Sjögren's Syndrome Foundation
www.sjogrens.org
The Moisture Seekers
30 Years
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SjogrensSyndromeFoundation @MoistureSeekers

Q&A

Q What is sicca syndrome?

A Sicca is a word derived from the Latin siccus, meaning "dry." Dryness of the exocrine glands, particularly the eyes and mouth, is referred to as "sicca syndrome" or "sicca complex" when there is no evidence of autoimmune disease present. While sicca symptoms occur in the vast majority of Sjögren's patients, not everyone with these symptoms has Sjögren's. Because of this, it is important to establish an autoimmune cause for the dryness. Sometimes other causes may be found, such as radiation therapy to the head, certain medications, or Hepatitis C or HIV infections. If no cause is found, the patient should be followed carefully for possible Sjögren's because it sometimes takes years for the diagnosis to become clear.

Dryness from Sjögren's may affect any organ in the body that secretes moisture. In addition to changing the quantity and quality of saliva and tears, dryness may manifest in the airways, nasal passages, sinuses, throat, skin, and in women, the vagina. Some Sjögren's patients initially present with recurrent sinus infections, severe vaginal dryness, chronic dry cough, and so on. All types of specialists, not just eye doctors and dentists, need to keep Sjögren's in mind as a diagnostic possibility, especially when dryness is severe, persistent, or accompanied by systemic symptoms such as fatigue and widespread muscle and joint pain. Dryness can be quite serious, causing dental disease, eye pain and even visual impairment. However, these issues should not detract from the often missed point that Sjögren's is much more than sicca syndrome. Sjögren's is a serious systemic autoimmune disease that can affect almost any organ in the body.

Sarah Schafer, MD

Q How can the recent gene discoveries help Sjögren's in the short and long term?

A For many years, scientists and clinicians had wondered if there were heritable aspects to Sjögren's syndrome (SS). Recent work by our group and others has shown that genetics do indeed play a role, with some individuals with genetic risk factors showing greater predisposition for developing SS. Previous genetic studies were limited in that they were conducted using relatively small groups of patients and focused on individual genes that were highly suspected to be involved in SS. As a result, these studies often resulted in conflicting reports. Using unbiased ap-

continued page 2 ▼

In This Issue

"Q&A" continued from page 1 ▼

proaches in a large-scale study, our group has convincingly identified 6 genes that contribute to SS in some way. Armed with this set of genes that we can confidently say play a role in SS, we can now focus our efforts on understanding how these genes predispose an individual to this disease.

Unfortunately, it is unlikely that an immediate impact of this knowledge on SS diagnosis and treatment will be felt. Important experimental studies must be conducted to understand the precise mechanisms by which disruptions in these genes contribute to SS. To further complicate matters, additional genes are likely to play a role in this complex disease. In related autoimmune disorders such as lupus and rheumatoid arthritis, more than 100 genes have been identified that influence each of these diseases. In fact, several of the genes identified in SS overlap with these related disorders and show similar effects. This will allow us to "piggy-back" on many of the important experimental findings that have already been made in other diseases, allowing us to prioritize our work on the genes whose altered functions are poorly understood. Certainly, ongoing efforts by our group and others seek to identify additional genes by evaluating larger groups of patients and controls and by surveying more of the human genome. Similarly, the impact of any newly identified genes must also be assessed.

The long-term impact on SS is much more promising. With the recent gene discoveries, we now know that two very important pathways are affected based on an individual's genetics. These pathways, called the Type I and Type II interferon pathways, are important first lines of defense against viruses and other pathogens and have long been implicated in the disease. However, we did not know that heritable factors played such an important role in their involvement. We also see evidence for the involvement of particular cell types in the disease based on an individual's genetics. All of this information will be helpful in the future as efforts to develop effective therapies targeting specific cell types are undertaken. It is not outside the realm of possibility that in the future a genetic test could help your physician not only diagnose SS, but also prescribe the best treatment for your particular genetic profile. While this work is slow and it will take time for our patients to see direct benefits, we have taken the important first steps toward a more comprehensive understanding of the factors at work in this disease. This knowledge will help us to design high-yield experiments that have the greatest potential to impact the development of effective, targeted therapeutics in the near future.

Christopher Lessard, PhD and 2013-2014 SSF Research Grant Recipient

continued page 6 ▼

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I used artificial tears often, like when watching movies.

So I saw my doctor—after all, these are my eyes.

