PURPOSE: To compare small incision lenticule extraction (SMILE) versus LASIK for post-refractive dry eye disease.

DESIGN: Prospective, comparative, nonrandomized clinical study.

PARTICIPANTS: Thirty patients scheduled for bilateral myopic SMILE and 30 age-, sex-, and refraction-matched patients scheduled for bilateral myopic LASIK were enrolled and followed for 6 months after the surgery.

METHODS: Complete evaluation of dry eye disease was performed at 1 and 6 months postoperatively, which included vision-related quality of life (Ocular Surface Disease Index [OSDI]), clinical examinations (tear film breakup time [TBUT], Schirmer I test, corneal staining), and tear osmolarity measurements, together with an overall severity score. Function and morphology of the corneal innervation were evaluated by corneal esthesiometry and subbasal nerve imaging using in vivo confocal microscopy (IVCM).

MAIN OUTCOME MEASURES: Overall analysis of dry eye disease and corneal innervation.

RESULTS: High incidence of mild to moderate dry eye disease was observed in both groups 1 month postoperatively, which remained significantly higher in the LASIK group than in the SMILE group 6 months after surgery (overall severity score [0-4]: 1.2±1.1 vs. 0.2±0.4, respectively, P < 0.01), leading to more frequent use of tear substitutes over the long term. Corneal sensitivity was better in SMILE than in LASIK eyes 1 month postoperatively (3.5±1.79 vs. 2.45±2.48, respectively, P < 0.01) and then recovered to statistically similar values at 6 months. Corneal nerve density, number of long fibers, and branchings as assessed by IVCM were significantly higher in the SMILE group compared with the LASIK group 1 and 6 months after surgery. Corneal sensitivity was negatively correlated with dry eye-related corneal damage (R² = 0.48, P < 0.01), and the long fiber nerve density was independently correlated with the OSDI score (R² = 0.50, P < 0.01) and the Schirmer test (R² = 0.21, P < 0.01) 6 months postoperatively.

CONCLUSIONS: The SMILE procedure has a less pronounced impact on the ocular surface and corneal innervation compared with LASIK, further reducing the incidence of dry eye disease and subsequent degradation in quality of life after refractive surgery.