The Moisture Seekers

Sjögren's Syndrome Foundation

www.sjogrens.org

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Q *I have Sjögren's and suffer with peripheral neuropathy. I have heard about a prescription topical NSAID, Voltaren Gel, that may relieve pain and numbness. What can you tell me about this medication?*

A Appropriate symptomatic relief of pain, in Sjögren's patients as well as with any rheumatic syndromes, requires identifying the salient pathogenic mechanisms — i.e. WHY is the underlying pain occurring? Although the following classification may be oversimplification, conceptualizing pain as "nocioceptive" versus "neuropathic," provides insights into the role and limitations of topical NSAIDs such as Voltaren for neuropathic pain.

"Nocioceptive" pain is classified as pain stemming from known or proposed, "tissue" destruction. The underlying tissue can be a bone, a tendon, or a joint. Such an example of nocioceptive joint pain in a patient with Sjögren's might be osteoarthritis, or inflammation of joints directly attributable to "active" Sjögren's disease. Diverse causes of joint pain can be effectively treated by oral use of NSAIDs. Such NSAIDs interfere with pathways which contribute to joint pain and inflammation.

However, "neuropathic" pain occurs because of dysfunction of nerves. Such nerves may be functionally abnormal because they "short-circuit" or because they fire irregularly and spontaneously. A wide range of neuropathic pain medications, targets the abnormal electric cabling which contributes to neuropathic pain. There is less evidence suggesting that NSAIDs may interfere with mechanisms relevant to neuropathic pain.

As noted above, the distinction between neuropathic versus nocioceptive pain may be oversimplified. New research is showing that there may limited cases in which NSAIDs may have a role in neuropathic pain. Nevertheless, such research is unproven and still in its infancy. Further studies might be necessary to evaluate topical NSAIDS in neuropathic pain. However, from a mechanistic sense, I would ordinarily not resort to use of NSAIDs in neuropathic pain. Therefore, my advice would be to creatively work with your neurologists to apply the wide armamentarium of agents which can be effective for neuropathic pain and defer topical use of NSAIDs until there is better research explaining its role and proposed mechanisms.

Julius Birnbaum, MD

Q *I have Sjögren's and have recently been diagnosed with GERD. What are the long-term complications of GERD?*

A Acid reflux, or GERD (gastroesophageal reflux disease), can cause symptoms of heartburn, chest pain, trouble swallowing, sore throat or unexplained cough. Many factors, such as obesity, smoking, or presence of a hiatal hernia, can contribute to GERD. As saliva helps to neutralize refluxed acid, individuals with Sjögren's may develop GERD symptoms due to lack of saliva.

The vast majority of individuals with GERD will not develop significant complications, especially when it is appropriately treated with lifestyle modification or medications. In patients with severe GERD, long-term complications that may arise include ulcerations of the esophagus (esophagitis), stricture formation (scarring of the esophagus that can cause difficulty swallowing), hoarse voice, chronic cough, or asthma exacerbation.

With chronic acid reflux, the lining of the esophagus can undergo a transformation from normal esophageal cells (squamous cells) to a different cell type (intestinal cells). This change, known as Barrett's esophagus, is completely without symptoms but does increase the risk of developing precancerous changes

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of the esophagus. The risk of Barrett's esophagus progressing to esophageal cancer is 0.5% per year and probably less in individuals maintained on acid reducing medications. Barrett's esophagus is diagnosed through endoscopic examination and is typically managed with close surveillance and monitoring. Individuals with chronic acid reflux or on long-term acid suppression medications should discuss their risk of Barrett's esophagus with their physician.

Matthew Nichols, MD

Q *I understand that autoimmune diseases can occur in families and I am concerned that my daughters may develop Sjögren's or another autoimmune disease. What is the recommendation for testing for autoimmune diseases?*

A The second question is the easier to answer. NO routine screening is helpful for the "future, potential" risk of developing Sjögren's. The most helpful thing is to be familiar with the myriad of potential symptoms/signs of Sjögren's and related autoimmune diseases/disorders. If any concerning signs develop, then one can start the investigative process. As someone with Sjögren's, you probably have experienced that this is not often a simple, straightforward process. There is no reason to be over-worried, as it is not highly likely that your daughters would develop the same autoimmune process as you.

Yes, there is a genetic component for all autoimmune diseases. However, it is very dilute because multiple genes (polygenetic) are involved. Historically, the HLA-DR3 (histocompatibility) type has had the tightest connection with Sjögren's. HLA-DQ1/DQ2 has some association with more severe Sjögren's. Also, genes are modified by the environment, medications, viruses, etc, thus adding even more complexity to the susceptibility of autoimmunity. This process currently is an active area for research and is referred to as "Epigenetics" (gene modification).

The strongest genetic association is actually just the increased risk of developing autoimmune reactions in general. If a family member has Sjögren's, then there is a ~30-35% chance of developing an autoimmune disorder (PMID (Pub Med) # 12453311). Furthermore, it is usually some other disease, not the same one that the family member has.

Worrying will not help or change anything for your daughters. We know stress (different for different people) can trigger the immune system in a way to start an autoimmune process or make it worse. This is a further reason to be informed but not worry about it.

Nancy Carteron, MD, FACR

Q *You've heard all the hype about green tea and Sjögren's... is it for real?*

A Green tea, botanical name Camellia sinensis, derives its primary benefit from its high concentration of antioxidant, anti-inflammatory, anti-carcinogenic

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Available by prescription only.

Restasis®
(Cyclosporine Ophthalmic Emulsion) 0.05%

Q

Why aren't artificial tears enough for me?

A

They provide temporary relief. If your type of Chronic Dry Eye causes inflammation which decreases your ability to make tears, use RESTASIS®. I do.

Alison Tendler MD,
RESTASIS® User, *Eye Doctor*

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 anti-inflammatory eye 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. RESTASIS® should not be used while wearing contact lenses. If contact lenses are worn, they should be removed prior to use. 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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see next page for important product information.

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Go to restasis29.com, or call 1-866-311-2412 for a free kit.
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Dr Tendler is an actual patient and is compensated for appearing in this advertisement.

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Sterile, Preservative-Free

INDICATIONS AND USAGE
RESTASIS® ophthalmic emulsion is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

CONTRAINDICATIONS
RESTASIS® is contraindicated in patients with active ocular infections and in patients with known or suspected hypersensitivity to any of the ingredients in the formulation.

WARNING
RESTASIS® ophthalmic emulsion has not been studied in patients with a history of herpes keratitis.

PRECAUTIONS
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 reinserted 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 males significantly exceeded the control value.

