Fifteen years ago the first international workshop on dry eye was organized to bring together experts from around the world to discuss and establish the first internationally recognized criteria for definition, classification, diagnosis and treatment of dry eye disease. These deliberations, which took place over a two-year period, resulted in the publication of a major report in 1995. This report has stood as the standard reference document for clinicians and researchers throughout the world.

As major advances have developed in the fields of molecular biology, cellular mechanisms, and new technologies, which allow researchers to explore important facets of the disease, our new understanding has led to significant discoveries, the development of more effective treatments and the promise of a new generation of pharmaceutical products.

With this background of change, a new international dry eye workshop was organized over the last four years. Over 70 experts from diverse scientific disciplines gathered at several meetings and produced a new updated report which has just been published. As Chair of the Subcommittee on Definition and Classification, I will summarize the most important aspects of this new report.

You might ask, “Why is it important to define dry eye?” There has been much confusion about the nature of this condition since it is associated with a number of other conditions such as systemic autoimmune disease, aging, hormonal insufficiency, drugs and refractive surgery. What is now clear is that dry eye is a real disease with specific changes in the tear film and surface of the eye regardless of which risk factor(s) led to its onset.

Scientists Discover Candidate Salivary Markers for Sjögren’s Syndrome

Three years ago, scientists supported by the National Institute of Dental and Craniofacial Research (NIDCR), part of the National Institutes of Health, began taking the first full inventory of the proteins that normally are produced in our salivary glands. Now, one of those scientists and his colleagues offer a first glimpse into how this new research tool can be applied to detect subtle changes in the protein content of a person’s saliva that may be linked to an oral or systemic disease. As reported in the November issue of the journal Arthritis and Rheumatism.
In addition, new discoveries have shown that dry eye disease has significant effects on vision as the tear film breaks up between blinks, leading to difficulties in driving and reading. Other new discoveries relate to the role of inflammation in damaging the cells of the eye surface. So an updated definition was formulated to reflect these new findings and relate them to the well-established hallmarks of dry eye disease (i.e. tear film instability and increased concentration of salts in the tears also known as increased tear osmolarity). The new definition of dry eye disease in the Dry Eye Workshop (DEWS) report is as follows:

Dry eye is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability, with potential damage to the ocular surface. It is accompanied by increased osmosality of the tear film and inflammation in the ocular surface.

This definition emphasizes the most important features of dry eye disease which lead to the symptoms of discomfort, pain, blurred vision and damage to the surface of the eye. The reason this is so important is that scientists and practicing doctors now will have a framework to better understand what has gone awry. This is a prerequisite to developing an effective treatment plan.

In the previous dry eye workshop in the early 1990s the experts identified two major types of dry eye disease. The first of these is a deficiency of tear production by the tear-producing lacrimal glands. In addition, there is a second very common form of the disease in which there is excessive loss of tears through evaporation into the atmosphere. This latter condition occurs most often when the oil glands of the eyelid, which retard the loss of tears, are not working well. In fact, this feature of dry eye disease may be more common even than the deficient production of tears. Recent studies have shown that in most patients there is a combination of both elements. This should not be surprising since some of the same cellular and chemical abnormalities affect both the tear-producing and the oil-producing glands.

The DEWS report confirms the previous classification but further develops this concept and explains how events occurring in the tear film, such as a break-down in the tear film and an increased concentration of salts, are closely related to damage to the cells of the cornea and conjunctiva. In fact, these abnormal changes at the surface of the eye lead to symptoms of pain, blurred vision, a decrease in reading time, difficulties driving and a general decline in the quality of life. One study assessing the impact of dry eye disease on quality of life equated this disease with severe cardiac disease.

The subcommittee report emphasized that the two essential features of all types of dry eye are a tear film that is breaking up between blinks and a highly concentrated tear film which is injurious to the cells of the eye surface which it bathes. The effect is tears which are high in salt content rather like the water of
the Dead Sea or the Great Salt Lake. In both of these environments very few living things will grow. In like manner, the cells of the eye surface are damaged and inflammation is stimulated which further damages the cells, resulting in premature cell death and frank sores on the eye.

These processes are particularly apparent in Sjogren’s syndrome-associated dry eye disease. In this condition there is a systemic component in which inflammatory cells from the general circulation are added to the ongoing inflammation on the eye surface leading to extensive destruction of the tissue with more severe symptoms, including pain and visual loss.

Another factor to consider is the effect on the patient’s environment both within the body and outside. Aggravating internal conditions which worsen the disease process include a decrease in blinking which reforms the tear film, abnormalities in lid movement which may worsen loss of tears to evaporation, and the use of a variety of systemic and local eye drugs. Systemic drugs which adversely affect tear production include antihistamines, beta-blockers which are used for cardiac conditions, anti-spasmodics used to control bowel activity, diuretics and some psychiatric drugs. A good rule of thumb is that any pill which produces dry mouth can decrease tear production.

External environmental factors can exert a significant stress on an already compromised tear film. The most commonly encountered external factors include climate conditions and artificial environments with low humidity, such as the interior of an airplane. This is particularly noticeable on long plane trips. Occupational and recreational activities can stress the tear film, such as the use of computer screens over three hours per day (this results in a decrease in blinking). Bicycle and motorcycle riding create significant wind stress. In all of these situations there is increased loss of tears to evaporation.

The report on definition and classification is but one subcommittee report among a number of others which deal with other topics such as diagnosis, management and treatment, clinical studies to develop new treatments, studies on how widespread the disease is and recommendations for future research. Progress is being made on all these fronts, and while it is never fast enough for those suffering, it is indeed encouraging and augurs well for significant advances in the coming years. ■

### Friends Helping Friends Campaign

There is still time to send in your donations!