And she said I have a disease.

My eye doctor said I have reduced tear production caused by inflammation due to a disease called Chronic Dry Eye. That's a big deal.

She told me I can use artificial tears for temporary relief. But to make more of my own tears, she prescribed RESTASIS® (Cyclosporine Ophthalmic Emulsion) 0.05% for continued use, twice a day in each eye, 12 hours apart, every day.

Approved Use

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

Do not use RESTASIS® Ophthalmic Emulsion if you are allergic to any of the ingredients. To help avoid eye injury and contamination, do not touch the vial tip to your eye or other surfaces. RESTASIS® should not be used while wearing contact lenses. If contact lenses are worn, they should be removed prior to the use.

Important Safety Information (cont'd)

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 the Brief Summary of the full Product Information.

Individual results may vary.

Available by prescription only.

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Talk to your eye doctor about RESTASIS® today.

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RESTASIS® (Cyclosporine Ophthalmic Emulsion) 0.05%

BRIEF SUMMARY—PLEASE SEE THE RESTASIS® PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION.

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 known or suspected hypersensitivity to any of the ingredients in the formulation.

WARNINGS AND PRECAUTIONS
Potential for Eye Injury and Contamination
To avoid the potential for eye injury and contamination, be careful not to touch the vial tip to your eye or other surfaces.

Use with Contact Lenses
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.

ADVERSE REACTIONS
Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In clinical trials, the most common adverse reaction following the use of **RESTASIS®** was ocular burning (17%).

Other reactions 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).

Post-marketing Experience
The following adverse reactions have been identified during post approval use of **RESTASIS®**. Because these 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.

Reported reactions have included: hypersensitivity (including eye swelling, urticaria, rare cases of severe angioedema, face swelling, tongue swelling, pharyngeal edema, and dyspnea); and superficial injury of the eye (from the vial tip touching the eye during administration).

USE IN SPECIFIC POPULATIONS
Pregnancy
Teratogenic Effects: Pregnancy Category C
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 5,000 and 32,000 times greater (normalized to body surface area), respectively, than the daily human dose of one drop (approximately 28 mcL) of 0.05% **RESTASIS®** twice daily 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 3,000 and 10,000 times greater (normalized to body surface area), 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 postpartum, a maternally toxic level, exhibited an increase in postnatal mortality; this dose is 7,000 times greater than the daily human topical dose (0.001 mg/kg/day) normalized to body surface area assuming that the entire dose is absorbed. No adverse events were observed at oral doses up to 15 mg/kg/day (2,000 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.

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis: 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 80 times greater (normalized to body surface area) than the daily human dose of one drop (approximately 28 mcL) of 0.05% **RESTASIS®** twice daily into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed.

Mutagenesis: Cyclosporine has not been found to be 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).

Impairment of Fertility: 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 2,000 times the human daily dose of 0.001 mg/kg/day normalized to body surface area) for 9 weeks (male) and 2 weeks (female) prior to mating.

PATIENT COUNSELING INFORMATION
Handling the Container
Advise patients to not allow the tip of the vial to touch the eye or any surface, as this may contaminate the emulsion. To avoid the potential for injury to the eye, advise patients to not touch the vial tip to their eye.

Use with Contact Lenses
RESTASIS® should not be administered while wearing contact lenses. Patients with decreased tear production typically should not wear contact lenses. Advise patients that 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.

Administration
Advise patients that 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.

Rx Only

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 Please allow 8 weeks for delivery of your rebate check. APC18SR13 Certificate expires 12/31/2014

I Stood Up...

Ladies High Tea for Sjögren's

Remi, who was diagnosed with Sjögren's after being sick for several years, was inspired to host a fundraising event after she and her husband attended the 2013 *SSF National Patient Conference*. Not wanting to be defined by her Sjögren's, she attended the Conference to become more informed about her disease, but left with much more.

"I was stunned by what I saw at the Conference, hundreds of women and a few men, virtually all suffering from the same disease, as well as additional autoimmune disorders. I felt this frisson, an immediate and heartwarming interconnectedness. I also felt heartsick, knowing that so many were suffering so much. Knowing that over four million people suffer from this disease is one thing, seeing several hundred women gathered together made it far more real. It was at that moment that I decided I would do something to help," said Remi.

Once back at home, Remi enlisted the help of a friend and together they brainstormed about what fun event they could host for their friends and a "Ladies' High Tea for Sjögren's" was born! She then reached out to other friends to help split up the duties that come with planning and hosting a fundraising event.