In the 24-month oral (diet) rat study, conducted at 0.5, 2, and 8 mg/kg/day, pancreatic islet cell adenomas significantly exceeded the control rate in the low dose level. The hepatocellular carcinomas and pancreatic islet cell adenomas were not dose related. The low doses in mice and rats are approximately 1000 and 500 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.

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) 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 fetotoxic as indicated by increased pre- and postnatal mortality and reduced fetal weight together with related skeletal retardations. These doses are 30,000 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 embryofetal toxicity 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.

Offspring 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

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Based on package insert 71876US14B Revised February 2010

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 Please allow 8 weeks for delivery of your rebate check. APC32DL11 Certificate expires 12/31/2011

Team Sjögren's Goes TURKEY!

That's right – thanks to the success of our *Wharf to Wharf Team Sjögren's* event this past July in Santa Cruz, California (see team photo)… we are branching out and going Turkey!

We are looking for 50 of you to organize a team and run in your local *Turkey Trot* on Thanksgiving. It's simple – just recruit your family and friends to join you as part of your *Team Sjögren's* and help us raise awareness and funds for the SSF. Just imagine –if each team raised just $750 and we had 50 teams across America – we would raise enough to fund another Sjögren's research grant this next April!

Start to recruit family and friends… and run for *Team Sjögren's* on Thanksgiving!

Here is how it works:

Create a team by signing up on our *Turkey Trots Across America* website – by visiting www.firstgiving.com/ssf website. Recruit team members to join you in raising awareness and funds. And if you can't recruit anyone to join you – run or walk yourself!

Encourage each team member to create a firstgiving fundraising page and collect donations.

Register for your local *Turkey Trot* by contacting the race coordinators or visiting their website.

Then on Thanksgiving day – join with your team, by all wearing *Team Sjögren's* running shirts and proudly representing the Sjögren's Syndrome Foundation at the walk or run in your local *Turkey Trot*! Get information on how to get a *Team Sjögren's* shirt by visiting our www firstgiving.com/ssf website website.

Visit www.firstgiving.com/ssf website to learn more or contact Cynthia Williamson at the Sjögren's Syndrome Foundation at 301-530-4420, ext 205.

Just imagine – if each team raised just $750 and we had 50 teams across America – we would raise over $35,000 and be able to fund another Sjögren's research grant this next April! We hope you will join with us!

How to find a local Turkey Trot?

Finding a local *Turkey Trot* for Thanksgiving is easy. Just visit www.active.com and type *Turkey Trot* in the keyword search, then sort by state. You will find a listing of local *Turkey Trots*. Also, contact a local running store to find out about a local *Turkey Trot,* too. If you are having trouble finding a *Turkey Trot*, contact the Foundation and we can help you find one in your area!

Once you find a local race, register to enter the race on their website and then visit the SSF's site to learn how you can earn *Team Sjögren's* running shirts! ■

Pictured to the right is this year's Wharf to Wharf Team Sjogren's*! Special thanks to Estrella Bibbey for recruiting family and friends to join her at this year's race! Collectively, the team raised over $20,000! Imagine your team photo in our Turkey Trot wrap-up article! Start today recruiting your runners and walkers!*

"Questions & Answers" continued from page 2 ▼

polyphenolic compounds also known as flavanoids. Green tea contains multiple flavanoids, with epigallocatechin gallete (EGCG) highest in concentration and considered to be the most active. Oxidation is a necessary physiologic process and is moderated by antioxidant activity. The balance between the oxidation and anti-oxidation is a continuous process going on all the time in the body. If oxidation and inflammation overwhelm antioxidant activity, it can cause cellular damage that is associated with most health conditions, including cardiovascular disease, autoimmunity, cancer and even premature aging. Accordingly, increased consumption of foods high in antioxidants is a very beneficial way to build up antioxidant stores and prevent disease.

Since Sjögren's syndrome is uncontrolled inflammatory oxidation leading to destruction of exocrine glands, increased consumption of green tea with its high content of antioxidant EGCG can be helpful. A typical cup of green tea contains 250-350 mg of EGCG. Daily consumption recommendations are derived from Asian cultures (i.e., Japanese and Chinese) with lower incidence of many chronic diseases that consume approximately 3 cups per day. Green tea can also be taken in supplement form. To achieve equivalent dosing, the supplement must indicate standardized measurement of EGCG content and dose at 250-350 mg of EGCG 3x per day. It is worth mentioning that black and green teas all originate from the same tea leaves. However, when black tea is manufactured, it is dried and oxidized which consumes much of the EGCG content. Therefore, green tea is clearly the better alternative in terms of antioxidant benefit.

Given all the above, it must be said that green tea is no "magic elixir" for Sjögren's syndrome or any other chronic disease. Treatment of complex chronic disease requires comprehensive care. As a naturopathic physician, I work to understand the causes of disease. Inflammation and oxidative damage is a component of nearly every disease. Unfortunately, the standard western diet is high in pro-inflammatory foods such as processed carbohydrates (sugar and refined flours), hydrogenated oils, food additives, preservatives, colorings, and very low in health-promoting minimally processed fruits and vegetables. If one is consuming a diet such as this, adding green tea to your daily intake will have minimal benefit. When I work with any patient, treatment always includes an anti-inflammatory diet rich in antioxidants as a foundation for health. From there I will then add in specific health-promoting nutrients such as green tea. If addition of green tea will help patients consume less soda, fruit juices, and coffee, it can be a great addition to their comprehensive treatment plan, but certainly not a cure on its own.

In summary, green tea has many health-promoting benefits and it is a great option for a daily warm or cold beverage. However, to derive the greatest results it should be part of a whole foods diet rich in colorful fruits and vegetables and low in highly processed foods.

Keith Wilkinson, NMD (Naturopathic Physician)

Q *Could I take a blood test that shows I'm positive SS-A and SS-B and then a few years later not show the same results?*

A Yes, for a couple of reasons. First, most commonly there are several techniques and commercial kits for testing for SS-A and SS-B, and they vary in sensitivity. Thus, the results may vary from lab to lab. Secondly, the titer of antibody being produced may decrease or increase with therapy, time, and disease activity. The ability to have an anti-SS-A or SS-B antibody is most likely genetically determined. People with Sjögren's may test negative for SS-A and SS-B antibodies but may have signs and symptoms identical to people with Sjögren's who test positive for SS-A and SS-B antibodies. In my series of patients with Sjögren's, having SS-A and SS-B antibodies and high gammaglobulin levels increases the risk for more systemic problems and progression to lymphoma.

