Terpineol (sometimes also called Terpinen-4-ol) has more of an effect than tea tree oil at a concentration of 25%. At a concentration of 10%, 4-Terpineol has more of an effect than tea tree oil at a concentration of 50%. It also has even greater miticidal effects than tea tree oil.[8]

DR. KARPECKI: *How does the safety profile of 4-Terpineol compare to that of tea tree oil?*

DR. COOPER: Allergic reactions and toxicity are not uncommon with tea tree oil, whereas the use of 4-Terpineol in the Cliradex wipe has been rigorously studied and found to be safe and effective for everyday use.[7]

DR. KABAT: The unique Cliradex packaging also plays a role. Prolonged storage of tea tree oil can lead to oxidation and loss of efficacy.[7] In fact, some tea tree oil ingredients neutralize each other over time, rendering them ineffective.[9]

DIAGNOSING DEMODEX BLEPHARITIS

DR. KARPECKI: *Demodex blepharitis is an extremely common, but overlooked, external disease problem. It causes ocular surface inflammation and can exacerbate many pre-existing ocular surface conditions, including dry eye, chalazion, meibomian gland dysfunction and pterygium.[2,4] What is the incidence in your practice?*

DR. SCHACHTER: We performed a study in my practice and found that 28 out of 100 consecutive patients had *Demodex* blepharitis.

DR. KARPECKI: *How do you go about making a diagnosis? Do you rely on a microscope or can you identify it clinically at the slit lamp?*

DR. HAUSWIRTH: Initially, it was very helpful to have a microscope. However, the more you look for it, the more you recognize the more overt clinical signs, and the less you really need a microscope. Today I make a clinical diagnosis simply by examining the lashes. Cylindrical dandruff is the main thing I look for. I also evaluate for brittleness or absence of some of the lashes, which can be signs in patients with low amounts of cylindrical dandruff. In almost every patient, you can base your diagnosis on this clinical appearance alone.

> *"Cliradex was developed by scientists and is commercially prepared, which gives me more peace of mind and appears more professional in the patient's view." - Dr. Schachter*

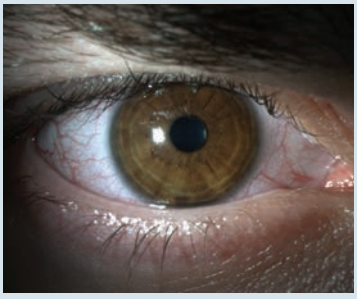
DR. SCHACHTER: I agree. The research clearly shows that cylindrical dandruff is pathognomonic for *Demodex*.[10]

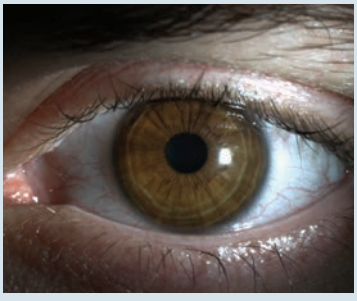
DR. KARPECKI: *The prevalence of Demodex folliculorum and Demodex brevis is truly astounding. In fact, 100% of patients aged 70 years and older are estimated to carry a colony of 1000 to 2000 mites.[11] While we know that age is a significant risk factor, should we also take a hard look for this in younger patients?*

DR. SCHACHTER: Absolutely.

CASE STUDY #1

A 23-year-old white male (optometry student) complained of persistent ocular irritation, especially toward the end of the day. Lid scrubs and artificial tears were not helpful.





After being diagnosed with *Demodex* (severe infestation), the individual was treated with Cliradex® Complete and Cliradex® wipes.

He made a full recovery and still performs lid cleansing on a regular basis with a surfactant cleaning agent.

You can find this in the pediatric population as well. In fact, I've found a fair amount when I started looking for it closely. For instance, if a younger patient is presenting with recurrent styes, take a good close look.

DR. KARPECKI: *Are there any other warning signs that should cause us to pause and look more closely for potential infestation?*

DR. SCHACHTER: Pterygia should alert you to at least look since this occurs at increased frequency when *Demodex* blepharitis is present.[3-4] Another common sign is conjunctival hyperemia.

DR. HAUSWIRTH: Indeed, ocular demodicosis perpetuates chronic inflammation, and this is shown through the increase in interleukin-17, making it a significant risk factor for conjunctival issues like pterygium and pinguecula.[4]

DR. SCHACHTER: Blepharitis has many untoward effects, with conjunctival injection being the most common. Other effects include lid redness, allergy and increased incidence of chalazion.[2,3] I'm also on the lookout for lid telangiectasia, lid inflammation, madarosis, uneven lash distribution, and a scalloped appearance to the lid margin due to lash distention.