With the support and help of her family, friends and the SSF, Remi began to share her journey with Sjögren's. In addition to figuring out event logistics, she set up an online donation page, contacted local business for donations and began talking about Sjögren's and the work of the SSF. "When I was first diagnosed, I was overwhelmed by fear and despair. Fortunately, I found the SSF. They gave me comfort, information and hope. I don't know where I would be without their support."

Then after three months of planning, Remi and guests celebrated at the "Ladies' High Tea for Sjögren's," raising almost $3,000.00!

Even more than the event itself, Remi remarks that the best part of the whole process was being able to find her voice. Explaining, "Being diagnosed with an autoimmune was overwhelming and terrifying. I felt frightened into silence. I was afraid that if I spoke about what I had, it would somehow make the disease more real, more potent. Instead, when I found my voice I discovered a tremendous amount of love and support – a whole lot to be grateful!"

We hope Remi's story inspires you to talk about Sjögren's or host a small community event to help those in your life better understand the disease.

Thank you Remi for Standing up for Sjögren's! ■

"Q&A" continued from page 2 ▼

How can I manage my vasculitis so that it doesn't become too severe?

Vasculitis usually manifests with purplish skin lesions on the legs and sometimes the trunk. It is usually associated with high levels of gammaglobulin in the serum. The skin may become easily irritated and even break down in areas where numerous lesions develop. The skin around the ankles is most susceptible. Skin breakdown and ulcerations may form.

Although severe vasculitis from Sjögren's may require hydroxychloroquine (Plaquenil), oral corticosteroids and immunosuppressive medications, milder forms can be managed with simple conservative measures.

Skin breakdown occurs with greater frequency when there is fluid accumulation around the ankles so measures that minimize edema (excess fluid accumulation) in the legs can be helpful. Such measures include elevation of the legs and the use of support hose. When sitting, your legs should be propped up on a chair and not left dangling for too long. Support hose to control edema should be of the above-knee variety. Hose that bunch up below the knee may actually act like a tourniquet and impede blood flow in the legs making edema worse.

Mild trauma to the skin of the legs can also favor skin ulceration so wearing pants may provide an extra layer of protection. Edema can also be controlled with diuretics. Some patients with vasculitis may benefit from low dose aspirin to keep the blood vessels open.

Of course these conservative measures should also be applied in instances when immunosuppressive therapy is needed. Consult with your doctor if diuretic therapy or low dose aspirin is right for you.

Herbert S. B. Baraf, MD, FACP, MACR

Q Is there a speculation as to what's driving this big upswing in the diagnosis of men and children with Sjögren's?

A My gut feeling is that it has to do with the improvements in awareness and medical and dental education in recent years. The Sjögren's Syndrome Foundation has spent years trying to train the physicians and nurse practitioners about how prevalent and serious the disease is. We finally have a celebrity who unfortunately was diagnosed with Sjögren's and although nobody likes to see somebody become ill, it has done a lot to help the entire public realize how serious it is, particularly the idea that people look a lot better than they feel and that it may take years to diagnose it unless you take the symptoms seriously. I can tell you at the University of Pennsylvania, where I work, the oldest medical school in the United States, we only started giving our first Sjögren's lecture to the first year medical students about four years ago. And that was only after years of me fighting with the curriculum committee to get it included in the rheumatology course for the first year students. So, we've made a lot of progress and I think that's an example of the benefits of all this work.

Frederick B. Vivino, MD, MS, FACR

Q I've heard that pulmonary hypertension is associated with sleep apnea? How can I tell if my symptoms are because of Sjögren's or sleep apnea and does it make a difference in how I treat it? A woman in my local Sjögren's support group says that her PH has been a lot better after a using a BiPAP machine at night. Should I use one too?

A The pulmonary circulation is made up of blood vessels connecting the right side of the heart to the lungs. Pulmonary hypertension is a condition in which the blood pressure in the pulmonary circulation becomes too high. When untreated for prolonged periods of time, pulmonary hypertension may result in excess strain on the right side of the heart.

The symptoms of pulmonary hypertension are often not obvious until the condition has progressed. Thus, patients with mild or occasionally moderate levels of pulmonary hypertension may be relatively asymptomatic. The symptoms, when they occur, include shortness of breath (initially only with exertion), fast heart rate (especially with exertion), fatigue, dizziness, and in more advanced cases fainting spells. When the right side of the heart becomes excessively strained, patients may experience leg-swelling, belly-swelling, or chest pains.