Daniel Small, MD, MMSc, FACP, FACR

Q *What is blepharitis? How do you treat it?*

A Blepharitis is a term denoting inflammation of the eyelids. It includes styes and even allergic reactions of the lids. The most common use of the term, however, refers to a condition involving the oil glands of the lid margin (about 20-25 openings in each lid) that produce the outer layer of tears. This oily layer serves to retard evaporation of the tears, thus conserving them. When inflammation affects these oil-producing glands, there is increased evaporative loss of tears. Studies have shown that up to two-thirds of patients with Sjögren's dry eye have this form of blepharitis. This condition is called posterior blepharitis or meibomian gland dysfunction and is the most common form of dry eye disease.

The most common form of treatment is the use of moist heat to the lids, cleansing of the lid margins and the use of oral antibiotics such as tetracycline. This regimen can result in significant improvement of the symptoms of irritation and pain. In more severe cases the use of locally applied steroids can be helpful. Current research is studying the use of locally applied hormone preparations and newer antibiotics to reduce inflammation and normalize the oil secretion.

Michael A. Lemp, MD

Q *Are problems with kidneys commonly associated with Sjögren's syndrome?*

A There are several renal problems that can occur with Sjögren's syndrome, but fortunately they do not occur frequently. Inflammation of the filtering part of the kidney nephron, the glomerulus, can occur; this condition is called

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For patients with Sjögren's syndrome

DRY-MOUTH SYMPTOMS DON'T HAVE TO BE SO DISTRACTING.

If you experience dry-mouth symptoms due to Sjögren's syndrome, then you already know how distracting these can be to your daily life. It might be time to ask about EVOXAC® (cevimeline HCl), a prescription treatment that works by stimulating the production of your body's own natural saliva.

Talk to your doctor to see if EVOXAC can help, or visit DiscoverEVOXAC.com.

Please see important information about EVOXAC below.

Important Safety Information

What is EVOXAC?

- EVOXAC (cevimeline HCl) is a prescription medicine used to treat symptoms of dry mouth in patients with Sjögren's syndrome.

Who Should Not Take EVOXAC?

- You should not take EVOXAC if you have uncontrolled asthma, allergies to EVOXAC or a condition affecting the contraction of your pupil such as narrow-angle (angle-closure) glaucoma or inflammation of the iris.

What should I tell my Healthcare Provider?

- Tell your healthcare provider if you have any of the following conditions:
  - History of heart disease;
  - Controlled asthma;
  - Chronic bronchitis;
  - Chronic obstructive pulmonary disease (COPD);
  - History of kidney stones;
  - History of gallbladder stones
- Tell your healthcare provider if you are trying to become pregnant, are already pregnant, or are breastfeeding.
- Tell your healthcare provider about all medications that you are taking, including those you take without a prescription. It is particularly important to tell your healthcare provider if you are taking any heart medications especially "beta-blockers".
- If you are older than 65, your healthcare provider may want to monitor you more closely.

General Precautions with EVOXAC

- When taking EVOXAC use caution when driving at night or performing other hazardous activities in reduced lighting because EVOXAC may cause blurred vision or changes in depth perception.
- If you sweat excessively while taking EVOXAC drink extra water and tell your health care provider, as dehydration may develop.
- The safety and effectiveness of EVOXAC in patients under 18 years of age have not been established.

What are some possible side effects of EVOXAC?

- In clinical trials, the most commonly reported side effects were excessive sweating, headache, nausea, sinus infection, upper respiratory infections, runny nose, and diarrhea.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch, or call 1-800-FDA-1088.

Please visit www.EVOXAC.com for full Product Information for EVOXAC.

For patients having difficulty affording their Daiichi Sankyo medication, please call the Daiichi Sankyo Patient Assistance Program at 1-866-268-7327 for more information or visit www.dsi.com/news/patientassitance.html.

Please see a brief summary of Important Information for EVOXAC on the next page.

Evoxac® (cevimeline HCl) 30 mg Capsules

Brief Summary – See package insert for full Prescribing Information.

EVOXAC® Capsules

(cevimeline hydrochloride)

INDICATIONS AND USAGE
Cevimeline is indicated for the treatment of symptoms of dry mouth in patients with Sjögren's Syndrome.

CONTRAINDICATIONS
Cevimeline is contraindicated in patients with uncontrolled asthma, known hypersensitivity to cevimeline, and when miosis is undesirable, e.g., in acute iritis and in narrow-angle (angle-closure) glaucoma.

WARNINGS
Cardiovascular Disease:
Cevimeline can potentially alter cardiac conduction and/or heart rate. Patients with significant cardiovascular disease may potentially be unable to compensate for transient changes in hemodynamics or rhythm induced by EVOXAC®. EVOXAC® should be used with caution and under close medical supervision in patients with a history of cardiovascular disease evidenced by angina pectoris or myocardial infarction.

Pulmonary Disease:
Cevimeline can potentially increase airway resistance, bronchial smooth muscle tone, and bronchial secretions. Cevimeline should be administered with caution and with close medical supervision to patients with controlled asthma, chronic bronchitis, or chronic obstructive pulmonary disease.

Ocular:
Ophthalmic formulations of muscarinic agonists have been reported to cause visual blurring which may result in decreased visual acuity, especially at night and in patients with central lens changes, and to cause impairment of depth perception. Caution should be advised while driving at night or performing hazardous activities in reduced lighting.

PRECAUTIONS
General:
Cevimeline toxicity is characterized by an exaggeration of its parasympathomimetic effects. These may include: headache, visual disturbance, lacrimation, sweating, respiratory distress, gastrointestinal spasm, nausea, vomiting, diarrhea, atrioventricular block, tachycardia, bradycardia, hypotension, hypertension, shock, mental confusion, cardiac arrhythmia, and tremors.

Cevimeline should be administered with caution to patients with a history of nephrolithiasis or cholelithiasis. Contractions of the gallbladder or biliary smooth muscle could precipitate complications such as cholecystitis, cholangitis and biliary obstruction. An increase in the ureteral smooth muscle tone could theoretically precipitate renal colic or ureteral reflux in patients with nephrolithiasis.

Information for Patients: Patients should be informed that cevimeline may cause visual disturbances, especially at night, that could impair their ability to drive safely.

If a patient sweats excessively while taking cevimeline, dehydration may develop. The patient should drink extra water and consult a health care provider.

Drug Interactions:
Cevimeline should be administered with caution to patients taking beta adrenergic antagonists, because of the possibility of conduction disturbances. Drugs with parasympathomimetic effects administered concurrently with cevimeline can be expected to have additive effects. Cevimeline might interfere with desirable antimuscarinic effects of drugs used concomitantly.