DR. KARPECKI: *Are any patient-reported symptoms good indicators of Demodex blepharitis?*

DR. SCHACHTER: Patient symptoms often include itchy lids, burning, and a foreign body sensation. But sometimes, patients don't report symptoms. Like many ocular surface diseases, blepharitis is a condition where signs and symptoms don't always match. As such, it is often overlooked, which is unfortunate since blepharitis is a chronic, progressive condition. The more you let it progress, the harder it will be to treat. For this reason, in our practice, we routinely screen for the disease and treat it early.

DR. KABAT: One thing that we know about *Demodex* is that they are more active at night. When I have patients who report itching of their eyelids and irritation of their eyes in the evening, I absolutely want to rule out *Demodex*.

SELECTING AN AGENT

DR. KARPECKI: *There are a variety of different types of blepharitis and lid disease. And, for several years we've been able to effectively address a whole host of bacteria on the lids—including Staph. epidermidis, Staph aureus., MRSA, Serratia and others. The antimicrobial armamentarium has grown quite strong. Do we really need to add 4-Terpineol preparations to the arsenal?*

DR. COOPER: There's a definite need for multiple products in this category. Clearing out bacteria, as many of the other products on the market do,

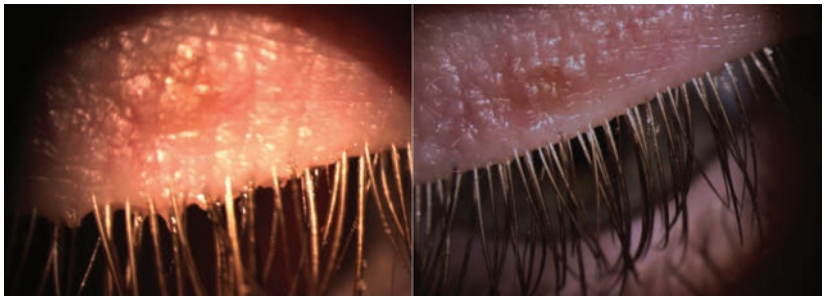
is critical. But in the case of *Demodex* mites, which are the most common cause of blepharitis, Cliradex gets to the root of the cause. Cliradex kills the mite—not just the bacteria it leaves behind.

DR. SCHACHTER: I agree. Cliradex is my go-to choice because I believe it's the most effective at killing the mites. As most blepharitis tends to be due to *Demodex* infestation, the best way to treat it is to attack the culprit. While many lid scrubs do a good job of cleaning up the waste of *Demodex* (think janitor) Cliradex attacks the cause of blepharitis (think exterminator).

DR. KABAT: I use a number of agents in my practice, and think there is value in all of them. But when I see *Demodex*, I want to use something that's miticidal—and Cliradex is my treatment of choice in this category.

STRUCTURING TREATMENT

DR. KARPECKI: *4-Terpineol products are now available in two forms—the wipes that patients use at home and the in-office treatments (Cliradex Complete Advanced Lid Hygiene Kit). Cliradex Complete consists of a formulation for in-office application that has a stronger concentration of the isolated 4-Terpineol. Does anyone have experience with this formulation and is this how you should initiate treatment in most Demodex cases?*



Twenty-two year-old male diagnosed with Demodex blepharitis. One month after Cliradex use.

DR. HAUSWIRTH: In my clinical experience, wipes alone work well in most of my patients—probably 18 out of 20. I reserve in-office treatment for more severe cases, and for difficult (or perhaps noncompliant) patients who don't improve after four to six weeks on Cliradex wipes.

DR. KARPECKI: *When do you use in-office treatment and how often do you need to repeat treatment?*

DR. COOPER: It varies. Much of my decision is based on the entire constellation of the ocular surface disease and the amount of inflammation that's being sparked by the *Demodex*. If it's significant, I'll repeat treatment. But, I don't often need to.

DR. HAUSWIRTH: There are two situations in which I've found a need for repeat treatment: rosacea and hypersecretory seborrheic blepharitis. Rosacea is tough because it's chronic and you're dealing with an entire inflammatory dermatitis issue that's harder to control. But with good compliance, the improvement is tremendous. And rosacea patients really love Cliradex. It seems to soothe their skin and cool everything down. The other aggressive presentation that has led me to repeat treatment is hypersecretory seborrheic blepharitis. Greasy lashes seem to create a better environment for mites to thrive. In these patients it's not uncommon to perform two or three treatments. But, in most other cases, one treatment seems to suffice.