Pulmonary hypertension is usually diagnosed by echocardiogram (heart ultrasound). There are a large number of medical conditions that can cause pulmonary hypertension. Sjögren's syndrome and sleep apnea are only two of these causes. Pulmonary hypertension is thought to be a relatively uncommon complication of Sjögren's syndrome, although the more we look for it, the more we seem to find it. When it does occur, it tends to be mild or occasionally moderate in nature. Severe pulmonary hypertension in Sjögren's syndrome seems to be rare.

Unfortunately, it is difficult to determine whether sleep apnea or Sjögren's syndrome is responsible for causing pulmonary hypertension based on symptoms alone. It

is even possible that both Sjögren's syndrome and sleep apnea together may contribute to a patient's symptoms. Furthermore, there are a number of other ways in which Sjögren's syndrome can affect the lung, and many of these cause similar symptoms to pulmonary hypertension, especially shortness of breath.

The first step is to see a pulmonologist who can evaluate you by taking a history and performing a physical exam. Part of the history and physical exam will involve screening you for the possibility of sleep apnea. In addition, the physician will be able to evaluate you to see if there are other causes for your symptoms, some of which may be associated with Sjögren's syndrome. Based on the history and physical he/she will be able to perform further diagnostic testing. They can order an echocardiogram to diagnose your pulmonary hypertension if this has not already been done. If indicated, they can also order a sleep study to confirm whether you have sleep apnea. Only once they have figured out what is responsible for your symptoms can they proceed with treatment.

Treatment for these two distinctive causes of pulmonary hypertension is very different. In general, treatment of sleep apnea, involves the use of what is known as non-invasive ventilation- the two most common types are called CPAP and BiPAP. If your sleep study is positive for sleep apnea, the testing center will usually set you up with either CPAP or BiPAP if needed (occasionally sleep apnea can be treated without non-invasive ventilation). Sleep apnea should be treated, even if you do not have pulmonary hypertension. If you do have pulmonary hypertension caused by sleep apnea, treatment with non-invasive ventilation may be beneficial in reducing or even reversing your pulmonary hypertension. This form of treatment will not have any effect on your pulmonary hypertension caused by Sjögren's syndrome.

Treatment of pulmonary hypertension caused by Sjögren's syndrome is very different and not as clear-cut as treatment of pulmonary hypertension caused by sleep apnea. In general, depending on the severity of the pulmonary hypertension, treatment may involve the use of drugs that suppress the immune system to control Sjögren's syndrome, and/or the use of specialized drugs that treat the pulmonary hypertension directly. However, studies supporting the use of these agents in the treatment of Sjögren's syndrome-related pulmonary hypertension are few and far between, and these treatments should only be administered by a specialist, or team of specialists, who

continued page 10 ▼

Coordinate a **Bold Blue Day** for Sjögren's!

What is Bold Blue Day?

Imagine your colleagues or classmates trading in their tailored slacks or dresses for a day in **blue jeans** or **bold blue** to raise vital funds for Sjögren's research and awareness.

Ask your company or your school (even your kid's school) to consider doing a dress down day for the SSF.

How does it work?

Each person choosing to dress down would donate a suggested amount to the SSF as their fee for participating. Some companies suggest $5 while others companies/schools let each person decide how much they want to donate.

What if your company doesn't ever allow jeans?

Then just have a BOLD BLUE DAY – where on a certain day everyone chooses to wear their favorite BOLD BLUE outfit! Then collect donations for the SSF that day as well.

To receive more information or have a "Bold Blue Day" kit sent to you, contact Steph Hilton at (800) 475-6473 ext. 227 or shilton@sjogrens.org to receive your "Bold Blue Day" kit.

Sjögren's Syndrome Foundation

April

Breakthrough Bullet:

"UNLESS someone like you cares a whole awful lot, nothing is going to get better. It's not" – The Lorax, Dr. Seuss

50% in 5 years
Sjögren's syndrome FOUNDATION

We knew it would take an army to achieve our 5-*Year Breakthrough Goal*- but just imagine a future where Sjögren's is taken more seriously by the medical community and you never have to hear "Show What?" A future where Sjögren's is a household name and you helped make it happen!