If you have collected donations from friends and/or family for our 2008 Friends Helping Friends campaign, please remember to return them to the SSF by March 14th along with your Collection Summary Form.

*Sjögren’s Syndrome Foundation-FHF*

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Thank you for joining us in this effort to increase awareness, one friend at a time!
tis and Rheumatism, the scientists detected 42 proteins and 16 peptides in saliva that clinically discriminated between people with the primary form of Sjögren’s syndrome and healthy volunteers. These data far surpass previous efforts to identify protein biomarkers for primary Sjögren’s syndrome, a chronic autoimmune condition of the salivary and tear glands that affects about two million Americans, mainly women. The scientists also identified 27 distinct gene transcripts that were over produced in the saliva of those with primary Sjögren’s syndrome. The Inside Scoop spoke with the study’s senior author Dr. David Wong, a scientist at the University of California at Los Angeles School of Dentistry. He offered his thoughts on the paper’s findings, its implications, and the recent research progress with salivary diagnostics.

Some people have asked “Why develop saliva as a diagnostic fluid? Isn’t blood good enough?”

One part of the answer is saliva can be readily collected. That’s a big plus. As most dentists and physicians will tell you, they treat patients everyday who wince at a needle poking their skin or mouth. Saliva also is easier than blood to store and, if needed, to ship. But there’s a second part to this answer that really is worth emphasizing.

What’s that?

The salivary glands do not exist in isolation from the rest of the body. In other words, they are not just a series of glands that secrete fluid into the mouth. The salivary glands are connected to the rest of the body through blood vessels that nourish them and neural networks that innervate them. So, they contain information about health and disease and, with its ease of collection, saliva could serve as an ideal diagnostic fluid. That’s been the vision that has moved the concept forward through the years.

That movement was relatively slow during the 20th century. Where did things stand with salivary diagnostics just five years ago?

Well, salivary diagnostics was fairly well defined in terms of its physiology and biochemistry. The scientific gaps arose in defining its clinical utility. As I mentioned, we didn’t know whether or not saliva could become a mainstream diagnostic fluid. It’s still not a mainstream diagnostic fluid, but things have changed in a very good way over the last few years.

How so?

A real turning point was NIDCR’s support of a consortium of laboratories – which included my lab at UCLA – to inventory for the first time the proteins produced in the major salivary glands. Here at UCLA, we also assembled independently a companion inventory of over 3,000 gene transcripts produced in the saliva. With these two toolboxes – I call them diagnostic alphabets – we can begin to evaluate more methodically and systematically the potential of saliva as a diagnostic fluid for oral and systemic diseases.

You can cast a wide net.

Exactly. Before the arrival of these toolboxes, we basically were shooting in the dark. If we heard a research group had found a promising biomarker in blood or urine for a given disease, we looked in saliva to see if it was there, too. We were playing a “me-too” game. What was lacking was a solid scientific foundation to develop the full diagnostic potential of saliva. With these toolboxes now in hand, the game has changed. We can look de novo for signs of a given disease. In other words, we know healthy people have on average 1,166 distinct proteins in their saliva. That gives us 1,166 places to look for measurable changes in protein expression that might be indicative of disease.

And you can do so by comparing the molecular content of saliva from a healthy person with that of an individual known to have Sjögren’s or another disease? Is this what you and your colleagues did in this paper?

That’s exactly right. In our pilot study, we collaborated with Dr. Arjan Vissink and his group in the Netherlands. Arjan has studied Sjögren’s for many years, and he provided saliva samples from 10 people diagnosed with primary Sjögren’s. We compared the samples with those from 10 healthy volunteers. We cast our investigative net, measured the protein content in both groups, and pulled out 42 proteins and 16 peptides that were either over or under expressed in the Sjögren’s group. So, these data really highlight the maturation of the salivary proteome as a diagnostic tool.

What about the other toolbox?

We opened the transcriptome toolbox and profiled the gene transcripts in the saliva. Using very stringent criteria, we found 27 gene transcripts that were significantly
If you are one of the thousands of Sjögren's syndrome patients 1-4 who is experiencing difficulty chewing and swallowing food, speaking, or even sleeping at night because of a chronic dry mouth, consult your health care provider and ask if EVOXAC® (cevimeline HCl) is right for you. EVOXAC is available by prescription only.

EVOXAC is indicated for the treatment of symptoms of dry mouth in patients with Sjögren's syndrome.

Every patient reacts differently to medication and some may not experience positive results.

The information provided in this ad is not intended to replace a health care provider consultation. Ultimately, your health care provider will determine whether EVOXAC is right for you. Please consult your health care provider about this information and about the risks and benefits of EVOXAC.

