Glaucoma treatment has traditionally been limited to either low or high risk options. Glaucoma drops and lasers are low risk, but can have limited effectiveness. On the other hand, surgical options can be more effective, but are more risky and invasive. This has resulted in a significant treatment gap with few options for those patients with moderate glaucoma that need a treatment that lies safely in between the two. Fortunately, for patients suffering from glaucoma, this gap has been successfully reduced in the last 3-4 years, with several new treatment options being FDA approved in just the last few months. One of these promising new options is the Xen Gel Stent.

The stent itself is a tube that is made out of a permanent gelatin material. It is 6mm in length and is as thin as a strand of hair. The stent is injected from within the eye to drain excess eye pressure out of the eye into a fluid filled space on the outside of the eye. This shunts excess fluid away from the eye to control eye pressure. This is accomplished in most cases without sutures and only 2 small incisions similar to cataract surgery. Early experience in the U.S. has been very promising. Long-term studies have shown that on average eye pressures in the low to mid teens can be obtained with reductions in eye drops.

Although this new device has been available in the U.S. only a few months, Drs. Lewis and Brubaker have extensive experience with this new device. Both doctors have served on medical missions in Central America, bringing this technology to glaucoma patients that would otherwise be unable to afford care. Following these rewarding experiences, and recognizing the benefit of this device, they were committed to offering this device to their patients here in Sacramento as soon as possible. Once available in February, Sacramento Eye Consultants was one of the first practices to offer this service in the United States. The biggest challenge with the Xen Gel Stent, as with all new devices, is that insurance coverage is minimal at this point. In spite of this, reception of the device has been enthusiastic and early results have been rewarding.

Glaucoma has traditionally been a challenging disease with difficult treatment options. Fortunately, with recent advancements, treatment has become less invasive while improving efficacy. Finally the glaucoma treatment gap that has existed for so long seems to be narrowing.

**RESEARCH UPDATE**

**Glaucoma and Dry Eye Studies:** Currently we are enrolling for a 20 month glaucoma study. We are also enrolling patients with dry eyes for a 4 week study. Both are conducted at our Sacramento office.

Looking forward, we are gearing up for another glaucoma study as well as a cataract study later this year.

If you are interested in finding out more information, please contact: Jaime or Alice at 916-649-1515 or jaimep@saceye.com or alicem@saceye.com.
**FDA APPROVAL AND INSURANCE AUTHORIZATION: A DISCONNECT**

By Richard Lewis MD

Many patients schedule an office visit after hearing that a new treatment has been FDA approved. There is excitement about new technology and new therapeutic approaches to their eye problems. Patients may be aware of the lengthy and rigorous process, including several phases of clinical trials, required to prove safety and effectiveness of this new medication or surgery for a specific indication or problem. These trials are conducted in multiple offices throughout the country and can involve thousands of patients and millions of dollars over a number of years before the FDA will give their seal of approval. The FDA does a very good job of insuring safety of a treatment before releasing it on the market.

Yet, when a patient requests access to new therapy, there is one final hurdle we must cross before we can prescribe. This is the challenge of insurance coverage. There is a lag between FDA approval of a new therapy and insurance authorization. This may be just a few months, but more often it is several years before insurance companies will approve coverage. This lag has to do with the medical review board of each specific insurance company agreeing that the new procedure is safe, effective, and equal to or better than existing therapy. Their basis for approving new technology often depends on sufficient evidence from clinical trials. The requirement for published evidence, the insurance companies will deny coverage. Of course, the patient could pay in cash, but many of us feel that our insurance premiums should cover non-experimental, FDA-approved treatments. Patients and doctors are both frustrated, as the latest and possibly most effective, treatments cannot receive insurance authorization. Patient appeals to the Insurance Commissioner of the State of California may help, but all of this is quite lengthy and may delay treatment.

Our office seeks prior authorization for every surgery. When it is denied, our only option is to use older technology or ask the patient to guarantee payment, or another method, called an ABN (Advanced Beneficiary Notice). Neither of these options are ideal, but that is the disconnect between FDA Approval and insurance authorization.

**NEUROSTIMULATION: A NEW TREATMENT OPTION FOR DRY EYE DISEASE**

By Samuel Lee, MD

Dry Eye Disease is currently treated in a variety of ways including artificial tears, warm compresses, punctal plugs, prescription eye drops, and a number of other methods. Many people would agree that the way we currently treat this disease is limited, with millions of people suffering with their symptoms each day.