Currently there are an estimated 3 million Americans suffering from Sjögren's who are still undiagnosed and struggling to figure out why their health is deteriorating. Even though Sjögren's is 3 times more common than related diseases such as Lupus or Multiple Sclerosis, general awareness of Sjögren's is still low. And while we are making progress, we need your help now more than ever.

The SSF has asked a lot of our members over the years. We've asked you to volunteer as local support group leaders/ phone contacts, to step up as Awareness Ambassadors, to talk to your family about Sjögren's and much more. You have always inspired us by your passion and willingness to help others, which is why we continue to do everything possible to get patients the care desperately needed. The SSF strives to be the catalyst that changes the face of Sjögren's but we cannot do it alone.

With April being Sjögren's Awareness Month, make this the time you take a stand and help us reach our Goal!

- Think about hosting a Bold Blue Day
- Purchase SSF Awareness bracelets
- Talk to your family about Sjögren's
- Host your own SSF event
- Ask your doctors if they know about the SSF

"Unless someone like you cares a whole awful lot, nothing is going to get better. It's not"
– The Lorax, Dr. Seuss

in memoriam

In Memory of Rose Doren
Nancy Chase

In Memory of Mary Lynn Tipton
Telise Johnsen & Roland Berns

In Memory of Julie Gibson Rohloff
Partner Friends at
Ogden Gibson Broocks Longoria & Hall LLP
Holly & Glen Bell
Julie & Phil Caggiano

In Memory of Louise Gibson
Mr. & Mrs. Giulio Donatich

In Memory of Michael Goldman
Mary Ann Chiarello

In Memory of Judith M. Gan
Janet Bitton
Eyal & Michele Bitton
Laura & Brett Deshay
David & Joyce Plasse
Theresa & Rich Pangretic
Maven & Lynwood Pollard
Tony & Anastasia Orsini
Brian & Karen Janiga
Paul Mandell
Richard Wilde

In Memory of Bertram Charap MD
Lynne & Lance Forstot

In Memory of Waltraud Schlanzky
Paula Peterson

Sjögren's Syndrome Foundation
Legacy of Hope

in honor

In Honor of Kay Shager
Mardelle Shager

In Honor of Paula Sosin
Lydia Armstrong
Alaina Wong
Laurie Trombley

In Honor of Elaine Harris
Francine & David Penner
Lynne & Andy Levin
The John & Sally Thornton Foundation

In Honor of Bonnie Litton
Sandy & Brian Salita

"Q&A" continued from page 7 ▼

has experience in the care of patients with pulmonary hypertension and/or Sjögren's syndrome.

Adrian Shifren, MD
Assistant Professor of Medicine at
Washington University School of Medicine

Q *I'm thinking about getting punctal plugs, what are the pros and cons for having it done?*

A Punctal plugs have both pros and cons. The pros are that they are a safe method to retain tears on the ocular surface and have value in relieving symptoms when tear production is borderline or if the duration of applied tear substitutes needs to be prolonged. They are helpful as adjunctive treatment in the management of dry eye disease.

The cons are that when applied in the presence of inflammation that can occur as part of dry eye disease, they may aggravate symptoms by allowing the inflamed tear to have prolonged contact with the surface of the eye. Therefore, my recommendation is to treat the underlying inflammation before placing the plugs. Another con is that they can fall out and need frequent replacement. Rarely, the plug can provoke a localized inflammatory reaction in the tissue of the eyelid and produce a granuloma at the opening of the tear drainage puncta.

On balance, punctal plugs are a useful adjunctive treatment for dry eye disease but should be used in conjunction with other therapies to control inflammation.

Gary Foulks, MD

Q *Both of my lower punctals closed about 3 months ago and now my eyes feel dry again. Is it possible for the punctum to reopen or to re-insert punctual plugs?*

A Yes, it is possible that the punctal orifice can reopen as the scar tissue remodels itself. If your dry eye symptoms were controlled while the puncta were closed and you did not have overflow tearing at that time there are options you can consider. First, it is possible to reinsert punctal plugs. Often it requires the use of a different (smaller) plug than was initially used. Another option is to have the opening closed by using mild electrocautery or laser closure of the puncta that produces a complete scarring of the opening. Permanent closure should not be done if you had overflow tearing (epiphora) at any time during you previous plugs were in place.