Safety considerations

- The most common side effects are: excessive sweating, headache, nausea, sinusitis, upper respiratory infections, rhinitis, and diarrhea
- You should not take EVOXAC if you have uncontrolled asthma, eye inflammation, narrow-angle (angle-closure) glaucoma, or allergies to EVOXAC
- Before taking EVOXAC, tell your doctor if you have a heart condition, controlled asthma, chronic bronchitis, emphysema, a history of kidney disease or gallstones, or if you are taking any heart medications, especially “beta-blockers.” If you have any of these conditions, your doctor will monitor you under close medical supervision while you are taking EVOXAC
- Tell your doctor and pharmacist if you are taking prescription or over-the-counter medications to avoid any possible drug interactions
- The safety and effectiveness of EVOXAC in patients under 18 years of age have not been established
- Special care should be taken if you are elderly
- You should be careful when driving at night or performing hazardous activities in reduced lighting while taking EVOXAC
- If you sweat excessively while taking EVOXAC, you may become dehydrated. To prevent this, drink extra water and talk to your doctor

Please see brief summary of full prescribing information on following page.
### References


### EVOXAC® Capsules (cevimeline hydrochloride)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Placebo (n = 164)</th>
<th>Placebo (n = 164)</th>
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</thead>
<tbody>
<tr>
<td>Headache</td>
<td>14.4% 20.1%</td>
<td>12.3% 10.9%</td>
</tr>
<tr>
<td>Sinusitis</td>
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<td>12.3% 10.9%</td>
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<td>Upper Respiratory</td>
<td>12.3% 10.9%</td>
<td>12.3% 10.9%</td>
</tr>
<tr>
<td>Tract Infection</td>
<td>11.4% 9.1%</td>
<td>11.4% 9.1%</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>8.8% 6.8%</td>
<td>8.8% 6.8%</td>
</tr>
<tr>
<td>Abdominal Infection</td>
<td>6.8% 5.1%</td>
<td>6.8% 5.1%</td>
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<tr>
<td>Urinary Infection</td>
<td>6.8% 5.1%</td>
<td>6.8% 5.1%</td>
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<tr>
<td>Coughing</td>
<td>6.8% 5.1%</td>
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<td>Pharyngitis</td>
<td>5.2% 4.4%</td>
<td>5.2% 4.4%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>4.4% 3.3%</td>
<td>4.4% 3.3%</td>
</tr>
<tr>
<td>Rash</td>
<td>4.4% 3.3%</td>
<td>4.4% 3.3%</td>
</tr>
</tbody>
</table>

### ADVANCED ADVERSE REACTIONS

- Headache
- Sinusitis
- Upper Respiratory Infections
- Tract Infection
- Dyspepsia
- Abdominal Infection
- Urinary Infection
- Coughing
- Pharyngitis
- Vomiting
- Rash

### Management of Overdose:

In the event of an overdose, supportive management is important. The patient should be monitored for signs and symptoms of toxicity. If the overdose is severe, induced vomiting or gastric lavage may be necessary. Activated charcoal may also be administered to adsorb any undigested drug. The patient should be closely monitored for evidence of toxicity, and supportive care should be provided as necessary. If the patient is unconscious, intubation and mechanical ventilation may be required to support respiration.

### Additional Information:

- **EVOXAC® (cevimeline hydrochloride)**
- **Brand Name:** EVOXAC
- **Generic Name:** Cevimeline hydrochloride
- **Uses:** For the symptomatic treatment of xerophthalmia associated with Sjögren’s syndrome, Sjögren’s-like syndrome, and Sjögren’s-like syndrome of the eye.
- **Dosage:** Cevimeline hydrochloride capsules are available in strengths of 30 mg and 60 mg.
- **Contraindications:** Cevimeline hydrochloride is contraindicated in patients with uncontrolled asthma, known hypersensitivity to cevimeline or any excipients, and in patients who are receiving concurrent anticholinergic therapy.
- **Warnings:** Cevimeline hydrochloride should be used with caution in patients with a history of glaucoma, prostatic hypertrophy, bladder outflow obstruction, and urinary retention.
- **Precautions:** Cevimeline hydrochloride should be used with caution in patients with a history of urinary tract obstruction, cerebral arteriosclerosis, and cardiovascular disease.
- **Adverse Reactions:** The most common adverse reactions associated with the use of cevimeline hydrochloride are dry mouth, flushing, headache, and nasal congestion.
- **Overdosage:** In the event of an overdose, supportive management is important. The patient should be monitored for signs and symptoms of toxicity. If the overdose is severe, induced vomiting or gastric lavage may be necessary. Activated charcoal may also be administered to adsorb any undigested drug. The patient should be closely monitored for evidence of toxicity, and supportive care should be provided as necessary. If the patient is unconscious, intubation and mechanical ventilation may be required to support respiration.
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- **Dosing:** Cevimeline hydrochloride capsules are available in strengths of 30 mg and 60 mg.
- **Storage:** Store at room temperature, 20° to 25°C (68° to 77°F), and protect from moisture.
- **Packaging Information:** Each capsule contains 30 mg or 60 mg of cevimeline hydrochloride. Each capsule also contains the inactive ingredients gelatin, lactose monohydrate, sodium lauryl sulfate, and titanium dioxide.

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upregulated in the Sjögren’s group. What’s really striking here is 19 of the 27 genes are involved in various aspects of the inflammatory process.

So that tells you that you’re in the right ballpark? Sjögren’s syndrome is an autoimmune disease, and the inflammatory process is reflected in the saliva.

Correct. This suggests to me that saliva contains the constituents to reconstruct the disease process. It will be exciting to explore this possibility further and tease out more information of potential diagnostic value. Right now, a person faces a battery of expensive and time consuming tests to get a diagnosis of primary Sjögren’s syndrome. Salivary diagnostics could make it simple, quick, and painless.

What is the sensitivity and specificity of the markers that you found? How tightly do they correlate with the disease?

That hasn’t been determined yet. Nor do we know which of these molecules might be associated with early disease and thus might be important for early detection. Keep in mind, our findings are only research leads at this point. Each protein and gene transcript must be validated in at least two follow up studies to be considered as a marker of disease.

Do you plan to follow up these leads in the near future?

Absolutely. We are in the midst of planning a larger validation study right now.

What do you have in mind?

