

## Small Incision Lenticule Extraction (SMILE) in 2015

Dan Z Reinstein, MD, MA(Cantab), FRCSC, DABO, FRCOphth, FEBO

Medical Director, London Vision Clinic, London, UK; Clinical Professor of Ophthalmology, Department of Ophthalmology, Columbia University Medical Center, New York, NY, US; Clinical Professor of Ophthalmology, Centre Hospitalier National d'Ophthalmologie, Paris, France

### Abstract

Following the early work by Sekundo et al. and Shah et al., small incision lenticule extraction (SMILE) using the VisuMax femtosecond laser (Carl Zeiss Meditec) has become increasingly popular. The accuracy of the lenticule dimensions has been verified using very-high-frequency digital ultrasound and optical coherence tomography. Visual and refractive outcomes and safety have been shown to be similar to LASIK. A number of studies have demonstrated a lower reduction and faster recovery of corneal sensitivity and subbasal nerve fiber density after SMILE than LASIK, as expected since the anterior stroma is disturbed only by the small incision. The potential biomechanical advantages of SMILE have been modeled based on the nonlinearity of tensile strength through the stroma. Extraction of an intact lenticule has also given rise to new applications such as cryopreservation of the lenticule for later reimplantation, and a new procedure, endokeratophakia, in which a myopic SMILE lenticule is implanted into a hyperopic patient.

### Keywords

Small incision lenticule extraction (SMILE), femtosecond laser, keyhole, flapless procedure

**Disclosure:** Dan Z Reinstein, MD, MA(Cantab), FRCSC, DABO, FRCOphth, FEBO, is a consultant for Carl Zeiss Meditec (Jena, Germany) and has a proprietary interest in the Artemis technology (ArcScan Inc, Morrison, Colorado) and is an author of patents related to VHF digital ultrasound administered by the Cornell Center for Technology Enterprise and Commercialization (CCTEC), Ithaca, New York. No funding was received in the publication of this article.

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**Received:** January 4, 2015 **Accepted:** January 8, 2015 **Citation:** *US Ophthalmic Review*, 2015;8(1):30–2 DOI: 10.17925/USOR.2015.8.1.30

**Correspondence:** Dan Z Reinstein, MD, MA(Cantab), FRCSC, DABO, FRCOphth, FEBO, London Vision Clinic, 138 Harley Street, London W1G 7LA, UK. E: [dzr@londonvisionclinic.com](mailto:dzr@londonvisionclinic.com)

Ever since femtosecond lasers were first introduced into refractive surgery, the ultimate goal has been to create an intrastromal lenticule that can then be removed in one piece manually, thereby circumventing the need for incremental photoablation by an excimer laser. This was achieved in 2005, presented at the American Academy of Ophthalmology (AAO) meeting in Las Vegas in 2006, and published in 2008 with the Femtosecond Lenticule Extraction procedure (FLEX) in which a lenticule was manually removed after lifting a flap,<sup>1</sup> 11 years after this had first been demonstrated in rabbit eyes with a picosecond laser.<sup>2</sup> Following the successful implementation of FLEX, a new procedure called small incision lenticule extraction (SMILE) was developed; an all-femtosecond laser, keyhole, flapless procedure that is in the process of revolutionizing corneal refractive surgery and realizing Jose Ignacio Barraquer's original concept of keratomileusis.<sup>3,4</sup>

The SMILE procedure is gaining popularity following the results of the first prospective trials<sup>5–7</sup> and more recent reports that have demonstrated that the visual and refractive outcome is similar to laser *in situ* keratomileusis (LASIK),<sup>8–18</sup> and there have now been over 140,000 procedures performed worldwide with more than 300 surgeons regularly doing SMILE. The feasibility of the procedure has been proved by studies on the surface

quality of the lenticules,<sup>19,20</sup> wound healing and inflammation,<sup>21–23</sup> and the accuracy of the lenticule thickness parameters have been verified using very-high-frequency digital ultrasound<sup>24,25</sup> and optical coherence tomography (OCT).<sup>26–29</sup>

The safety has also been demonstrated to be similar to LASIK<sup>30</sup> and our recent publication has shown that there are no concerns in treating patients with SMILE for low myopia.<sup>17</sup>

In terms of safety, SMILE also brings two advantages over LASIK, relevant to the most common complication: dry eye, and the most serious complication: ectasia. Both of these advantages stem from the minimally invasive pocket incision nature of the procedure as this results in maximal retention of anterior corneal innervation as well as structural integrity.