Gary Foulks, MD

continued page 12 ▼

NEW

NeutraSal® Sjögren's Syndrome Support Kit

Containing:

- Eye Vitamin and Mineral Supplement for Dry Eye and Dry Mouth Comfort*
- Sugar Free Dry Mouth Gum with Xylitol

* Compare to the ingredients in Ocuvite™ (Bausch and Lomb).

NeutraSal®
(Supersaturated Calcium Phosphate Rinse)

What is NeutraSal®

NeutraSal® is an advanced electrolyte solution indicated in the treatment of dry mouth (xerostomia) in patients with Sjögren's Syndrome. NeutraSal® consists of single use packets of dissolving powders that when mixed with water creates an oral rinse supersaturated with calcium, phosphate and bicarbonate ions.

- Clinically proven to relieve the symptoms of dry mouth in Sjögren's Syndrome patients with no reported side effects or drug to drug interactions
- Calcium and phosphate ions have been shown to aid in the the prevention of dental caries (cavities) and promote the remineralization of the teeth in normal saliva
- Sodium bicarbonate ions reduce the acidity of the saliva in the mouth and break up accumulating mucus
- The pH of NeutraSal® is similar to normal saliva which may protect the mouth against potential opportunistic fungal (oral thrush) and bacterial infections

NEW

NeutraSal® Burning Mouth Syndrome Support Kit

Containing:

- Alpha Lopic Acid for Burning Mouth Comfort*
- Sugar Free Dry Mouth Gum with Xylitol

† This statement has not been evaluated by the FDA. This product (alpha lipoic acid) is not intended to diagnose, treat, cure or prevent any disease.

Available at No Cost with Every NeutraSal® Prescription

#1 New Product for Xerostomia in the U.S.**

Available at No Cost with Every NeutraSal® Prescription

NeutraSal® is a prescription item. For additional information on NeutraSal® or the Direct Access Program, please visit www.neutrasal.com or call 866-963-8881 ext #1.

DIRECT ACCESS PROGRAM

The Direct Access Program is designed to provide access to NeutraSal® treatment for all patients regardless of their insurance coverage or financial condition. The program includes no out-of-pocket costs (co-pay) for most patients and free trial medication for patients without coverage. The NeutraSal® Direct Access Program and Support Kits are only available through the NeutraSal® Specialty Pharmacy Network. (Not valid for local retail pharmacies).

Proud Sponsor

Sjögren's Syndrome Foundation

INVADO PHARMACEUTICALS

**Based on Q1-Q4, 2013 IMS Data and Published SEC-10k Data.

"Q&A" continued from page 10 ▼

Q What are the benefits of using vaginal moisturizers/lubricants?

A Vaginal moisturizers and lubricants can be very beneficial for women who are experiencing vaginal dryness or discomfort during intercourse. Frequent causes of vaginal dryness include: menopause, antibiotics and other medications, douching, diabetes, contraceptives and autoimmune disorders.

Vaginal moisturizers are used daily or less frequently as needed to keep the vagina constantly moist. Most vaginal moisturizers are packaged in a single dose applicator. They can be messy and may require the use of a panty liner. I recommend that moisturizers be used at bedtime so they can sit in the vagina overnight, allowing for better absorption. If used during the day, some product will be lost due to the gravity of an upright position. If the moisturizer is effective long term it may allow a couple to enjoy more spontaneous intimacy.

Lubricants can be used alone prior to intercourse, or in addition to a vaginal moisturizer to provide comfort. They may come packaged in a onetime use package or a multiuse container or tube. They are meant to provide short term comfort.

Examples of moisturizer products are:

- Replens® – works by hydration of dry vaginal cells
- Luvena® – preservative free, helps maintain beneficial flora and correct ph of vagina, provides anti yeast proteins and natural antibacterial enzymes, provides long lasting moisture barrier
- Yes™ – water based bioadhesive gel that adheres to the vaginal walls to lubricate, moisturize and protect surface layers of the vagina, hypoallergenic, hormone free, condom compatible, not a contraceptive, contains no chemicals, skin irritants, sugars, glycerin or parabens, clear gel that do not produce white discharge
- Silent Secret by Astroglide®
- Moist Again

Examples of lubricant products are:

- K-Y® SILK-E moisturizer and lubricant
- Astroglide®
- Vagisil® Intimate lubricant
- Luvena®

Check the internet, your pharmacy or health food store for additional products. Finding a product(s) that work best for you are by trial and error, and may take some time and research. If a product irritates your skin or causes discomfort internally, discontinue its use immediately.