We’ll need to have at least 50 people with primary Sjögren’s and 50 healthy volunteers. That’s the general design. But we’ll need to do these independent validation studies at least twice. You do the first study to validate the markers and then, based on its findings, you build a prediction model. In the second validation study, you independently test the reliability of the prediction model. If the outcome is good, you can begin to envision an algorithm, possibly combine the most informative molecules into a panel of diagnostic markers, and proceed to clinical testing.

You’ve already ploughed through this validation process in your work with salivary markers for oral cancer.

That’s right. In December 2004, my lab published a paper that reported on four gene transcripts that were
elevated in the saliva of patients with oral squamous cell carcinoma. Since then, my lab has worked extremely hard to take these markers through the validation process. I’m pleased to say that a few weeks ago, these salivary oral cancer RNA biomarkers were validated as markers for oral squamous cell carcinoma by the Early Detection Research Network, or EDRN. The EDRN is an initiative supported by the National Cancer Institute that develops and validates markers for the early detection of cancer.

Where do these gene transcripts come from?

They come from almost every conceivable source. The transcripts are in the ductal fluid secreted into the mouth as saliva. They’re obviously in the acinar and ductal cells of the salivary glands, as well as in gingival crevicular fluid. That leaves open the issue of transcripts reaching the salivary glands from a distant disease site, and we’re studying that question right now using animal models. Hopefully, these studies will fill in some of the blanks. But, as mentioned earlier, the larger point is you cannot draw a line between the mouth and the rest of the body. If a part of the body is unhealthy, it will be reflected elsewhere. The real blessing here is that this information seems to be reflected in a non-invasive fluid that we can readily collect in the mouth.

In the Sjögren’s paper, you evaluated saliva collected from the parotid gland, one of the major salivary glands, and whole saliva. Whole saliva is the total secretion from all of the major and minor salivary glands. You found that whole saliva had more diagnostic value. Was this surprising and why?

It was surprising. If you had asked me to guess beforehand, I would have said the parotid fluid would be more informative. That’s because most of the oral pathology that we are aware of with Sjögren’s occurs in the parotid gland. It would seem like a logical place to look for signs of disease, particularly because whole saliva contains other glandular constituents as well as gingival crevicular fluid. So, it was an unexpected but welcome outcome.

Why “welcome?”

Let’s say a rheumatologist wants to take a saliva sample. He or she won’t need to ask a patient to sit down for an hour to have a parotid gland drained. The doctor can collect a whole saliva sample in a matter of seconds.

It sounds like this paper has ramped up your work load?

Well, it’s a good position to be in. I might add that about 5 percent of those with Sjögren’s syndrome develop malignant lymphoma, and we’re looking into that, too. Now that we have these toolboxes, I think the field will move much faster to crack saliva’s diagnostic codes. But we still need that one big research victory. Imagine the day when there’s a news headline that saliva can be used for the early detection of a systemic disease. If the science is good and credible, you can almost begin to see how the table will turn. Now we knock on doors for help. The day that happens, they will be knocking our doors.
We gratefully acknowledge the contributions of our members and friends.

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RESTASIS® Ophthalmic Emulsion helps increase your eyes' natural ability to produce tears, which may be reduced by inflammation due to Chronic Dry Eye. RESTASIS® did not increase tear production in patients using topical steroid drops or tear duct plugs.

**Important Safety Information:**
RESTASIS® Ophthalmic Emulsion should not be used by patients with active eye infections and has not been studied in patients with a history of herpes viral infections of the eye. The most common side effect is a temporary burning sensation. Other side effects include eye redness, discharge, watery eyes, eye pain, foreign body sensation, itching, stinging, and blurred vision.

Find out more about a $20 rebate offer!
See next page for details.

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Go to restasis6.com or call 1-800-677-9716 for a free information kit.

Available by prescription only.

(Cyclosporine Ophthalmic Emulsion) 0.05%

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Mail this certificate along with your original pharmacy receipt

In vitro gave indication of a positive effect (i.e., induction of SCE). Significantly exceeded the control rate in the low dose level. The hepatocellular carcinomas and pancreatic islet cell adenomas found for lymphocytic lymphomas in females, and the incidence of hepatocellular carcinomas in the 24-month oral (diet) rat study, conducted at 0.5, 2, and 8 mg/kg/day, evidence of a statistically significant trend was

RESTASIS® Ophthalmic Emulsion has not been studied in patients with a history of herpes keratitis. General: For ophthalmic use only.

Information for Patients: The emulsion from one individual single-use vial is to be used immediately after opening for administration to one or both eyes, and the remaining contents should be discarded immediately after administration. Do not allow the tip of the vial to touch the eye or any surface, as this may contaminate the emulsion. RESTASIS® should not be administered while wearing contact lenses. Patients with decreased tear production typically should not wear contact lenses. If contact lenses are worn, they should be removed prior to the administration of the emulsion. Lenses may be reinset 15 minutes following administration of RESTASIS® Ophthalmic Emulsion.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Systemic carcinogenicity studies were carried out in male and female mice and rats. In the 78-week oral (diet) mouse study, at doses of 1, 4, and 16 mg/kg/day, evidence of a statistically significant trend was found for lymphocytic lymphomas in females, and the incidence of hepatocellular carcinomas in mid-dose makes significantly exceeded the control value.

Cyclosporine has not been found mutagenic/genotoxic in the Ames Test, the V79-HGPRT Test, the micronucleus test in mice and Chinese hamsters, the chromosome-aberration tests in Chinese hamster bone-marrow, the mouse dominant lethal assay, and the DNA-repair test in sperm from treated mice. A study analyzing sister chromatid exchange (SCE) induction by cyclosporine using human lymphocytes in vitro gave indication of a positive effect (i.e., induction of SCE). No impairment in fertility was demonstrated in studies in male and female rats receiving oral doses of cyclosporine up to 15 mg/kg/day (approximately 15,000 times the human daily dose of 0.001 mg/kg/day) for 9 weeks (male) and 2 weeks (female) prior to mating.

