SMILE Clinical Compendium
Peer-reviewed journal articles
Contents

Introduction of SMILE technology

Clinical advantages of SMILE
- Corneal sensitivity and dry eye
- Nerve fibre regeneration
- Corneal biomechanical stability
- Higher order aberrations

Visual outcomes
- Myopia
- Low myopia
- Moderate to high myopia
- Myopic astigmatism
- Comparison with LASIK

Treatment parameters
- Cap thickness
- Energy setting
- Laser firing pattern
- Optical zone
- Incision size
- Nomogram

Surgical techniques
- Pocket irrigation
- Alternative surgical techniques
- Rescue instruments

SMILE enhancement

Possible complications
- Safety and complications
- Suction Loss
- Diffuse lamellar keratitis
- SMILE and forme fruste keratoconus

Safety related investigations
- VisuMax laser cut quality and accuracy
- Changes to cornea curvature and power
- Wound healing/inflammatory response
- Effect on endothelial cells
- Effect on the ocular posterior segment
- Centration accuracy

Experimental applications
- SMILE and lenticule re-implantation
- SMILE with collagen cross linking
- SMILE with keratoplasty/keratotomy

Future development
- Hyperopia correction
Introduction of SMILE technology

“The all-femtosecond-based flap-free intracorneal refractive procedure has been documented to be a predictable, efficient, and safe procedure for correction of myopia and astigmatism.”

Jesper Hjortdal, Clinical Professor, Department of Ophthalmology, Aarhus University Hospital, Denmark

“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.”

Dan Z Reinstein, Medical Director, London Vision Clinic, London, UK

Small-incision lenticule extraction.  

Advances in refractive surgery.  

Small Incision Lenticule Extraction (SMILE) in 2015.  
Cornea 2015 Apr, Reinstein DZ

New developments in the lenticule extraction procedure.  
US Ophthalmic Review 2014 Apr, Hjortdal J, Ivarsen A

Small incision lenticule extraction (SMILE) history, fundamentals of a new refractive surgery technique and clinical outcomes.  
Eye and Vision 2014, Reinstein DZ, Archer TJ, Gobbe M

One-year refractive results, contrast sensitivity, high-order aberrations and complications after myopic small-incision lenticule extraction (ReLEx SMILE).  
Graefes Archive for Clinical Experimental Ophthalmology 2014 May, Sekundo W, Gertnere J, Bertelmann T, Solomatin I

Efficacy, safety, predictability, contrast sensitivity, and aberrations after femtosecond laser lenticule extraction.  
Journal of Cataract & Refractive Surgery 2014, Vestergaard AH, Grauslund J, Ivarsen AR, Hjortdal JØ

Femtosecond laser refractive surgery: small incision lenticule extraction vs. femtosecond laser-assisted LASIK.  
Current Opinion in Ophthalmology 2015 July, Lee JK, Chuck RS, Park CY
Clinical advantages of SMILE

Corneal sensitivity and dry eye

“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.”
Denoyer et al, Ophthalmology 2015 Apr

“Dry eye after corneal refractive surgery usually occurs transiently. The SMILE procedure had better dry eye parameters (Schirmer secretion test without anesthesia, tear break-up time) and relatively fewer subjective symptoms (the McMonnies questionnaire) than LASIK.”
Xu et al, Journal of Refractive Surgery 2014 Mar

Dry eye disease after refractive surgery: comparative outcomes of small incision lenticule extraction versus LASIK. Abstract

Dry eye after small incision lenticule extraction and LASIK for myopia. Abstract
Journal of Refractive Surgery 2014 Mar, Xu Y, Yang Y

Comparison of dry eye and corneal sensitivity between Small Incision Lenticule Extraction and femtosecond LASIK for myopia. Full text
PLOS one 2013 Oct, Meiyan Li, Jing Zhao, Yang Shen, Tao Li, Li He, Hailin Xu, Yongfu Yu, and Xingtao Zhou

Corneal sensitivity after small-incision lenticule extraction and laser in situ keratomileusis. Abstract
Journal of Cataract & Refractive Surgery 2015 Aug, Reinstein DZ, Archer TJ, Gobbe M, Bartoli E

Comparison of corneal sensitivity between FS-LASIK and femtosecond lenticule extraction or small-incision lenticule extraction for myopic eyes. Full text
Graefe’s Archive for Clinical and Experimental Ophthalmology 2013 Oct, Wei S, Wang Y

Early outcomes of corneal sensitivity changes after small incision lenticule extraction and femtosecond lenticule extraction. Abstract

Influence of femtosecond lenticule extraction and small incision lenticule extraction on corneal nerve density and ocular surface: A 1-year prospective, confocal, microscopic study. Abstract

Central corneal sensitivity after small incision lenticule extraction versus femtosecond laser-assisted LASIK for myopia: a meta-analysis of comparative studies. Full text
BioMed Central Ophthalmology 2015 April, He M, Huang W, Zhong X
Clinical advantages of SMILE

Nerve fibre regeneration


Confocal comparison of corneal reinnervation after Small Incision Lenticule Extraction (SMILE) and Femtosecond Laser In Situ Keratomileusis (FS-LASIK). Full text PLOS One 2013 Dec, Meiyan Li, Lingling Niu, Bing Qin, Zimei Zhou, Katherine Ni, Qihua Le, Jun Xiang, Anji Wei, Weiping Ma, Xingtao Zhou


Early corneal nerve damage and recovery following small incision lenticule extraction (SMILE) and laser in situ keratomileusis (LASIK). Abstract Investigative Ophthalmology & Vision Science 2014 Mar, Mohamed-Noriega K, Riau AK, Lwin NC, Chaurasia SS, Tan DT, Mehta JS