A woman should see a physician if a feeling of vaginal dryness, burning, stinging is ongoing. A yeast infection or other vaginal infection could be the cause. If your gynecologist or medical doctor is unable to guide you or does not seem familiar with this problem, try to locate another physician or a vaginosis specialist.

Lynn Pettruzzi, RN

Q I'd like to host an SSF fundraising event but don't know if it would be too much for me to take on- where would I start?

A I would strongly encourage folks to consider hosting a fundraising event for the SSF. I would suggest that you choose an event that you think would be fun. Constrain the size to what fits your comfort level. I am by nature an introvert– so if I can do this, then I feel confident most anyone can! Work with family and a group of trusted and dear friends. Fundraising will have its stressful moments. Having wonderful people you can rely on with you throughout the process is essential. Give yourself sufficient planning time. If you don't hear back from someone you've contacted, send a second e-mail, make a follow-up phone call. Truthfulness, humility and humor go a long way. Tell your story. Make it personal. Give potential donors an honest, real person they can connect with, someone they'll want to support. Help others understand the phenomenal work the SSF does, so they'll realize what their gifts will do. Be prompt and gracious with your thank-you notes. Expressing your heartfelt gratitude within a reasonable amount of time makes everyone feel wonderful.

Remi Langum, Sjögren's patient. View more of her story on page 5 to see how she stood up for Sjögren's with her "Ladies' High Tea" event!

Q Do you recommend Rituxan® to help neuropathies?

A I don't think there has been any evidence saying that Rituxan® is either efficacious or ineffective for neuropathies. Neuropathies need to be thought of as different syndromes, and each of those syndromes have different causes which might be differentially affected by the Rituxan®. If you have a neuropathy that is suggestive of a vasculitis, and that would be something that is more asymmetric, then certainly Rituxan® could be effective, but then your doctor would want to go through the usual diagnostic paradime. The diagnosis of

continued page 14 ▼

You Can Make a Difference this April!

Tips for Raising Awareness

You can help make Sjögren's a household name! By simply sharing your story and telling others about the SSF, people will begin to realize how common Sjögren's is. Below are a few SSF tips to help you share. Start small by picking one or two things that you can do to help and go from there!

Here are some tips to help you share:

- Think about why sharing is important to you and tell that story
- Follow the SSF Blog & social media accounts that are listed on sjogrens.org
- Share SSF materials, such as this newsletter, and social media posts with friends and family
- Hang a "Bold Blue Day" flyer at your gym or community center
- Check your newspaper for a local reporter to share Sjögren's information with
- Leave past newsletters at your library, pharmacy or wellness center
- Host your own SSF awareness event

Whether you are a patient, healthcare provider, family member or friend, we hope you will get more connected with the Sjögren's Syndrome Foundation and help us raise awareness for this common, yet little known disease.

We have many different opportunities for you to get involved, from purchasing a 2014 Awareness Kit to becoming a Sjögren's Awareness Ambassador! Please visit www.sjogrens.org or call Ayu with the SSF at (301) 530-4420, ext. 210 to learn more!

"Q&A" continued from page 12 ▼

vasculitis is not just a cursory diagnosis, but is something that you can see in electro diagnostic studies and would usually need to have tissue confirmation. If you have evidence that the neuropathy is being driven by a vasculitis, then Rituxan® makes mechanistic sense. There are other types of neuropathies, which we know don't respond to drugs like Rituxan.® Then we'll use IVIG or something else. So, I think you have to go to your doctor and say "what type of neuropathy do I have, how do you know it's vasculitis, what are the blood markers, and do you want to do a biopsy?" The evidence that Rituxan® works "yes-no" for neuropathies is just an over simplification. You have to say: "what is the neuropathy, how do you characterize it, what does it do to you, and then how do you treat it?"