Drugs which inhibit CYP2D6 and CYP3A3/4 also inhibit the metabolism of cevimeline. Cevimeline should be used with caution in individuals known or suspected to be deficient in CYP2D6 activity, based on previous experience, as they may be at a higher risk of adverse events. In an *in vitro* study, cytochrome P450 isozymes 1A2, 2A6, 2C9, 2C19, 2D6, 2E1, and 3A4 were not inhibited by exposure to cevimeline.

Carcinogenesis, Mutagenesis and Impairment of Fertility:
Lifetime carcinogenicity studies were conducted in CD-1 mice and F-344 rats. A statistically significant increase in the incidence of adenocarcinomas of the uterus was observed in female rats that received cevimeline at a dosage of 100 mg/kg/day (approximately 8 times the maximum human exposure based on comparison of AUC data). No other significant differences in tumor incidence were observed in either mice or rats.

Cevimeline exhibited no evidence of mutagenicity or clastogenicity in a battery of assays that included an Ames test, an *in vitro* chromosomal aberration study in mammalian cells, a mouse lymphoma study in L5178Y cells, or a micronucleus assay conducted *in vivo* in ICR mice.

Cevimeline did not adversely affect the reproductive performance or fertility of male Sprague-Dawley rats when administered for 63 days prior to mating and throughout the period of mating at dosages up to 45 mg/kg/day (approximately 5 times the maximum recommended dose for a 60 kg human following normalization of the data on the basis of body surface area estimates). Females that were treated with cevimeline at dosages up to 45 mg/kg/day from 14 days prior to mating through day seven of gestation exhibited a statistically significantly smaller number of implantations than did control animals.

Pregnancy:
Pregnancy Category C.
Cevimeline was associated with a reduction in the mean number of implantations when given to pregnant Sprague-Dawley rats from 14 days prior to mating through day seven of gestation at a dosage of 45 mg/kg/day (approximately 5 times the maximum recommended dose for a 60 kg human when compared on the basis of body surface area estimates). This effect may have been secondary to maternal toxicity. There are no adequate and well-controlled studies in pregnant women. Cevimeline should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers:
It is not known whether this drug is secreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from EVOXAC®, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

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

Geriatric Use:
Although clinical studies of cevimeline included subjects over the age of 65, the numbers were not sufficient to determine whether they respond differently from younger subjects. Special care should be exercised when cevimeline treatment is initiated in an elderly patient, considering the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy in the elderly.

ADVERSE REACTIONS
Cevimeline was administered to 1777 patients during clinical trials worldwide, including Sjögren's patients and patients with other conditions. In placebo-controlled Sjögren's studies in the U.S., 320 patients received cevimeline doses ranging from 15 mg tid to 60 mg tid, of whom 93% were women and 7% were men. Demographic distribution was 90% Caucasian, 5% Hispanic, 3% Black and 2% of other origin. In these studies, 14.6% of patients discontinued treatment with cevimeline due to adverse events.

The following adverse events associated with muscarinic agonism were observed in the clinical trials of cevimeline in Sjögren's syndrome patients:

Adverse Event	Cevimeline 30 mg (tid) n*=533	Placebo (tid) n=164
Excessive Sweating	18.7%	2.4%
Nausea	13.8%	7.9%
Rhinitis	11.2%	5.4%
Diarrhea	10.3%	10.3%
Excessive Salivation	2.2%	0.6%
Urinary Frequency	0.9%	1.8%
Asthenia	0.5%	0.0%
Flushing	0.3%	0.6%
Polyuria	0.1%	0.6%

*n is the total number of patients exposed to the dose at any time during the study.

In addition, the following adverse events (≥3% incidence) were reported in the Sjögren's clinical trials:

Adverse Event	Cevimeline 30 mg (tid) n*=533	Placebo (tid) n=164	Adverse Event	Cevimeline 30 mg (tid) n*=533	Placebo (tid) n=164
Headache	14.4%	20.1%	Conjunctivitis	4.3%	3.6%
Sinusitis	12.3%	10.9%	Dizziness	4.1%	7.3%
Upper Respiratory Tract Infection	11.4%	9.1%	Bronchitis	4.1%	1.2%
Dyspepsia	7.8%	8.5%	Arthralgia	3.7%	1.8%
Abdominal Pain	7.6%	6.7%	Surgical Intervention	3.3%	3.0%
Urinary Tract Infection	6.1%	3.0%	Fatigue	3.3%	1.2%
Coughing	6.1%	3.0%	Pain	3.3%	3.0%
Pharyngitis	5.2%	5.4%	Skeletal Pain	2.8%	1.8%
Vomiting	4.6%	2.4%	Insomnia	2.4%	1.2%
Injury	4.5%	2.4%	Hot Flushes	2.4%	0.0%
Back Pain	4.5%	4.2%	Rigors	1.3%	1.2%
Rash	4.3%	6.0%	Anxiety	1.3%	1.2%

*n is the total number of patients exposed to the dose at any time during the study.

The following events were reported in Sjögren's patients at incidences of <3% and ≥1%: constipation, tremor, abnormal vision, hypertonia, peripheral edema, chest pain, myalgia, fever, anorexia, eye pain, earache, dry mouth, vertigo, salivary gland pain, pruritus, influenza-like symptoms, eye infection, post-operative pain, vaginitis, skin disorder, depression, hiccup, hyporeflexia, infection, fungal infection, sialoadenitis, otitis media, erythematous rash, pneumonia, edema, salivary gland enlargement, allergy, gastroesophageal reflux, eye abnormality, migraine, tooth disorder, epistaxis, flatulence, toothache, ulcerative stomatitis, anemia, hypoesthesia, cystitis, leg cramps, abscess, eructation, moniliasis, palpitation, increased amylase, xerophthalmia, allergic reaction.