Pregnancy-Teratogenic Effects: Pregnancy category C.

Teratogenic Effects: No evidence of teratogenicity was observed in rats or rabbits receiving oral doses of cyclosporine up to 300 mg/kg/day during organogenesis. These doses in rats and rabbits are approximately 300,000 times greater than the daily human dose of one drop (28 µL) of 0.05% RESTASIS® BID into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed.

Non-Teratogenic Effects: Adverse effects were seen in reproduction studies in rats and rabbits only at dose levels toxic to dams. At toxic doses (rats at 30 mg/kg/day and rabbits at 100 mg/kg/day), cyclosporine oral solution, USP was embryo- and testotoxic as indicated by increased pre- and postnatal mortality and reduced fetal weight together with related skeletal malformations. These doses are 50,000 and 100,000 times greater, respectively, than the daily human dose of one drop (28 µL) of 0.05% RESTASIS® BID into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed. No evidence of embryotoxicity or teratogenicity was observed in rats or rabbits receiving cyclosporine at oral doses up to 17 mg/kg/day or 30 mg/kg/day, respectively, during organogenesis. These doses in rats and rabbits are approximately 17,000 and 30,000 times greater, respectively, than the daily human dose.

Onset of rats receiving a 45 mg/kg/day oral dose of cyclosporine from Day 15 of pregnancy until Day 21 post partum, a maternally toxic level, exhibited an increase in postnatal mortality; this dose is 45,000 times greater than the daily human topical dose. 0.001 mg/kg/day, assuming that the entire dose is absorbed. No adverse events were observed at oral doses up to 15 mg/kg/day (15,000 times greater than the daily human dose).

There are no adequate and well-controlled studies of RESTASIS® in pregnant women. RESTASIS® should be administered to a pregnant woman only if clearly needed.

Nursing Mothers: Cyclosporine is known to be excreted in human milk following systemic administration but excretion in human milk after topical treatment has not been investigated. Although blood concentrations are undetectable after topical administration of RESTASIS® Ophthalmic Emulsion, caution should be exercised when RESTASIS® is administered to a nursing woman.

Pediatric Use: The safety and efficacy of RESTASIS® Ophthalmic Emulsion have not been established in pediatric patients below the age of 16.

Geriatric Use: No overall difference in safety or effectiveness has been observed between elderly and younger patients.

ADVERSE REACTIONS
The most common adverse event following the use of RESTASIS® was ocular burning (17%). Other events reported in 1% to 5% of patients included conjunctival hyperemia, discharge, epiphora, eye pain, foreign body sensation, pruritus, stinging, and visual disturbance (most often blurring).

Rx Only
Based on package insert 71271US15FP revised February 2004

Follow these 3 steps:

1. Have your prescription for RESTASIS® filled at your pharmacy.
2. Circle your out-of-pocket purchase price on the receipt.
3. Mail this certificate along with your original pharmacy receipt (proof of purchase) to Allergan RESTASIS® Ophthalmic Emulsion $20 Rebate Program, P.O. Box 6513, West Caldwell, NJ 07007

For more information, please visit our Web site, www.restasis1.com.

REXSIS® Rebate Terms and Conditions: To receive a rebate for the amount of your prescription co-pay (up to $20), enclose this certificate and the ORIGINAL pharmacy receipt in an envelope and mail to Allergan RESTASIS® Ophthalmic Emulsion $20 Rebate Program, P.O. Box 6513, West Caldwell, NJ 07007. Please allow 8 weeks for receipt of rebate check. Receipts prior to March 1, 2007 will not be accepted. One rebate per consumer. Duplicates will not be accepted. See rebate certificate for expiration date. Eligibility: Offer valid for prescriptions reimbursed or paid under Medicare, Medicaid, or any similar federal or state healthcare program including any state medicaid, pharmaceutical assistance programs. Void in the following states: if any third-party payer reimburses you or pays for any part of the prescription price: Massachusetts. Offer void where prohibited by law, taxed, or restricted. Amount of rebate not to exceed $20 or co-pay, whichever is less. This certificate may not be reproduced and must accompany your request for a rebate. Offer good only for one prescription of RESTASIS® Ophthalmic Emulsion and only in the USA and Puerto Rico. Allergan, Inc. reserves the right to rescind, revoke, and amend this offer without notice. You are responsible for reporting receipt of a rebate to any private insurer that pays for or reimburses you, for any part of the prescription filled, using this certificate.

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Help Control Inflammation by Eating Right

by Aimee Magrath, BHSc (Nat.), ND, Dip., Nut., Cert. IV Rem. Mass., MATMS [the following article is reprinted from the September 2007 issue of Lupus Links, the newsletter of The Lupus Association NSW in Australia.]

Aimee was diagnosed with SLE as a young teenager and struggled with ill-health throughout her schooling years. Now, more than 15 years on, Aimee is a qualified naturopath and nutritionist, working from a practice located in the heart of Pennant Hills, Australia. She has been medication free for over 10 years now, managing her condition with a combination of natural therapies. Aimee consults on a wide variety of conditions, with a special interest in allergies, chronic fatigue conditions and children’s illnesses. She treats people of all ages, from infants to the elderly, using a diverse range of modalities including herbal medicine, nutrition, iridology, homeopathy, counseling and flower essences.

