Refractive editor’s corner of the world
SMILE uses femtosecond laser for corneal refractive procedure

by Ellen Stodola EyeWorld Staff Writer

The SMILE technique is a new method used with the VisuMax 500 kHZ femtosecond laser (Carl Zeiss Meditec, Jena, Germany) that provides lenticule extraction without creating a LASIK flap. John Doane, MD, Discover Vision Centers, Kansas City, Kan.; and Vance Thompson, MD, Vance Thompson Vision, Sioux Falls, S.D., discussed the procedure, the FDA-monitored trial, and some advantages and disadvantages.

What is the SMILE procedure?

The acronym SMILE stands for small incision lenticule extraction. “Instead of creating a flap, we make a lenticule of tissue within the stroma with an anterior and posterior pass of the femtosecond laser to create a three dimensional piece of tissue that is manually removed through a 2-3 mm or 60 degree incision at the 7.5 mm optical zone,” Dr. Doane said. “The SMILE technique is a ‘new age twist’ on a previous corneal refractive concept that has been utilized in the past but abandoned due to better techniques, specifically excimer laser refractive procedures.”

The “new age twist” that Dr. Doane referred to is the use of the femtosecond laser in this technique, and the “corneal refractive concept” is the removal of a convex-shaped lenticule of tissue from within the corneal stroma to flatten the central cornea and reduce myopia. SMILE requires certain characteristics of the femtosecond laser for it to work correctly. Dr. Doane said the laser needs to have a high numerical aperture. This means the x, y, and z spot placement of photodisruption must be exquisite, he said.

“If this is achieved, near perfect depth placement of contiguous spots can occur at the lowest single spot energy, and thus excimer laser-like refractive precision can be achieved.” This is a tall order for a femtosecond delivery system, he said.

Where do we stand in the FDA trials?

SMILE is being studied in the U.S. at 5 centers. In addition to Dr. Thompson and Dr. Doane, the investigational centers are with William Culbertson, MD, and Sonia Yoo, MD, Miami; John Vukich, MD, Madison, Wis.; and Jon Dishler, MD, Greenwood Village, Colo.

“Patients enrolled in the study have spherical myopia in the range of −1 to −10 D and up to −0.50 D cylinder, although cylinder is not being treated,” Dr. Thompson said. SMILE is performed in one eye, and the non-study eye is treated with LASIK.

“We have been impressed with the accuracy of the SMILE procedure,” he said. Preliminary clinical trial results were presented at the 2014 ASCRS•ASOA Symposium & Congress, representing data from 315 eyes. So far, refractive predictability has been impressive in the study. Some risks identified were loss of suction and difficult lenticule removal without tissue loss with retained tissue. The enrollment goal in the clinical trial is 340 eyes, Dr. Thompson said.

Advantages of SMILE

Dr. Thompson said that the option of being able to do an intrastromal procedure in one step without a flap is exciting. “In general we have the same visual and refractive results as LASIK, but our experience and the literature support less dry eye and improved corneal sensation with the SMILE procedure,” he said. The possibility of improved biomechanics is another advantage. “The incision through the epithelium, Bowman’s, and the underlying stroma is much smaller compared to the size of the side-cut incision made during LASIK, and thus subsequent foreign body sensation is minimal and transient with the SMILE
procedure,” he said. The photodisruption with SMILE is also advantageous, Dr. Doane said. “The glaring difference between femtosecond laser photodisruption and excimer laser refractive procedures is that with excimer laser techniques, the cornea stroma being treated is exposed to the environment of open air, so relative humidity, the speed with which the procedure is completed, temperature, barometric pressure, and air purity that the excimer laser beam are exposed to can vary from case to case, surgeon to surgeon, and locale to locale,” he said.

With the SMILE technique because the photodisruption is done in a relative vacuum intrastromally within the cornea and the epithelium is not disrupted, the environmental factors will not impact outcomes. “This is a significant factor in moderate and higher myopic treatments,” Dr. Doane said.

Disadvantages of SMILE

As this is a new procedure, there are still some issues that need to be worked out. Dr. Doane said that the exact range of the technique is not currently known, and it is uncertain if compound myopic astigmatism, mixed astigmatism, and simple or compound hyperopic astigmatism can all be treated.

Another issue is how to enhance patients undergoing this technique if that need arises. “At present we are left with creating a LASIK flap by extension of the small incision of SMILE and reflecting the flap and ablating with an excimer laser in a LASIK-like retreatment, or we have to do PRK,” he said.

When compared with LASIK, the visual recovery after SMILE is slightly slower, Dr. Thompson said. Additionally, the lenticule extraction requires the surgeon to be comfortable with lamellar corneal dissection, so this means there would be a learning curve. “Like any surgery there are risks,” he said. “When dissecting in a lamellar fashion, if the surgeon is too aggressive or if there is an undiagnosed corneal scar, a cap perforation can occur in the SMILE procedure just like a flap perforation can occur in LASIK.”

Does SMILE have the potential to replace LASIK?

Dr. Doane thinks that SMILE has the potential to replace or compete commercially with LASIK “for simple and compound myopia of all ranges that is suitable for corneal refractive surgery.” The technique has great predictability for both higher and lower corrections.

“As of February 2014, more than 100,000 SMILE procedures have been performed worldwide and more than 300 surgeons are certified,” Dr. Doane said. Despite hesitation and skepticism early on, he thinks that SMILE is now an accepted contender in refractive surgery in the U.S.

Dr. Thompson thinks that the SMILE procedure has the potential to help numerous patients. “I predict that, like PRK and LASIK, we will find the best refractive errors and corneas to treat and that all 3 will coexist as options for patients who desire to lessen their dependency on optical devices,” he said. “The SMILE procedure is an exciting new procedure and like anything new, it deserves critical study and long-term follow-up. The early results have been very promising.”

Editors’ note: Drs. Doane and Thompson have financial interests with Carl Zeiss Meditec.

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