In 2010, Michael Ackermann, PhD, began a biodesign fellowship at Stanford University with the task to observe in the field of ophthalmology and to look for an opportunity to improve on a currently unmet clinical need. He quickly came to the conclusion that we are not offering adequate care to our dry eye patients, and decided to look for a way to improve upon tear production. This led him to look into neurostimulation as a method to stimulate tear production from the lacrimal nerve. Neurostimulation is widely used in neurology as a way to stimulate the nerves that are causing chronic pain. A Transcutaneous Electrical Nerve Stimulation (TENS) unit is a neurostimulator that works by sending stimulating pulses across the skin to the nerve in order to prevent pain signals from reaching the brain. Adapting this principle with an understanding of the neural pathways that are involved in stimulating tear production, Ackermann and his team sought to stimulate a branch of the trigeminal nerve in the nasal cavity in order to stimulate tear production.

Ackermann’s company Oculeve has developed a neurostimulator which is inserted into the nasal passage upon use to stimulate a nerve for tear production. Our office is very familiar with this device, as we were part of the original clinical trials to prove efficacy and safety. Ackermann’s company was acquired by Allergan in 2015 and FDA approved the device April 24, 2017. The neurostimulator is now being branded as TrueTear and offers patients the opportunity to use this device between two and ten times per day, for symptoms of dry eye. Patients will soon be able to order this device through a handful of select offices, including Sacramento Eye Consultants.

Dr. Lewis moderating a panel on FDA policies at Glaucoma 360 in San Francisco Jan 2017.
INTRODUCING MODERN CATARACT SURGERY TO THE
OPHTHALMOLOGY TRAINING PROGRAM IN HONDURAS

By Patricia Sierra, MD

Give a man a fish, you feed him for a day. Teach a man to fish, you feed him for a lifetime." This famous Chinese proverb reminds us of the importance of sharing our knowledge with others.

Modern cataract surgery usually can restore vision lost to a cataract (a clouding of the natural lens inside the eye) with recovery of good vision within a few days or weeks. The procedure, called phacoemulsification or “phaco,” involves the use of a high-frequency ultrasound that gently removes the cloudy lens in an effective and efficient manner. This procedure is performed through smaller incisions than previous surgical techniques for cataract removal, promoting faster healing and reducing the risk of cataract surgery complications.

Unfortunately, in certain parts of the world, modern cataract surgery techniques are not available to patients with cataracts due to the high cost of the surgical equipment required to perform phacoemulsification.

Honduras is a very small and poor country in Central America. It is also the country in which I was born and raised. During my trips back to Honduras, I became aware that the technique of phacoemulsification was not part of the training program curriculum at the only residency training program for eye doctors.

With the help of a team of US surgeons and donations from our local ophthalmology call group, SEE International (a charity organization that promotes surgical missions around the world) and Mercy General Hospital, we were able to put together an expedition to Honduras. This mission provided the necessary supplies and equipment required to start performing phacoemulsification surgery at the Honduran ophthalmology residency program. Surgical training was provided to the faculty and residents to help them develop the skills necessary to perform modern cataract surgery.

Sacramento Eye Consultants have been performing collagen crosslinking for progressive corneal weakening related to keratoconus and post-LASIK ectasia since FDA approval of the Avedro KXL crosslinking unit last summer. We were also instrumental in the clinical trial to help obtain FDA approval for this device in the US. The procedure takes approximately 1 hour and is an office-based procedure done to help strengthen the cornea to help reduce progression of the disease. Collagen Crosslinking is an important part of keratoconus management, and gives us hope that one day we can eliminate or at least drastically reduce the need for corneal transplantation for keratoconus in the future.

Meet Our New Staff Members!

We are very pleased to welcome new staff members Connie (left) and Mercedes (below).

Please say ‘hello’ the next time you are in the office.
NEW LOCATION!

Drs. Brubaker, Lee, and Sierra are now seeing patients at our new location in Lincoln.

Conveniently located at:
845 Twelve Bridges Drive, Suite 130
Lincoln, CA 95648

For an appointment, call us at
(916) 649-1515