August 2016 Update from US Institute for Advanced Sinus Care and Research

Dear ENS Community,

Attached is our update for our 2016 efforts to prevent and cure ENS. We are happy to announce that we will begin offering PRP/Acell/Adipose Derived Stem Cell impregnated implants as a new experimental therapy for patients with ENS due to large turbinate volume loss. See below for details.

1. What therapies are you now offering for the treatment of ENS?

Effective August 1, 2016, our institute will begin offering 3 types of therapies for ENS. The first is the use of PRP/Acell injections for patients with turbinate dysfunction following surgery without significant volume loss. We have treated over 250 patients with this therapy and have a greater than 75% improvement rate with this therapy. The prices for this therapy will remain $1985 for the first injection and consultation and $1635 for subsequent injections. We are also pleased with our initial efforts and experience using PRP/Acell/Adipose Derived Stem Cells harvested from a liposuction from patients. We will continue to offer this as an alternative to our traditional PRP/Acell injections. We have treated 20 patients with these procedures and have not seen any adverse side effects with this therapy. We expect these injections to have a success rate similar to or greater than our traditional PRP/Acell injections. The prices for this therapy will be $2850 for the first injection and $2500 for subsequent injections. We will also begin offering implants for patients with significant volume loss. Instead of using Alloderm, which is a material that I do not like due to an approximately 20% rejection rate when used in hernia and breast reconstruction, we will be using a new material known as Biodesign from Cook Medical, Inc. Biodesign is made similar to Acell from sheets of porcine extracellular matrix and have proven studies showing that new blood vessels and nerves are able to grow into the material. We will be impregnating these implants with PRP/Acell/and Adipose-derived stem cells harvested from a liposuction or abdominal surgery. The prices for this therapy will be $7635. Unfortunately, we have tried to get insurance to cover these procedures but they have been deemed experimental and will not be covered by insurance.

2. Why are you now offering implant surgery again?

For many years I had tried Alloderm implants for volume reconstruction with mixed results. For some it helped but for approximately 25% the implants would extrude over time and induce a foreign body inflammatory reaction that was harmful and would cause scarring. Similar results were reported in other body areas that Alloderm was used. In fact, there is a class action lawsuit against Alloderm (www.schmidtlaw.com/alloderm-class-action-lawsuit). There are over 300 lawsuits against Alloderm use in the state of New Jersey alone. Many of my colleagues who use Alloderm have reported on the need to perform another operation and remove the Alloderm in a small group of patients. As a result, I felt that the risk of further harm by using Alloderm was too much for me to continue to offer this as an implant material. I have been searching for a more suitable alternative. Recently, Cook Medical reported on their new material known as Biodesign that in speaking with their representatives was created very similarly to the material used in Acell. Biodesign has several advantages in my opinion over Alloderm.

First, it is non-cross-linked, which allows blood vessels easier ability to grow into the tissue. Cross-linked biologic grafts such as Alloderm inhibit vascular ingrowth and have been associated with chronic inflammation and encapsulation. (Novitsky, et. al. The biology of biologics: basic science and clinical concepts. Plast Reconstr Surg. 2012;130(5)9s-17s. Second, it does not contain meaningful amounts of elastin, which interfere with the body's ability to organize and deposit collagen. As a result, I feel it will be a much safer material than Alloderm with less extrusion and less chronic inflammation. Also, by directly depositing adipose-derived stem cells into the material, I hope that it will act as a scaffold to allow for new tissue regeneration to occur in the turbinate.

3. Has there been any progress on ENS advocacy?

There have been several exciting events on the advocacy front. First, Dr. Steven Houser convened a conference call and meeting scheduled in September for ENS awareness that is open to all practicing otolaryngologists. Initially, we are working to potentially develop a diagnosis code for this disease. Also, I was named to a two-person task force to develop recommendations for a political action committee of the American Rhinologic Society. This committee will hopefully be proactive in helping to eradicate ENS.

4. Any new changes and progress on the clinical trial front?

Dr. Jayakar Nayak and his colleagues at Stanford University have developed a validated, disease specific questionnaire known as the ENS6Q to follow the progress of patients with ENS. This work won the award for the top clinical science paper at the 2016 Spring Meeting of the ARS. This will be a very valuable tool to follow patients with ENS and compare treatment protocols from different doctors across the country. We will start implementing the use of the ENS6Q on January 1, 2017 for all of our ENS patients.

That's all for now. Best wishes, Shu Das