DR. KABAT: I would add one final challenging presentation to the list for potential repeat treatment with Cliradex Complete: patients who have significant dermatochalasis. This physical barrier partially shields mites from eradication, sometimes requiring another round of ammunition.

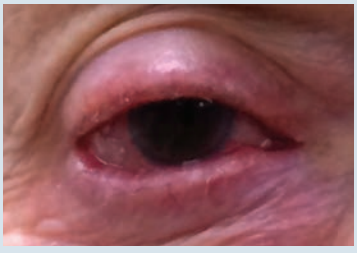
DR. SCHACHTER: It's in these more severe cases that the in-office Cliradex is especially important to control the mite population. The best way to support the in-office treatment is continued hygiene with Cliradex.

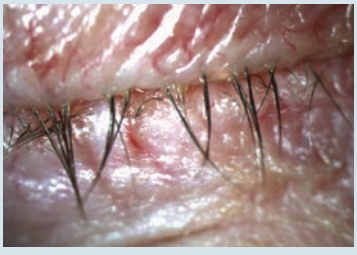
DR. KARPECKI: *What is your maintenance recommendation for the Cliradex wipes?*

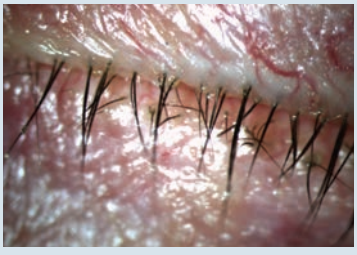
DR. SCHACHTER: In most

CASE STUDY #2

An 82-year-old white female (retired artist) presented with chronic red eyes and a longstanding history of dry eye symptoms.







The patient was unhappy with her appearance and vision. Diagnosed with *Demodex* (severe infestation) and rosacea, she was treated with BlephEx and Cliradex® wipes, twice daily for six weeks, resulting in good recovery and greatly improved symptoms (mites persisted, but at a much lower level). The individual continues to use Cliradex® on a daily basis because it makes her "feel clean" and keeps the associated redness from rosacea at a minimum.

cases, I follow-up in one month to make a final determination about how much longer to continue treatment.

DR. KARPECKI: *Is anyone performing an in-office Demodex treatment in conjunction with a BlephEx procedure?*

DR. KABAT: Yes, I've found that debulking the accumulated debris, improves efficacy. *Demodex* tend to burrow down into the lash follicle and can be partially shielded by a distinct layer of tissue or debris. By removing this, you give Cliradex and Cliradex Complete easier access to the mites.

DR. HAUSWIRTH: I agree that removing the superficial crust prior to treatment leads to a better or faster result. However, I use a simple golf club spud or a PRK spatula to manually manipulate it off the lash base. My experience is that I can actually remove more debris that way, in addition to some of the dead skin that lies in between the lashes.

OCULAR HYGIENE: THE BIGGER PICTURE

DR. KARPECKI: *You've heard the saying, "If no one ever got sick, there'd be no need for doctors." This simply is not true. Our most important job as doctors is to prevent patients from getting sick in the first place—or at least to keep them from getting sicker. Dentists apply this concept quite effectively, although it took their profession 40 years to implement. Eye care, on the other hand, has a long way to go, but I expect we'll implement it very quickly. In fact, ocular surface disease accounts for one in five visits to eye care practitioners.*[12] *Much of this, as you know, is preventable. Does anyone have suggestions on how to start doing things differently regarding preventative care and looking at progressive diseases like blepharitis differently so we keep patients healthier?*

DR. HAUSWIRTH: I agree that we still have a long way to go before we're operating from a truly preventative standpoint, but optometry as a profession is moving in that direction—particularly with blepharitis and meibomian gland dysfunction. It's now well accepted that these pathologies are best managed early. The next step is getting the optometric community to be a little more assertive about the importance of assisting patients in developing good habits—much as dentistry has done with teeth brushing. It's exciting to see the movement in that direction because, as optometrists, we can own this space.

DR. KARPECKI: *Twenty years ago, we didn't have meibography and we didn't know the impact that inflammation has on the glands. But thanks to new instrumentation and diagnostic*

technology, now we do and we see progressive advanced disease and complete loss of glands. Does this change our obligation to patients?

DR. SCHACHTER: Many ocular surface conditions are slow, chronic and progressive. We can't ignore them just because the patient isn't complaining yet. That's not in their best interest. It's not what I would want for my own family and it's not what I want for my patients. When I see a condition like blepharitis that I can make better with simple wipes, I'm going to let my patient know about it because, down the road a few years, that small step can make a big difference.