The following events were reported rarely in treated Sjögren's patients (<1%): Causal relation is unknown:

Body as a Whole Disorders: aggravated allergy, precordial chest pain, abnormal crying, hematoma, leg pain, edema, periorbital edema, activated pain trauma, pallor, changed sensation temperature, weight decrease, weight increase, choking, mouth edema, syncope, malaise, face edema, substernal chest pain

Cardiovascular Disorders: abnormal ECG, heart disorder, heart murmur, aggravated hypertension, hypotension, arrhythmia, extrasystoles, t wave inversion, tachycardia, supraventricular tachycardia, angina pectoris, myocardial infarction, pericarditis, pulmonary embolism, peripheral ischemia, superficial phlebitis, purpura, deep thrombophlebitis, vascular disorder, vasculitis, hypertension

Digestive Disorders: appendicitis, increased appetite, ulcerative colitis, diverticulitis, duodenitis, dysphagia, enterocolitis, gastric ulcer, gastritis, gastroenteritis, gastrointestinal hemorrhage, gingivitis, glossitis, rectum hemorrhage, hemorrhoids, ileus, irritable bowel syndrome, melena, mucositis, esophageal stricture, esophagitis, oral hemorrhage, peptic ulcer, periodontal destruction, rectal disorder, stomatitis, tenesmus, tongue discoloration, tongue disorder, geographic tongue, tongue ulceration, dental caries

Endocrine Disorders: increased glucocorticoids, goiter, hypothyroidism

Hematologic Disorders: thrombocytopenic purpura, thrombocythemia, thrombocytopenia, hypochromic anemia, eosinophilia, granulocytopenia, leucopenia, leukocytosis, cervical lymphadenopathy, lymphadenopathy

Liver and Biliary System Disorders: cholelithiasis, increased gamma-glutamyl transferase, increased hepatic enzymes, abnormal hepatic function, viral hepatitis, increased serum glutamate oxaloacetic transaminase (SGOT) (also called AST-aspartate aminotransferase), increased serum glutamate pyruvate transaminase (SGPT) (also called ALT-alanine aminotransferase)

Metabolic and Nutritional Disorders: dehydration, diabetes mellitus, hypercalcemia, hypercholesterolemia, hyperglycemia, hyperlipemia, hypertriglyceridemia, hyperuricemia, hypoglycemia, hypokalemia, hyponatremia, thirst

Musculoskeletal Disorders: arthritis, aggravated arthritis, arthropathy, femoral head avascular necrosis, bone disorder, bursitis, costochondritis, plantar fasciitis, muscle weakness, osteomyelitis, osteoporosis, synovitis, tendinitis, tenosynovitis

Neoplasms: basal cell carcinoma, squamous carcinoma

Nervous Disorders: carpal tunnel syndrome, coma, abnormal coordination, dysesthesia, dyskinesia, dysphonia, aggravated multiple sclerosis, involuntary muscle contractions, neuralgia, neuropathy, paresthesia, speech disorder, agitation, confusion, depersonalization, aggravated depression, abnormal dreaming, emotional lability, manic reaction, paroniria, somnolence, abnormal thinking, hyperkinesia, hallucination

Miscellaneous Disorders: fall, food poisoning, heat stroke, joint dislocation, post-operative hemorrhage

Resistance Mechanism Disorders: cellulitis, herpes simplex, herpes zoster, bacterial infection, viral infection, genital moniliasis, sepsis

Respiratory Disorders: asthma, bronchospasm, chronic obstructive airway disease, dyspnea, hemoptysis, laryngitis, nasal ulcer, pleural effusion, pleurisy, pulmonary congestion, pulmonary fibrosis, respiratory disorder

Rheumatologic Disorders: aggravated rheumatoid arthritis, lupus erythematosus rash, lupus erythematosus syndrome

Skin and Appendages Disorders: acne, alopecia, burn, dermatitis, contact dermatitis, lichenoid dermatitis, eczema, furunculosis, hyperkeratosis, lichen planus, nail discoloration, nail disorder, onychia, onychomycosis, paronychia, photosensitivity reaction, rosacea, scleroderma, seborrhea, skin discoloration, dry skin, skin exfoliation, skin hypertrophy, skin ulceration, urticaria, verruca, bullous eruption, cold clammy skin

Special Senses Disorders: deafness, decreased hearing, motion sickness, parosmia, taste perversion, blepharitis, cataract, corneal opacity, corneal ulceration, diplopia, glaucoma, anterior chamber eye hemorrhage, keratitis, keratoconjunctivitis, mydriasis, myopia, photopsia, retinal deposits, retinal disorder, scleritis, vitreous detachment, tinnitus

Urogenital Disorders: epididymitis, prostatic disorder, abnormal sexual function, amenorrhea, female breast neoplasm, malignant female breast neoplasm, female breast pain, positive cervical smear test, dysmenorrhea, endometrial disorder, intermenstrual bleeding, leukorrhea, menorrhagia, menstrual disorder, ovarian cyst, ovarian disorder, genital pruritus, uterine hemorrhage, vaginal hemorrhage, atrophic vaginitis, albuminuria, bladder discomfort, increased blood urea nitrogen, dysuria, hematuria, micturition disorder, nephrosis, nocturia, increased nonprotein nitrogen, pyelonephritis, renal calculus, abnormal renal function, renal pain, strangury, urethral disorder, abnormal urine, urinary incontinence, decreased urine flow, pyuria

In one subject with lupus erythematosus receiving concomitant multiple drug therapy, a highly elevated ALT level was noted after the fourth week of cevimeline therapy. In two other subjects receiving cevimeline in the clinical trials, very high AST levels were noted. The significance of these findings is unknown.

Additional adverse events (relationship unknown) which occurred in other clinical studies (patient population different from Sjögren's patients) are as follows:

cholinergic syndrome, blood pressure fluctuation, cardiomegaly, postural hypotension, aphasia, convulsions, abnormal gait, hyperesthesia, paralysis, abnormal sexual function, enlarged abdomen, change in bowel habits, gum hyperplasia, intestinal obstruction, bundle branch block, increased creatine phosphokinase, electrolyte abnormality, glycosuria, gout, hyperkalemia, hyperproteinemia, increased lactic dehydrogenase (LDH), increased alkaline phosphatase, failure to thrive, abnormal platelets, aggressive reaction, amnesia, apathy, delirium, delusion, dementia, illusion, impotence, neurosis, paranoid reaction, personality disorder, hyperhemoglobinemia, apnea, atelectasis, yawning, oliguria, urinary retention, distended vein, lymphocytosis

The following adverse reaction has been identified during post-approval use of EVOXAC®. Because post-marketing adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Post-Marketing Adverse Events: *Liver and Biliary System Disorders:* cholecystitis

MANAGEMENT OF OVERDOSE
Management of the signs and symptoms of acute overdosage should be handled in a manner consistent with that indicated for other muscarinic agonists: general supportive measures should be instituted. If medically indicated, atropine, an anti-cholinergic agent, may be of value as an antidote for emergency use in patients who have had an overdose of cevimeline. If medically indicated, epinephrine may also be of value in the presence of severe cardiovascular depression or bronchoconstriction. It is not known if cevimeline is dialyzable.

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I Stood Up...

