Refractive surgery: Is the new small-incision lenticule extraction (SMILE) technique equal to or better than the standard flap-and-ablation (FS-LASIK) technique for treating high-degree myopia?

Hansen, Rasmus Søgaard; Lyhne, Niels; Grauslund, Jakob; Vestergaard, Anders Højslet

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Eye Surgery for Nearsightedness: Small-incision lenticule extraction (SMILE) vs. Femtosecond laser in situ keratomileusis (FS-LASIK)

Rasmus Søgaard Hansen, Niels Lyhne, Jakob Grauslund, Anders Hojslet Vestergaard
Department of Ophthalmology, Odense University Hospital & Institute of Clinical Research, University of Southern Denmark, Odense, Denmark

Introduction
Corneal laser surgery for myopia (nearsightedness) is increasingly popular and among the most performed surgical procedures today. For almost two decades LASIK has been the most widely used surgical technique for treating myopia, but a shift to the new less invasive SMILE technique might be underway. SMILE is proven efficient and safe for correction of myopia and low degrees of astigmatism. However, the literature is still sparse, especially for high degrees of myopia (Spherical equivalent (SE) refraction of -6.00 diopters (D) or more).

Objective
The aim of this study was to evaluate and compare accuracy, efficacy, visual acuity, safety and refraction up to 3 months after surgery with SMILE or FS-LASIK for high degrees of myopia and low degrees of astigmatism.

Method
Retrospective study of all eyes treated with SMILE or FS-LASIK for high degrees of myopia and low degrees of astigmatism from 2011 to 2013 at the Department of Ophthalmology, Odense University Hospital, Odense, Denmark.

Inclusion criteria: Best spectacle-corrected visual acuity (BSCVA) of 20/25 or better on Snellen chart before surgery, and no other ocular conditions than high degree myopia with or without astigmatism of maximum 3 D. Exclusion criteria: Eyes having undergone re-treatment.

Clinical examinations were performed pre-operatively and at 1 day, 1 week and 3 months post-operatively.

Results
In total, 545 SMILE eyes and 254 FS-LASIK eyes were included and analyzed.

Accuracy: After 3 months, 80% of SMILE eyes and 71% of FS-LASIK eyes (P=0.38) were within 0.50 D of attempted post-operative refraction, whilst 96% of SMILE eyes and 90% of FS-LASIK eyes (P=0.54) were within 1.00 D.

Efficacy: In 180 eyes the attempted post-operative refraction was 0 D. Of these, 69% of SMILE eyes and 83% of FS-LASIK eyes (P=0.55) had an uncorrected distance visual acuity (UDVA) of 20/25 or better at 1 day post-operatively. After 3 months, the results were 95% for SMILE eyes and 81% for FS-LASIK eyes (P=0.73). Moreover, the average UDVA was -0.03 ±0.09 (logMAR) in SMILE eyes and 0.04 ±0.15 (logMAR) in FS-LASIK eyes (P=0.05) after 3 months.

Visual acuity and safety: The percentage of eyes with BSCVA of 20/20 or better was unchanged after both procedures. In total, 2% (n=13) of SMILE eyes and 1% (n=2) of FS-LASIK eyes (P=0.17) had regained 2 or more lines of BSCVA after 3 months, whilst 0.2% (n=1) of SMILE eyes and no FS-LASIK eyes (P=1.00) had lost 2 or more lines of BSCVA. No flap or cap complications were reported.

Refraction: After 3 months, 89% of SMILE eyes and 76% of FS-LASIK eyes (P=0.17) had an SE refraction of -1.00 D or better. Before surgery, 76% of SMILE eyes had astigmatism of 1.0 D or less, and 96% after 3 months (P<0.05). For LASIK it was 68% before surgery, and 96% after 3 months (P<0.05).

Conclusion
Both FS-LASIK and SMILE was accurate, efficient and safe in treating high degrees of myopia and low degrees of astigmatism, and results was overall comparable up to 3 months after surgery.

Table 1: Baseline characteristics and outcomes 3 months after surgery. All values are average standard deviation (range).

<table>
<thead>
<tr>
<th>Measure</th>
<th>SMILE</th>
<th>LASIK</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>BSCVA (logMAR)</td>
<td>-0.04 to 0.05</td>
<td>-0.01 to 0.06</td>
<td>&lt;0.05*</td>
</tr>
<tr>
<td>SE (D)</td>
<td>-7.7 ±1.4</td>
<td>-7.9 ±1.7</td>
<td>0.22</td>
</tr>
<tr>
<td>SE attempted (D)</td>
<td>-0.6 ±0.6</td>
<td>-0.5 ±1.0</td>
<td>0.78</td>
</tr>
<tr>
<td>FS difference</td>
<td>0.2 ±0.5</td>
<td>-0.2 ±0.7</td>
<td>&lt;0.05*</td>
</tr>
</tbody>
</table>

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For all authors, None.