As many of us suffer from inflammation and pain at times, it is beneficial to be aware of particular foods that may help to reduce or promote inflammation. Foods work synergistically, so the more you can eat combinations of the anti-inflammatory foods listed below, the more powerful the effect. These are general guidelines only and any major dietary change should be discussed with a medical professional so your individual medical needs can be taken into account.

Choose Anti-Inflammatory Foods

Eaten regularly, the following foods can have anti-inflammatory effects in the body:

Garlic & Onions – Also contain sulfur for the repair and rebuilding of connective tissue.

Celery – Eat raw at least 3 times per week.

Fresh Papaya – Contains papain which reduces swelling and inflammation, and helps improve digestion.

Bioflavonoids – Rutin, quercetin and hesperidin are all types of bioflavonoids found in onions, berries and citrus fruits. They are powerful antioxidants and anti-inflammatory.

Cinnamon – Also aids digestion and improves circulation. This can be useful in Raynauds syndrome.

Chili/Cayenne – Contains capsaicin which decreases pain sensation by inhibiting the release of Substance P, a neurotransmitter responsible for transmitting pain sensations. It is also anti-inflammatory (However, it is a member of the nightshade family, so use with care).

Ginger – Potent anti-inflammatory, aids digestion, improves circulation and helpful for Raynauds syndrome. Add to cooking and drink ginger tea. Avoid excessive amounts if taking blood-thinning medication.

Turmeric – Contains curcumin, a potent anti-inflammatory agent. Add to cooking.

Oily fish (tuna, salmon, sardines), Flaxseeds, Walnuts – Contain omega 3 essential fatty acids which increase the production and activity of anti-inflammatory substances in the body.

Fresh Pineapple – Contains the enzyme bromelain which reduces swelling, inflammation and pain. Bromelain also improves digestion and can reduce excess mucus. It’s vital that the fruit is fresh, as freezing or canning processes destroy beneficial enzymes. Eat half a fresh pineapple or papaya daily.

Some other substances are also available in a supplement form, however, please see a naturopath for advice.

Avoid Pro-Inflammatory Foods

The following foods are known to promote the formation of inflammatory compounds in the body:

• Avoid alfalfa as it contains substances known to cause lupus flare-ups.

• Plants from the nightshade family – these are potato, tomato, eggplant, chili and capsicum – contain solanine, which can interfere with certain enzymes in the muscles and may cause pain and discomfort. People with chronic inflammatory conditions are often highly sensitive to this compound.

• Red meat has a form of fat that encourages inflammatory agents in the body. Choose lean cuts of meat, and try to vary your protein sources with fish and plant based protein such as legumes.

• Dairy products are broken down to pro-inflammatory substances in the body.

Aimee can be reached via her website: www.inbalancehealth.com.au.
Remembering Your Mother or Another Fabulous Lady on Mother’s Day

Make a donation in honor or in memory of your mother or a mother that you know! Your honoree or family member will receive a personalized Mother’s Day acknowledgement before May 11th from the Sjögren’s Syndrome Foundation. It will notify them of your thoughtful and generous gift in their honor. The Foundation will also acknowledge your gift in an upcoming issue of *The Moisture Seekers* newsletter.

Please choose a donation amount:  
☐ $25  ☐ $50  ☐ $100  ☐ other ______________

Name of person this donation is in honor of __________________________________________

Name of person this donation is in memory of _________________________________________

Who would you like the acknowledgment sent to?

Name ____________________________________________________________

Street Address __________________________________________________________________

City __________________________ State ________________ Zip __________

How would you like to be recognized on this letter? _______________________________________________________________________

Please provide your mailing address:

Name ________________________________________________________________

Street Address __________________________________________________________________

City __________________________ State ________________ Zip __________

Telephone __________________________ E-mail __________________________

Payment:  
☐ Check (enclosed)  ☐ VISA / Mastercard / American Express (circle)

CC Number: __________________________ Expiration Date: _______________________

Name as appears on card: _______________________________________________________________________

Signature: __________________________ Date: __________________________

Mail to: Sjögren’s Syndrome Foundation, 6707 Democracy Blvd., Suite 325, Bethesda, MD 20817
Fax to: 301-530-4415 (credit card payment only)
Once-daily,* preservative-free LACRISERT®
Extends tear life for all-day lubrication and protection

- Unlike artificial tears, LACRISERT® works continuously to stabilize and thicken tears for all-day relief¹
- LACRISERT® begins to gently dissolve and lubricate within minutes²

69% of Sjögren’s syndrome patients in a clinical study preferred LACRISERT® over artificial tears due to increased comfort†²

Most adverse reactions were mild and transient and included transient blurring of vision, ocular discomfort or irritation, matting or stickiness of eyelashes, photophobia, hypersensitivity, edema of the eyelids, and hyperemia. LACRISERT® is contraindicated in patients who are hypersensitive to hydroxypropyl cellulose. If improperly placed, LACRISERT® may result in corneal abrasion.

*Some patients may require the flexibility of twice-daily dosing for optimal results.¹
†In a 2-phase study of patients with dry eye: phase 1 was a 6-month, comparative, randomized, crossover study in 40 patients (37 with Sjögren’s syndrome); phase 2 was an open-label, follow-up study in 37 patients for 2 months to 18 months.²


For more information, visit www.LACRISERT.com or call 1-877-ATON-549.
Please see brief summary of Prescribing Information on adjacent page.
LACRISERT® (hydroxypropyl cellulose) OPHTHALMIC INSERT

DESCRIPTION
LACRISERT® Ophthalmic Insert is a sterile, translucent, rod-shaped, water soluble, ophthalmic insert made of hydroxypropyl cellulose, for administration into the inferior cul-de-sac of the eye. Each LACRISERT is 5 mg of hydroxypropyl cellulose. LACRISERT contains no preservatives or other ingredients. It is about 1.27 mm in diameter by about 3.5 mm long. LACRISERT is supplied in packages of 60 units, together with illustrated instructions and a special applicator for removing LACRISERT from the unit dose blister and inserting it into the eye.