Julius Birnbaum, MD, MHS

Q *Is there an issue for Sjögren's patients with the nervous system and how it communicates? Do problems with the nervous system contribute to Sjögren's?*

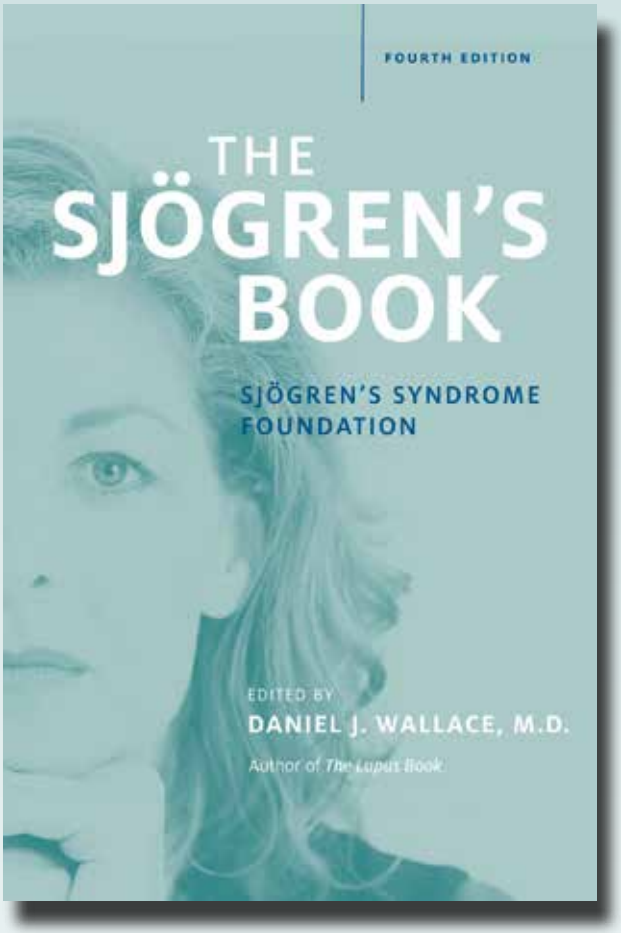
A Yes, they absolutely do. Sometimes the nervous system becomes damaged and you develop symptoms that mimic those of multiple sclerosis or you develop neuropathies in the legs with numbness and tingling in the legs which can cause a lot of discomfort and even progress, and interfere with walking. But, on another level, the nerves send signals to the glands to produce moisture and sometimes things happen to these nerves that interfere with this process. So that's a very important complication and something we're just beginning to study and understand.

Q *It seems that IBS (Irritable Bowel Syndrome) and Gluten sensitivity have some overlapping symptoms, is there a way of distinguishing between the two?*

A No there isn't because, IBS is a diagnosis of exclusion. We have tests that diagnose celiac disease but we don't have tests that diagnose gluten sensitivity. There's a gluten allergy we can test for, but gluten sensitivity is tricky. So because the same symptoms can cause gas, bloating, and discomfort, we tend to lump them together.

Now, many people with IBS can benefit from going on a gluten light diet. Going on a gluten free diet can be tricky and should only be done with the help of a dietician. However, a gluten light diet is still very healthy and very safe, as long as it's not too restrictive and for many people can lead to a big improvement in IBS type symptoms.

Matthew Nichols, MD



The Sjögren's Book – Fourth Edition

Edited by Daniel J. Wallace, MD

This edition of the Sjögren's handbook was completely revised and expanded in 2011 with **ALL NEW** chapters and the latest information on Sjögren's!

This book can be purchased using the order form below, online at www.sjogrens.org/ssfstore or by contacting the Sjögren's Syndrome Foundation office at 800-475-6473.

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The Sjögren's Book – Fourth Edition: Edited by Daniel J. Wallace, MD	$32.00	$28.00		
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If you would like to receive this newsletter but are not currently an SSF Member, please contact us! 800-475-6473

Be Part of the SSF Breakthrough Goal Team

2014 SSF Special Event Calendar

Join in the fun and help increase Sjögren's awareness. The SSF is very excited for all of our events coming this year. Look at our special event calendar below to see if there is a *Walkabout* or *Sip for Sjögren's* coming to your area.

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

April

25-26 ***National Patient Conference***
Chicago – Rosemont, Illinois

26 ***National Patient Conference Walkabout***
Chicago – Rosemont, Illinois

May

3 ***Philadelphia 10th Walkabout & Health Fair***
Philadelphia, Pennsylvania

10 ***Dallas Fort Worth Walkabout & Health Fair***
Dallas, Texas

31 ***NE Ohio Walkabout***
Ohio

June

1 ***Columbus Walkabout***
Columbus, Ohio

1 ***Atlanta Sips***
Atlanta, Georgia

14 ***Denver Walkabout***
Denver, Colorado

21 ***GWR Walkabout / Family Day***
Washington D.C. Area

22 ***Kansas City Run / Walkabout***
Parkville, Missouri

Sjögren's Walkabout

Team Sjögren's