The Sjögren's Book, Fourth Edition

The Sjögren's Syndrome Foundation is deeply grateful to the many professionals who have volunteered a tremendous amount of time and expertise to the newest edition of the SSF handbook. An astounding 66 authors contributed to making *The Sjögren's Book, Fourth Edition* possible. Published by Oxford University Press and edited by renowned rheumatologist Daniel J. Wallace, MD, the book contains 35 chapters – 11 more chapters than the previous edition.

What's new? Chapters on topics such as genetics, the nervous system (central, peripheral and autonomic), vasculitis, gynecology and pregnancy, the GI tract, lymphoma, musculoskeletal pain, Vitamin D, and an in-depth look at subjects related to living with Sjögren's and enhancing quality of life. The handbook strikes a unique balance to appeal to patients as well as medical professionals so each can easily find answers to their many questions and gain an understanding of the breadth and depth of the many complications that can occur in Sjögren's. Knowledge is power, and many patients and professionals call this book their "Bible" – their main resource for referral to learn more about all the aspects of Sjögren's, including pathology, diagnosis, signs and symptoms, treatment, management for daily living and future promise.

Since the last handbook was published in 2005, new discoveries and issues have come to light, and patient and professional members of the Foundation have voiced the need for updates and more thorough coverage of specific areas. Now the new edition is finally here, thanks to the devotion of our outstanding contributors.

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"Questions & Answers" continued from page 6 ▼

glomerulonephritis. This can be similar to the kidney disease seen in systemic lupus, but fortunately it is much less prevalent in patients with Sjögren's syndrome. It will often respond to steroids, cyclophosphamide, cellcept, or imuran therapy. Another kidney problem that can occur in about 1% of people with Sjögren's is an interesting potassium-losing nephropathy. People lose prodigious amounts of potassium due to a defect in the tubules of the kidney. Potassium replacement is usually all that is necessary for treatment. Another interesting problem that we have seen is interstitial nephritis. This usually is not due to Sjögren's but to the NSAIDs that a person may take for the aches and pains associated with Sjögren's. It will usually resolve with discontinuation of the medication and a short course of prednisone.

Daniel Small, MD, MMSc, FACP, FACR

Q *Is a burning sensation of the tongue and inside the mouth a typical symptom of Sjögren's?*

A burning sensation in the mouth can have various causes. It may occur in patients with Sjögren's syndrome but is not typical of that disease. When it does occur in such patients, it is usually a result of candidiasis (an overgrowth or infection by a common yeast), caused by decreased saliva production and changes in the oral flora. The burning sensation may also be associated with an underlying systemic disease such as diabetes or anemia or occur in patients who do not have an identifiable cause for it. This symptom is usually best addressed by a dentist in the specialty of Oral Medicine who can be located most easily within a school of dentistry. An internist can rule out an underlying systemic disease.

Troy E. Daniels, DDS, MS

Q *I have been experiencing an increased number of mouth sores, both canker and cold sores. Is this related to Sjögren's and what can I do to prevent them?*

A This may be related to Sjögren's, since the dry mucosa are more susceptible to trauma which can lead to aphthous ulcers (canker sores) and herpetic lesions (cold sores). There are no effective preventive remedies, although in cases of severe, recurrent herpetic ulcers an anti-viral cream or tablets can be used prophylactically to minimize the frequency and to shorten episodes. It is best to keep the mouth as moist as possible with frequent sips of water, avoid highly spiced foods, use hydrating rinses and gels, and consider the use of a secretogogue (topical or systemic) to increase salivary function. When ulcers are present, it is important to keep them clean using bland rinses. Your dentist can recommend topical agents which will coat the ulcers to reduce pain and make eating easier.

Philip C. Fox, DDS

Q *Is there an increased risk of cataract surgery complications for a person with dry eye?*

A Cataracts remain one of the leading causes of world blindness. For many countries, there are inadequate services, so treatment is either delayed or non-existent. Fortunately, in the United States and most developed countries, the monitoring and surgical treatment of cataracts is readily available and successful. Estimates are that about 40% of people over the age of 55 have some degree of cataract development, and this increases to about 90% of the population over the age of 75.

People with Sjögren's syndrome and other autoimmune conditions may be more prone to development cataracts. This is not as a direct result of the disease, but rather a result of some of the treatments for the disease. Steroids, for example, are often used with autoimmune diseases, and one of the side-effects of this medication is an increased risk of cataract development.

Other factors that can increase cataract development include: systemic diseases (e.g., diabetes), diet/nutrition, lifestyle issues (e.g., smoking), and long-term ultraviolet (UV) exposure. It is estimated that up to 1/3 of certain age-related cataracts are due to long-term, cumulative UV exposure. Surveys have shown that up to 90% of people know that UV can damage our skin, but only about 10% know that it can damage our eyes. Sunglasses can help, but based upon the size and coverage of some sunglasses, up to 50% of the UV might still reach our eyes. The optimal UV protection includes: a hat with a brim, UV-blocking sunglasses, and, for those people who wear contact lenses, a UV-blocking lens (the average contact lens blocks about 20% of UV, but some contact lens brands block between 70-100% of UV). We cannot do anything about previous "exposures" to factors that contribute to cataract development. However, it is never too late to enhance our current protection from these factors.

For those people who develop clinically significant cataracts, surgery has proven to be a safe and effective treatment option. The procedure can take as little as 10-15 minutes, and recovery typically involves only minor discomfort and a short period of time before resuming normal activities. Cataract surgery can not only clear up vision distorted by the clouding of the crystalline lens in the eye, but it can also reduce dependence on prescription glasses. Some newer lens implants can now even reduce the need for post-operative reading glasses.

People with dry eyes are understandably concerned about any medical or surgical treatment that could exacerbate their dry eyes. There are, indeed, surgeries for which dry eye patients are at greater risk. LASIK surgery (where a "flap" is created on the cornea) involves the cutting of some fine nerve endings on the front surface of the eye. These nerve endings help to send messages to the brain that the eyes need more tear coverage. It can take up to six months for these nerves to properly regenerate, and for some people, there is never

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In Memory of Anne Scott
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Mary Anne Lysy

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Howard & Kathleen Becker
Edward & Fay Boss
Ralph & Billye Curtis
With our deepest sympathy,
Drs. Larry Goldbaum & Ronald Rosenberg & Staff
Ken and Peggy Haynes
Brenda and Joe Hensley & Family
With our love and sympathy, Laura and Ray Murphy
Bev & Mike Walker
We are so terribly sorry for your loss.
With love from all your friends on Blue C

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Bill & Karen Desberg

In Honor of Bobby and Mort Weisenfeld, on the occasion of your Birthdays and Anniversary
Bert Cohen

In Honor of Anita Ulloa, "for just being terrific!"
Your friend, Anne Demeo

In Honor of Dr. Nancy Sawyer, for World Sjögren's Day
Kay Ashworth
Mindy Douglas
Mary Keene
Rachael S. Paden
Anne Rose

In Honor of Lila Kissin's 80th Birthday
With love from your children and grandchildren

In Honor of Mary H. Spencer
Paula Kephart

In Honor of Mary Wasner, in recognition of your daily struggles with Sjögren's syndrome
Hans Wasner

In Honor of Sheila Z. Syty, "Happy Birthday Shee!"
Aunt Jean

In Honor of Chari Risley's Birthday
Elizabeth Wyatt

"I Stood Up" continued from page 9 ▼

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IT'S TIME

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Each fall your local United Way, Combined Federal Campaign, state employee, and private employer payroll deduction campaigns begin. We hope you will remember the Sjögren's Syndrome Foundation when choosing where to allocate your donation.