INDICATIONS AND USAGE
LACRISERT is indicated in patients with moderate to severe dry eye syndromes, including keratoconjunctivitis sicca. LACRISERT is indicated especially in patients who remain symptomatic after an adequate trial of therapy with artificial tear solutions. LACRISERT is also indicated for patients with exposure keratitis, decreased corneal sensitivity, and recurrent corneal erosions.

CONTRAINDICATIONS
LACRISERT is contraindicated in patients who are hypersensitive to hydroxypropyl cellulose.

WARNINGS
Instructions for inserting and removing LACRISERT should be carefully followed.

PRECAUTIONS
General
If improperly placed, LACRISERT may result in corneal abrasion.

Information for Patients
Patients should be advised to follow the instructions for using LACRISERT which accompany the package. Because this product may produce transient blurring of vision, patients should be instructed to exercise caution when operating hazardous machinery or driving a motor vehicle.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Feeding of hydroxypropyl cellulose to rats at levels up to 5% of their diet produced no gross or histopathologic changes or other deleterious effects.

Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

Geriatric Use
No overall differences in safety or effectiveness have been observed between elderly and younger patients.

ADVERSE REACTIONS
The following adverse reactions have been reported in patients treated with LACRISERT, but were in most instances mild and transient: transient blurring of vision, ocular discomfort or irritation, matting or stickiness of eyelashes, photophobia, hyperosmolarity, edema of the eyelids, and hyperemia.

DOSAGE AND ADMINISTRATION
One LACRISERT ophthalmic insert in each eye once daily is usually sufficient to relieve the symptoms associated with moderate to severe dry eye syndromes. Individual patients may require more flexibility in the use of LACRISERT; some patients may require twice daily use for optimal results. Clinical experience with LACRISERT indicates that in some patients several weeks may be required before satisfactory improvement of symptoms is achieved.

Issued June 2007

SAVE THE DATE!

It's more than a walk... The Sjögren's Walkabout is a national awareness and fundraising event for the Sjögren's Syndrome Foundation. The non-competitive, family-fun event focuses on awareness of Sjögren's syndrome while helping to raise money to support the SSF’s research and education programs. Please come out and show your support.

Here’s our Spring 2008 Sjögren’s Walkabout Schedule:

- Wilmington, March 15
- Wrightsville Beach Park
- Salt Lake City, March 29
- Valley Fair Mall
- Long Island, March 29
- Broadway Mall
- Denver, June 7
- Denver Zoo
- Greater Washington Region, April 19
- Reston Town Center
- Dallas/Fort Worth, April 26
- Grapevine Mills
- Philadelphia Tri-state, May 3
- Tyler State Park

Want to participate in a Walkabout? Start today! Create your own webpage at www.firstgiving.com/ssf

For more information or if you would like to volunteer to help at a Walkabout Please call 1-800-475-6473 ext 217

Special thanks to our National Signature Sponsor

Would you like to help raise awareness of Sjögren’s syndrome in your community?

If so, contact us here at the office by calling toll-free (800) 475-6473 or through e-mail at tms@sjogrens.org.
The short answer is “yes …and no!” The lip biopsy, technically a labial minor salivary gland biopsy, is the single most accurate means of diagnosing the salivary exocrine component of Sjögren’s syndrome. However, it is not sufficient alone to establish a diagnosis of the entire syndrome. In Sjögren’s syndrome, there are characteristic changes in the minor salivary glands that can be seen when the tissues are fixed, stained and examined microscopically. Specifically, certain salivary cells are lost (acinar cells) and prominent collections (foci) of inflammatory cells arise which cluster around other salivary (ductal) cells. This is termed by pathologists a “peri-ductal mononuclear cell infiltrate with acinar dropout.” The pathologist actually assigns a score to the lip biopsy based on the amount of inflammatory infiltration. While the changes seen are characteristic of Sjögren’s syndrome, there are other conditions, such as graft-versus-host disease, hepatitis C and HIV-salivary gland dysfunction, in which a lip biopsy may appear similar on a routine exam. It is important to rule out these situations during diagnosis. If the changes in the minor glands appear to be the result of Sjögren’s syndrome, one must still have evidence of other exocrine involvement (lacrimal gland) in order to establish a definitive diagnosis of Sjögren’s. The lip biopsy is accurate in diagnosing salivary involvement in Sjögren’s syndrome and is a critically important part of the clinical evaluation.

The question that often arises is what does it mean when the symptoms and other tests are very suggestive of Sjögren’s syndrome – but the lip biopsy is negative? Patients may have dry eyes and a dry mouth, both subjective complaints and measurable decreases in tears and saliva, but the lip biopsy does not show the characteristic tissue changes or there are changes present but they are too mild. Patients – and their doctors – ask, “is this Sjögren’s syndrome?”

