

# Evaluation of a New Laser Refractive Vision Correction Using the TENEOTM 317 Model 2

NCT06997003

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Bausch & Lomb GmbH
Enrollment	81 participants

## Key Eligibility Criteria

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### Inclusion (13)

- Subjects already scheduled for bilateral refractive laser surgery targeting emmetropia (attempted MRSE is between and including -0.50 D and +0.50 D).
- Minimum 18 years of age.
- Have read, understood, and signed an informed consent form (ICF).
- Have a stable refraction (i.e., a change of d 0.50 D in sphere and cylinder) for both eyes as judged by the investigator.
- Have less than 0.75 D spherical equivalent (SE) difference between cycloplegic and manifest refractions at preoperative visit for both eyes.

... and 8 more (see full listing online)

### Exclusion (17)

- Subjects for whom the combination of their baseline corneal thickness and the planned operative parameters for the LASIK procedure would result in less than 250 microns residual stroma thickness in any eye.
- Tear Break-Up time (TBUT)  $\leq$  8 s in any eye.
- Mesopic pupil size larger than the optical zone of the planned treatment for any eye.
- History or evidence of active or inactive of corneal disease or infection in either eye (e.g., herpes simplex keratitis, herpes zoster keratitis, recurrent erosion syndrome, corneal dystrophy, etc.).
- Central corneal scars affecting visual acuity or unstable keratometry with irregular mires in any eye.

... and 12 more (see full listing online)

## Locations (1 total)

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Site 01, Zlín, Czech Republic, Czechia