If we are not listed on the contribution form, you usually may write in the Sjögren's Syndrome Foundation.

Tell your co-workers, friends, and family members how important it is to choose and write in the Sjögren's Syndrome Foundation on their campaign form, too.

If your employers will not allow you to write in the Sjögren's Syndrome Foundation, remind them that we are a national non-profit 501(c)(3) organization and qualify for most payroll deduction campaigns.

If they need more information, contact Sheriese DeFruscio at the SSF office (800-475-6473 ext. 212).

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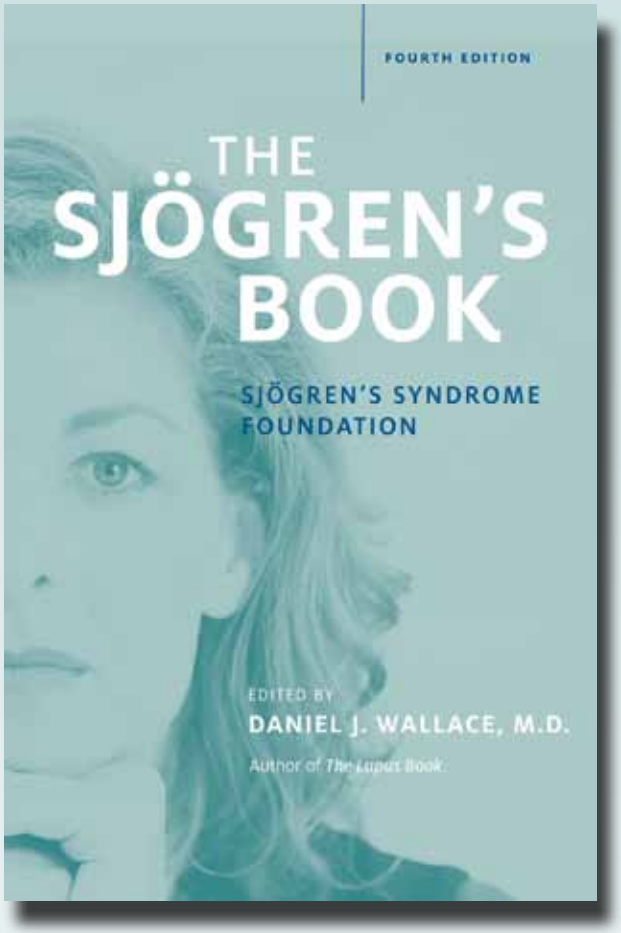

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"Questions & Answers" continued from page 10 ▼

a full return to normal levels. For cataract surgery, there is a small incision that is made near the edge of the cornea which facilitates the removal of the cloudy crystalline lens and the insertion of the clear lens implant. This incision, compared to the corneal flap in LASIK surgery, is quite small, so few corneal nerve endings are compromised. Additionally, the area affected by the incision will take some time to heal. During this brief period of time, this part of the cornea will not coat with tears well, so some dryness and/or foreign body sensation can temporarily occur.

Suffice it to say, any disruption to ocular surface or to the nerves that send messages to produce tears (particularly for Sjögren's patients) is noteworthy. However, these are not major concerns compared to the dramatic benefits in vision and quality of life that successful cataract surgery can provide.

Stephen Cohen, O.D.

Q How is the ear affected in Sjögren's? What are the treatments?

A Sjögren's syndrome (SS) patients, by way of their mucosal dryness, are prone to problems of Eustachian tube dysfunction. The Eustachian tube connects the middle ear to the back of the nose (nasopharynx) and this is how we can pinch the nose and "pop" the ears when swimming underwater or when flying in an airplane. When the secretions become thicker, as they do in SS, the Eustachian tube may become blocked by the thick mucous that accumulates. This results in a sensation of fullness in the affected ear with a tendency to hear one's own voice, heartbeat or breathing sounds louder in the affected ear. If Eustachian tube blockage persists for a long enough time, then fluid may accumulate in the middle ear (middle ear effusion) resulting in a clogged ear, inability to "pop" the ear, earache, and possibly infection if bacteria contaminates the fluid.

The solution for Sjögren's patients who have Eustachian tube dysfunction is to thin the nasal secretions and cleanse the nasal cavity. One method is to perform nasal saline irrigation. Using a Neti Pot or a nasal irrigation bottle (available through NeilMed, Inc.) one should mix the pre-measured packet of salt and baking soda in the correct amount of water (approximately 1/4 tsp table salt +1/4 tsp baking soda in 1 pint of water) and rinse the nose following the instructions included with the rinsing device. One hint is to lean forward over the sink with the head tilted forward towards the sink drain and with the head tilted to one side when applying the irrigation to the uppermost nostril. When half of the irrigation solution has passed through the nose, going in the uppermost nostril and exiting through the lower nostril, then reverse the head position and irrigate in the opposite direction.

Another method of thinning the nasal secretions is to use nasal saline spray throughout the day (Ocean Mist Spray, AYR spray mist, or any other brand) to wet and moisten the nose.

Controlling seasonal allergies with non-drying medications is also important to optimize the health of the nose and Eustachian tube.

David A. Bianchi, MD, FACS

Q Is it recommended or important to have dental sealants placed on teeth?

A Yes. Sealants are generally a good idea even for adults. While primarily performed as a preventive strategy in children, adults with higher risk for caries (like Sjögren's) may benefit from having sealants placed to add extra protection from dental caries.

Nelson L. Rhodus, DMD, MPH, FICD

Q During this past year, I have noticed a hoarseness to my voice. Could this be related to Sjögren's, and, if so, how can it be treated?