> *"Patients deserve to be educated about ocular wellness and hygiene just as they are about dental care." - Dr. Karpecki*

DR. KARPECKI: I agree. Patients deserve to be educated about ocular wellness and hygiene just as they are about dental hygiene.

DR. KABAT: Even well-educated eye care professionals sometimes don't know that they have *Demodex*. In fact, one of the earliest patients that I treated with Cliradex was a colleague who suffered from rosacea. We discovered the condition while in a workshop. He was appalled and embarrassed, but he agreed to give Cliradex a try and made a tremendous recovery. Another benefit of Cliradex that helps us position it as part of a hygiene regimen is that it's an all-natural solution that can be compared to washing your hands and face.

HOW TO TALK TO YOUR PATIENTS ABOUT MITES

DR. KARPECKI: *There is some debate about how graphic we should be when discussing Demodex with our patients. What are your opinions?*

DR. KABAT: I know that some of my colleagues think it's horrific to show patients what's living on their lashes, but I do show it to them because it definitely helps with compliance. I don't try to scare them, but I'm very honest and matter-of-fact about the condition.

DR. COOPER: I practice in a region where patients are pretty skeptical. So while I don't always need to do it, I do usually use the microscope and LCD screen. I put it on a slide and add a little fluorescein so they can see them wriggle around. It gets patients' attention and there's more buy-in with treatment. Otherwise, this naysayer patient subset might just be thinking "yeah, yeah, whatever."

DR. SCHACHTER: I understand your perspective and used to do that as well, but I don't anymore. I changed my strategy when one of my patients went home and shaved her head and her eyebrows. Now, I'm very cautious about alarming patients too much. To get my point across, I show patients the cylindrical dandruff with an anterior segment camera. They get to see the telangiectasias, the lash loss, the scalloped lid appearance, and the pyramidal extensions around the base of the lash. Then I explain that this is a common condition and that everybody has some mites, but this is what happens when you have too many. Typically, this description is enough to drive compliance for my patients.

DR. HAUSWIRTH: I agree with Dr. Schachter. I have not found the need to break out the microscope in a long time. I explain it in a very general sense and may elect to show the dandruff and the changes to the lid margin. Then I explain how inflammation affects the well-being of their tissue. In most cases, patients will buy in just on that alone.

DR. KARPECKI: It appears that we're split down the middle on this debate. Maybe that's for the best since it illustrates that we can get this important message across to patients, regardless of our personal communication styles.

Scan to watch Cliradex patient testimonials.

DR. SCHACHTER: We're taking a close look at ocular surface disease in our practice and deciding what kind of hygiene to set up for our patients. This is a big opportunity for us to set our practice apart. We want to get the message out that meibomian atrophy is much like a cavity, except it can't be fixed.

DR. KABAT: At our facility we've been able to carve out an entire service and are receiving referrals by making this a subspecialty area. You'd be surprised how quickly you might be doing nothing but ocular surface and hygiene once a week. It all begins by simply letting patients know that you can do more for them.

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PREPARING PATIENTS FOR THE "CLIRADEX TINGLE"

DR. KARPECKI: *What has been your clinical experience with respect to the "Cliradex Tingle" and how do you prepare patients for it?*

DR. KABAT: Most patients do just fine with the way it feels as long as they know what to expect. This begins by demonstrating how to use the product in the office. I tend to describe it as uncomfortable in the beginning so that patients are pleasantly surprised to find that it's not as harsh as they expected based on my description. Then, the technician opens it and lets the patient get a smell of it. Next, they let the patient try it. Be sure to explain that it is important to keep the eyes closed until the solution has fully dried

DR. COOPER: I suggest that patients put a very cold cloth on their face prior to administering the wipe at home. This simple act alone will calm down most sensitivities.

DR. KARPECKI: *Do you advise patients to use the wipe on their eyelids only?*

DR. SCHACHTER: Since Demodex proliferate, we have patients use the wipes on their entire face—beginning with the eyes. It's very important to be clear about how you use this product differently on the lid area. This is not a scrubbing or rubbing procedure. Explain that the goal is to saturate the base of the lashes and let it sit there for a short time before moving on to the forehead, cheeks and base of the ears and nose.

DR. KARPECKI: *Does the tingle diminish over time?*

DR. SCHACHTER: The first couple of days patients do feel the tingle, but the sensation gets a lot better within about a week. As a matter of fact, I've had some patients ask if it would be okay if they kept using Cliradex twice a day because they actually like the way it feels. They feel like it's effective.