It was expected that there would be less postoperative dry eye after SMILE. While the trunk nerves that ascend into the epithelial layer within the diameter of the cap will continue to be severed in SMILE, those that ascend outside the cap diameter, or that are anterior to the cap interface will be spared. A number of studies have demonstrated a lower reduction and faster recovery of corneal sensitivity after SMILE than LASIK,<sup>31–39</sup>

with recovery to baseline after 3–6 months after SMILE compared with 6–12 months after LASIK. Some studies have also used confocal microscopy to demonstrate a lower decrease in sub-basal nerve fiber density after SMILE than LASIK.<sup>34,38,40</sup>

The other major advantage of SMILE is the biomechanical profile as the anterior stroma above the lenticule remains uncut (except in the location of the small incision), unlike in LASIK where anterior stromal lamellae are severed by the creation of the flap. It has been shown that the vertical sidecut of a flap is responsible for almost all of the change in strain due to LASIK flap creation.<sup>41</sup> It has also been shown that the anterior corneal stroma is the strongest part of the stroma,<sup>42–45</sup> due to the greater interconnectivity of collagen fibers in the anterior stroma compared with the posterior stroma where the collagen fibers lie in parallel to each other.<sup>46</sup> Therefore, SMILE must leave the cornea with greater biomechanical strength than LASIK for the same amount of vision-correcting tissue removal. Not surprisingly, therefore, using a mathematical model based on the nonlinearity of tensile strength through the stroma, we have shown that SMILE leaves greater biomechanical strength even than photorefractive keratectomy (PRK) for the same amount of vision correcting tissue removal, as PRK involves ablating within the strongest anterior stroma.<sup>47</sup> Surgeons are accustomed to calculating the residual stromal thickness in LASIK as the amount of stromal tissue left under the flap, and therefore the first instinct is to apply this rule to SMILE. However, for the reasons given above, the actual residual stromal thickness in SMILE should be calculated as the total uncut stroma (i.e., the stroma above and below the lenticule). This biomechanically allows for much higher corrections to be achieved by SMILE than either LASIK or PRK.

Efforts to measure the biomechanical difference have been mixed, however, this is probably due to the difficulty of measuring this *in vivo*. Out of five studies where the ocular response analyzer (Reichert Inc., Depew, NY) was used, two contralateral eye studies reported that corneal hysteresis (CH) and corneal resistance factor (CRF) were slightly greater after SMILE than LASIK,<sup>48,49</sup> while three other studies reported no difference in either CH or CRF between the SMILE and LASIK groups.<sup>27,50,51</sup> However, it is likely that CH and CRF are not ideal parameters for measuring corneal biomechanics given that many studies show no change in CH and CRF after crosslinking.<sup>52</sup> Similar results have been reported using the CorVis ST tonometer (Oculus Optikgeräte GmbH, Wetzlar, Germany) with two studies finding no difference between SMILE and LASIK groups.<sup>53,54</sup> Meanwhile, Mastropasqua et al.<sup>55</sup> showed that after an initial increase, as expected due to tissue removal, the CorVis measurements were stable over the 3-month follow-up period.