There are a number of reasons why the lip biopsy may be negative. First, the individual may not have Sjögren’s syndrome. There are many causes of dry eyes and mouth, and it is important to search for these as a possible explanation. It would be a mistake to overlook another condition. Second, one could have Sjögren’s syndrome but minimal labial minor gland involvement. With time, a subsequent biopsy might be found to be positive. It is important to remember that the current classification criteria for Sjögren’s syndrome do not demand a positive biopsy to be considered a definitive case of Sjögren’s. The presence of specific serum autoantibodies (SS-A (Ro) and/or SS-B (La)) may substitute for the positive lip biopsy as a required component. So, you may be diagnosed with Sjögren’s syndrome without a positive lip biopsy.

Additionally, there are a number of possible technical explanations for a negative biopsy. There may be an insufficient number of minor glands in the specimen. This is often dependent on the procedure used and the experience of the surgeon. (The pathologist needs at least 4-6 minor glands for accurate reading.) Also, all minor glands in an individual are not involved to the same extent. One often can see areas of intense involvement adjacent to relatively normal-appearing tissue. Therefore, the results may be skewed due to sampling error – that is, by chance the sample may be a section with little inflammation. If the specimen had been taken an inch to either side, the results might be different. This is why obtaining a representative number of glands to examine is important. It is also possible that medications the patient has taken could influence the specimen, particularly anti-inflammatory agents. Finally, studies also have shown that different pathologists may score the same tissue differently. In practice, grading biopsies is not an exact science, unless extremely detailed and time-consuming methods are used. If the results of the biopsy do not match the clinical picture, it may be worthwhile to have the specimen re-read.

So, while a positive lip biopsy in a patient in whom confounding conditions have been ruled out is a very reliable indicator of the salivary component of Sjögren’s syndrome, a negative finding does not eliminate the possibility of a diagnosis of Sjögren’s. Diagnosis can be difficult, since there is no single test for Sjögren’s syndrome and the condition can present in so many different ways. Regardless of the cause, symptoms and signs must be managed and good communication with your doctor is essential. The lip biopsy is a very important tool in the evaluation of Sjögren’s syndrome, but it represents only a part of the diagnostic picture.
SSF National Patient Conference
Knowledge is the Key
April 11 - 12, 2008 • Phoenix, Arizona • Sheraton Crescent Hotel

Be curious always! For knowledge will not acquire you: you must acquire it.
—Sudie Back, French philosopher

As a Sjögren’s patient, it’s easy to feel confused or overwhelmed by the abundance of information available about the illness and how it affects your body. But now there’s an opportunity to UNLOCK YOUR INNER Sjögren’s EXPERT by learning from the best minds dealing with Sjögren’s. SSF programs are the best Sjögren’s patient education opportunities in the country. They have helped thousands GAIN A BETTER UNDERSTANDING OF SJÖGREN’S and will help you, too. Our panel of medical experts address an array of Sjögren’s syndrome topics; plus, you’ll have the rare chance to meet and share tips with your fellow Sjögren’s patients. This April, join your fellow Sjögren’s patients and their family members as well as medical professionals who specialize in Sjögren’s syndrome at the 2008 SSF National Patient Conference in sunny Phoenix, Arizona. Topics at this two-day event will include:

- Overview of Sjögren’s Syndrome
- Nurse-Patient Relationship
- Pulmonary Complications of Sjögren’s Syndrome
- Hormones & Estrogen Replacement Therapy
- Treatment of Dry Eye
- Fibromyalgia
- Sjögren’s from a Traditional and Non-Traditional Approach: Integrating Care from an Evidence Based Perspective
- Thyroiditis
- Research Update
- Brain Fog

I always come back from SSF seminars re-charged, armed with new information, and a better understanding of how to cope with my illness.
—Cathy Reppenhagen, Albany, NY
Space is limited. Please register early!

Registration Form

Registration fees include: Lunch each day, snacks and beverages, Friday evening dinner, hand-out material from speakers and entrance to exhibit area on Friday and Saturday.

1. Registrant information

ATTENDEE — Please complete all information

First name  MI  Last name

Company (optional)
Street address  City  State  Zip
Telephone  Fax
E-mail address

GUEST

First name  MI  Last name

2. Fees – please circle appropriate fee(s)

March 20th and before  March 21st and after

SSF MEMBERS (or spouse/guest)  $160 per person  $180 per person
NON-MEMBERS  $185 per person  $205 per person

TOTALS

3. Payment

☐ Check (enclosed)  ☐ VISA/MasterCard/American Express  (circle)

Number  Exp date
Name exactly as on card
Signature  Date

4. Send

By mail to: Sjögren’s Syndrome Foundation, Inc., c/o BB&T Bank, PO Box 890612, Charlotte, NC 28289-0612
By fax: (credit card payments only) to 301-530-4415

Confirmation: Written confirmation will be sent a few weeks prior to the conference.

Refunds: Refund requests must be made in writing. Registrants whose written requests are received by March 31st will receive a 75% refund. After that time, we are sorry that no refunds can be made.

Hotel: Rooms at the Sheraton Crescent Hotel are available for $149 per night plus tax if reservations are made by March 7th by calling 800-325-3535. Refer to the group name “Sjögren’s Syndrome Foundation” for the discounted rate.
Use our doctor recommended system to:

- Relieve symptoms of chronic dry eyes
- Enhance existing dry eye treatments
- Reduce puffiness
- Protect ocular surface during sleep
- Improve comfort during travel

Friends of the Sjogren’s syndrome foundation will receive:

15% off any purchase

To order online visit www.eyeeco.com. Select desired product and follow directions to buy/checkout. Enter the promotional code ‘SSF’ in the box directly above shipping method. Continue to payment. Your discount will appear on the receipt.

Or call toll free 1-888-730-7999 ext. 702.

Eyeeco will donate an additional 15% of your purchase to the Sjogren’s syndrome foundation.