A Sjögren's syndrome patients often have voice complaints. Hoarseness can be caused by several different factors which may include allergy, dryness of the throat and vocal cords, reflux-induced irritation of the voice box (larynx), or post-nasal drip. Some medications can also cause voice and throat symptoms (ACE inhibitors used to control blood pressure are the most common).

For Sjögren's patients with voice problems the first thing to do is optimize moisture to the throat by drinking plenty of clear liquids, avoid drying medications (antihistamines), and thin secretions with medications such as guaifenesin (Mucinex). I have found Throat Coat tea to be very helpful for many of my patients with dry throat syndromes. It can be found at most food stores with the herbal tea selections.

If there are concurrent symptoms of indigestion, heartburn, or reflux (acid regurgitation into the throat), then antacid therapy may be helpful to suppress over-production of stomach acid and prevent harmful reflux of secretions up to the level of the larynx. Other behavioral modifications to prevent reflux include avoidance of late night meals and snacks (nothing to eat for two hours before bedtime) and sleeping with the head elevated on a wedge or elevating the head of the bed on blocks, bricks, or lifts (available at Bed, Bath and Beyond or other bedding stores).

Post-nasal drip can be controlled with saline nasal mist or buffered saline nasal irrigation (see previous Q&A about the "ear and Sjögren's"). Saline gargles can also be very helpful for the dry throat. Use 1/4 tsp of salt and ¼ tsp of baking soda in a pint of water and gargle 3-4 times a day.

Hoarseness is common to everyone at one time or another. Protracted hoarseness lasting longer than 8 weeks is not common and can be a sign of a more serious underlying condition, especially in smokers and drinkers who are at

higher risk for throat cancers. If there are ever any symptoms accompanying hoarseness such as bloody mucous or sputum, unexpected weight loss, or lumps in the neck, then you should seek consultation with a specialist in Ear, Nose and Throat surgery.

David A. Bianchi, MD, FACS

Q *What are the dietary modifications and medications (both prescription and over-the-counter) used to treat GERD?*

A Lifestyle modifications can help with the GERD-related symptoms. These include losing weight (if you are overweight), raising the head of your bed by 6-8 inches, stopping smoking, avoiding eating just before bed and avoiding especially large meals. Small, frequent meals are better than two or three large meals in a day. Some foods, such as coffee, alcohol, fatty foods, chocolate, and peppermint, exacerbate acid reflux by causing relaxation of the sphincter at the bottom of the esophagus and should be reduced for optimal management of acid reflux.

There are three main types of medications that are used to control acid reflux: antacids, histamine blockers and proton pump inhibitors. Antacids, such as TUMS® or Rolaids®, are available over the counter without a prescription. They work for mild, intermittent symptoms. Because they work by neutralizing acid that is present within the stomach, they often give the most rapid response, but only work for a short time and do not work at preventing future reflux events.

Histamine blockers (such as Zantac® (ranitidine), Pepcid® (famotidine), and Tagamet® (cimetidine)) are available over the counter as well and are stronger and more effective than antacids; however, with regular, daily use they may become less effective over time

Proton pump inhibitors (PPIs) are the most effective medications at preventing GERD. They work by blocking the stomach's ability to secrete acid. Prilosec® (omeprazole) and Prevacid® (lansoprazole) are available both over the counter and with prescription. Prescription PPIs include Nexium®, Dexilant®, Protonix®, and Aciphex®. These medications are most effective at blocking acid production when taken on an empty stomach, about 15 to 45 minutes prior to eating. While generally quite safe, chronic high-dose PPI use may affect calcium absorption, potentially affecting bone density. While the data is still inconclusive as to this risk, often calcium and vitamin D supplementation is recommended in individuals at risk for bone fractures on chronic acid suppression therapy.

Matthew Nichols, MD

Q *Is it 'okay' for individuals with Sjögren's to have tooth whitening procedures? If yes, which procedures/products would you recommend?*

A Tooth whitening is generally a safe procedure that whitens the teeth by an oxidation reaction set off by a bleaching agent – most commonly carbamide peroxide or hydrogen peroxide. Whitening procedures are either supervised by a dentist or can be completed by over-the-counter products. Whitening will not work for all teeth, such as teeth with certain internal stains (e.g. tetracycline-induced stains) and teeth that have external stains such as coffee/tea stains or existing dental fillings. Teeth should be cleaned professionally prior to teeth whitening. Additionally, existing dental fillings will not change color by tooth whitening, so this must be taken into consideration before planning to whiten teeth. Some of the main side effects of tooth whitening include sensitivity to the teeth and gums. There is also the potential to bleach the teeth too much causing the teeth to become translucent.

There is not a contraindication for Sjögren's syndrome patients to have their teeth whitened, but caution should be exercised when a patient has teeth or gums that are already sensitive. Additionally, teeth should be professionally cleaned and evaluated for dental decay before considering tooth whitening. Therefore, consultation with a dentist prior to the start of tooth whitening would be prudent.

Michael T. Brennan, DDS, MHS

Do we have your e-mail address?

If you want to receive all the latest updates from the Sjögren's Syndrome Foundation, then you should make sure we have your most up-to-date e-mail address! The SSF is starting to share more information via e-mail, from news about the SSF and Sjögren's, to information about the latest treatments and medicines, to local Support Group updates and more. So contact us at ssf@sjogrens.org to be certain we have your latest e-mail address in our database, and then keep an eye out in your Inbox for Sjögren's news.

Just like all information you give the Foundation, your e-mail address will remain private and will never be given or sold to an outside organization.

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Join in the fun! 2011 SSF Special Event Calendar

Visit www.sjogrens.org or contact the SSF office to learn more about our events!

The SSF is very excited for all of our events coming this Fall. Look at our special event calendar below to see if there is a *Walkabout* or *Sip for Sjögren's* coming to your area.

October

23 ***Sip for Sjögren's – Northern California***
Spinnaker Restaurant, Sausalito, California
2pm – 5pm

29 ***Capital Region Walkabout***
The Crossings Colonie, New York
Registration: 8:30am
Walkabout Step-Off: 9:30am

30 ***Vermont Walkabout***
University Mall
South Burlington, Vermont
Registration: 10am
Walkabout Step-Off: 11am

November

6 ***Chicago Walkabout & Health Fair***
Yorktown Center, Lombard, Illinois
Registration: 10am – 11am
Health Fair: 10am -12noon
Walkabout Step-Off: 11am

Turkey Trots Across America
Throughout the United States
Find your local run at www.active.com
Create a team by signing up on our Turkey Trots Across America page at *www.firstgiving.com/ssf* website

sip for Sjögren's
a fine water tasting event

Team Sjögren's

Sjögren's Walkabout