Other evidence for biomechanical differences is that there is less induction of spherical aberration after SMILE compared with LASIK. In a recent study, we found that SMILE, though minimally aspheric, produced similar spherical aberration induction to the highly aspherically optimized laser blended vision profile.<sup>56</sup> However, as the ablation depth was lower for SMILE, the optical zone could be increased meaning that less spherical aberration was induced for equivalent tissue removal, thus improving the optical quality for the patient. These results are similar to other published studies: two studies have shown that there are fewer aberrations induced by SMILE than LASIK,<sup>13,14</sup> and one study showed that induction of aberrations was similar.<sup>12</sup>

The main disadvantage of SMILE currently is the slightly slower visual recovery experienced by some patients compared with LASIK: the day 1 visual acuity is on average slightly lower than LASIK.<sup>8</sup> However, significant improvements have been made in this area by using different energy and spot spacing settings<sup>57</sup> and the difference is now more like one or two lines difference in uncorrected distance visual acuity on postop day 1, equalizing by 2–3 weeks postoperatively.

One study described microdistortions in Bowman's layer after SMILE<sup>58</sup> identified by OCT, but with no clinically significant corneal striae at the slit-lamp. However, these microdistortions did not have an impact on visual acuity or quality. We have studied these central microdistortions and found that they can be minimized by appropriate centrifugal cap distension immediately at the end of the procedure to distribute redundant cap to the periphery.

Another aspect of SMILE that was thought to be a factor when compared with LASIK was that of enabling good centration, due to the absence of eye tracking. However studies have shown this to be in fact incorrect: the centration of SMILE is actually very straightforward and virtually takes care of itself. At the moment of contact between the individually calibrated curved contact glass and the cornea, a meniscus tear film appears, at which point the patient is able to see the fixation target very clearly—because the vergence of the fixation beam is focused according to the patient's refraction. At this point, the surgeon instructs the patient to look directly at the green light and once in position, the corneal suction ports are activated to fixate the eye in this position. In this way, the patient essentially autocentrates the visual axis and hence the corneal vertex to the vertex of the contact glass, which is centered to the laser system and the center of the lenticule to be created. We confirm centration accuracy by comparing the relative positions of the fixation light to the pupil border to the printed placido eye image which we post directly above the microscope. Using this technique, centration of SMILE has been shown to be similar to that achieved with LASIK using a modern eye tracker.<sup>59,60</sup>

The ability to surgically extract an intact refractive lenticule of stromal tissue using the SMILE procedure has opened up a number of further possible applications. It has been demonstrated that refractive lenticules can be cryopreserved successfully for 1 month in rabbits<sup>61,62</sup> and as long as 5–6 months in humans.<sup>63</sup> It has been suggested that these lenticules could be re-implanted as a method for restoring tissue in ectatic corneas, or provide an opportunity for reversing the myopic correction in a patient progressing to presbyopia,<sup>61,62</sup> and successful re-implantation was first demonstrated in rabbits.<sup>62</sup>

Alternatively, there is also the potential for implanting an allogenic lenticule obtained from a myopic donor patient into a hyperopic patient to correct the hyperopia, as originally proposed by Barraquer in 1980.<sup>4</sup> The first case of this endokeratophakia procedure was performed in 2012<sup>64</sup> and a series of nine eyes has also been reported.<sup>65</sup> Feasibility of the procedure has been demonstrated as corneal clarity was maintained, however, unintended posterior surface changes resulted in undercorrection of the effect.

Meanwhile, progress is being made on extending this technique to hyperopia with prospective studies currently running at the University of Marburg, Germany, under Professor Walter Sekundo using FLEX,<sup>65</sup> and at

the Tilganga Institute of Ophthalmology, Nepal, under Dr Kishore Pradhan and my group using SMILE,<sup>66</sup> with encouraging results.

The evolution of SMILE, a flapless intrastromal keyhole keratomileusis procedure, has introduced a new, minimally invasive method for corneal

refractive surgery. The visual and refractive outcomes of the procedure have been shown to be similar to LASIK, while there is increasing evidence for the benefits of SMILE over LASIK by leaving the anterior stroma intact including superior biomechanics and faster recovery of dry eye and corneal nerve reinnervation. ■

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