A
cross the globe, laser vision correction super-
seded incisional keratotomy as the dominant
form of corneal refractive surgery in the first half
of the 1990s. Since then, more than 34 million
eyes have undergone excimer laser vision correction (PRK,
LASIK, LASEK) worldwide.\(^1\) During my almost 20 years of
performing LASIK, internal surveys at my practice have
found that 99% of patients are happy with their result,
would have the procedure again, and would recommend
it to friends and family. More objectively, a March 2008
meta-analysis by the American Society of Cataract and
Refractive Surgery of 2,915 peer-reviewed articles pub-
lished during a 10-year period found a 95.4% rate of satis-
faction among LASIK patients worldwide.\(^2\)

Never complacent, refractive surgeons seek better pro-
cedures with a lower incidence of complications, fewer
side effects, and lower retreatment rates. Such an advance
may be imminent with the all-femtosecond-laser corneal
refractive surgery developed by Carl Zeiss Meditec and
dubbed SMILE (small-incision lenticule extraction; not
approved in the United States).

THE PROCEDURE

SMILE differs from LASIK in that an excimer laser is not
used to sculpt tissue and no photoablation is performed. Instead, the surgeon creates a lenticule of tissue with
a femtosecond laser and manually removes the tissue
through a short, arc-length incision. The lenticule is equi-

alent to the predicted shape of the Munnerlynn formula
ablation profile of the excimer laser.

The VisuMax laser (Carl Zeiss Meditec) creates a three-
dimensional refractive lenticule for myopic spherical and
compound myopic spherical treatments ranging from
1.00 to more than 10.00 D of myopia and up to 5.00 D
of astigmatism. The small-incision part of procedure’s
name refers to the replacement of a
270º flap with a 30º to 60º incision
through which the surgeon accesses
the intrastromal pocket and removes
the lenticule. The outer diameter of a
typical lenticule is 6.5 mm. The cap of
the entire pocket is 120 µm through-
out. The posterior surface of the lenticule is convex and
determined by the dioptic power treated. The greater the
myopia, the thicker the lenticule or more convex its poste-
rior surface for myopic treatments. The outer dimension of
the pocket is 7.5 mm, so the distance from the edge of the
lenticule to the periphery of the pocket is exactly 0.5 mm
for 360º, which provides room for the lenticule’s removal.

BENEFITS

The first and most obvious benefit of SMILE versus
LASIK is the avoidance of flap-related complications such
as slippage. No flap is created, Bowman layer is minimally
violated, and less anterior stroma is incised. For these
reasons, SMILE theoretically preserves the most biome-
chanically significant anterior one-third of the cornea, thus
maximizing corneal tensile strength. Greater preservation
of the anterior cornea with lesser interruption of the cor-
neal nerves may also mean fewer complaints of dry eye
from neurotropia after SMILE versus LASIK.

A unique feature of SMILE is that it is basically complet-
ed in a vacuum (ie, intrastromally). In contrast, the excimer
laser beam must traverse the final lens in the optical train
and pass through air to the corneal surface. During LASIK,
therefore, the room’s environment (eg, air purity, humid-
ity, barometric pressure, and temperature) affects the
laser’s photoablative ability and the amount of dry cornea
removed with each pulse of energy. The environment’s

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During a SMILE procedure, the closed environment of an intact cornea coupled to the femtosecond laser with a patient interface avoids this variability. This explains why a -10.00 D treatment is just as predictable as a -1.00 D diopter SMILE treatment (FDA data on file with Zeiss). In my experience, a -1.00 D SMILE procedure is as predictable as a -1.00 D excimer laser correction.

**MARKETPLACE**

Can SMILE compete with LASIK? In 1996, I wrote an article, “The Tenets of Refractive Surgery.” In it, I discussed the characteristics of the “ideal” refractive surgery procedure. The key points were (and remain) predictability, effectiveness, stability of the result, safety, and quality of vision. Lesser attributes included reversibility/adjustability, minimal wound healing, immediacy of the final refractive outcome, an ability to meet patients’ and providers’ expectations, and equivalence or superiority to glasses or contact lenses. LASIK meets these criteria better than any procedure that predates it. Can SMILE compete? Procedural counts may provide an indication. In 2009, 200 SMILE procedures were performed worldwide. The number climbed to 20,000 by December 2012, to 50,000 by the end of July 2013, and to 80,000 by December 2013.

**STATUS**

The US FDA clinical trial of SMILE is underway at five sites. The spherical myopia study will involve treatment of 340 eyes. Enrollment is expected to be complete in June 2014. Approval of the procedure could occur between 2016 and 2018. Laser vision correction, particularly LASIK, remains the king of the refractive jungle, but in the not-too-distant future, it could be challenged by SMILE. The outcome? As the late Charles Kelman, MD, said, “While doctors debate, patients decide.”

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