Subbasal nerve morphology, corneal sensation, and tear film evaluation after refractive femtosecond laser lenticule extraction. Abstract Graefe’s Archive for Clinical Experimental Ophthalmology 2013 Nov, Vestergaard AH, Grønbech KT, Grauslund J, Ivarsen AR, Hjortdal JØ

Corneal biomechanical stability

“Both SMILE and FS-LASIK can cause biomechanical changes in the cornea. However, changes in the cornea’s viscoelastic properties were less after lenticule extraction than after LASIK.” Wu et al, Journal of Cataract & Refractive Surgery 2014 Jun


Mathematical model to compare the relative tensile strength of the cornea after PRK, LASIK, and Small Incision Lenticule Extraction. Abstract Journal of Refractive Surgery 2013 Jul, Reinstein DZ, Archer TJ, Randleman JB
Clinical advantages of SMILE

Higher order aberrations

“ReLEx® SMILE produced satisfactory refractive outcomes with moderate induction of HOA and unaffected contrast sensitivity after 1 year.”
Graefe’s Archive for Clinical Experimental Ophthalmology 2014 Mar

“SMILE and FS-LASIK produced distinct changes in anterior corneal shape evident in different postoperative corneal curvatures and power measurements between the two groups. Postoperative HOAs were much lower after SMILE as compared to FS-LASIK.”
Gyldenkerne et al, Journal of Refractive Surgery 2015 Apr

Aberration compensation between anterior and posterior corneal surfaces after Small incision lenticule extraction and Femtosecond laserassisted laser in-situ keratomileusis
Abstract
Ophthalmic & Physiological Optic 2015 Jun, Li X, Wang Y, Dou R

Comparison of corneal shape changes and aberrations induced by FS-LASIK and SMILE for myopia.
Abstract

One-year refractive results, contrast sensitivity, high-order aberrations and complications after myopic small-incision lenticule extraction (ReLEx SMILE).
Abstract
Graefe’s Archive for Clinical and Experimental Ophthalmology 2014 Mar, Sekundo W, Gertnere J, Bertelmann T, Solomatín I

Statistical characteristics of aberrations of human eyes after small incision lenticule extraction surgery and analysis of visual performance with individual eye model.

Postoperative ocular higher-order aberrations and contrast sensitivity: Femtosecond lenticule extraction versus pseudo small-incision lenticule extraction.
Journal of Cataract & Refractive Surgery 2015 Mar, Tan DK, Tay WT, Chan C, Tan DT, Mehta JS

Optical quality and intraocular scattering after femtosecond laser small incision lenticule extraction.
Visual outcomes

“Small incision lenticule extraction for low myopia was found to be safe and effective with outcomes similar to those previously reported for LASIK.”
Reinstein et al, Journal of Refractive Surgery 2014 Dec

“SMILE is a predictable and safe technique for the surgical correction of moderate to high myopia.”
Albou-Ganem et al, Journal Français D’Ophtalmologie 2015 Mar

Myopia

One-year outcomes of small-incision lenticule extraction (SMILE): mild to moderate myopia vs. high myopia.

One-year results of Small Incision Lenticule Extraction (SMILE) in myopia.
Klinische Monatsblätter für Augenheilkunde 2014 Oct, Kunert KS, Melle J, Sekundo W, Dawczynski J, Blum M

Efficacy, predictability, and safety of small incision lenticule extraction: 6-months prospective cohort study.

Small-Incision Lenticule Extraction for myopia: Results of a 12-month prospective study.
Optometry & Vision Science 2014 Nov, Xu Y, Yang Y

Low myopia

Outcomes of Small Incision Lenticule Extraction (SMILE) in low myopia.
Journal of Refractive Surgery 2014 Dec, Reinstein DZ, Carp G

Moderate to high myopia

SMILE: Refractive lenticule extraction for myopic correction.
Visual outcomes

Myopic astigmatism


Comparison of astigmatic correction after femtosecond lenticule extraction and small incision lenticule extraction for myopic. Full text PLOS One 2015 Apr, Kobashi H, Kamiya K, Ali MA, Igarashi A, Elewa ME, Shimizu K


Comparison with LASIK

“Three-month results demonstrate that refractive accuracy, dry eye, contrast, and induced aberrations are better following SMILE rather than LASIK.” Ganesh et al, Journal of Refractive Surgery 2014 Sep

“SMILE and FS-LASIK are safe, effective, and predictable surgical procedures to treat myopia. SMILE has a lower induction rate of higher-order aberrations and spherical aberration than the FS-LASIK procedure.” Lin et al, Journal of Refractive Surgery 2014 Apr

Comparison of visual and refractive outcomes following femtosecond laser assisted LASIK with SMILE in patients with myopia or myopic astigmatism. Abstract Journal of Refractive Surgery 2014 Sep, Sri Ganesh, Rishika Gupta


Treatment parameters

"Undercorrection of 0.25 D and small effects of patient age and corneal curvature suggest that the standard nomogram for SMILE need only minor adjustments. This study suggests that safety and efficacy are not influenced to any clinically significant degree by easily discernible patient factors."

Hjortdal et al, Journal of Refractive Surgery 2012 Dec

Cap thickness

Conicalateral eye comparison between femtosecond Small Incision Intrastromal Lenticule Extraction at depths of 100 and 160μm.

Abstract


SMILE procedures with four different cap thicknesses for the correction of myopia and myopic astigmatism.

Abstract


Energy setting

Effect of femtosecond laser setting on visual performance after small-incision lenticule extraction for myopia.

Abstract


Laser firing pattern

Effect of different femtosecond laser-firing patterns on collagen disruption during refractive lenticule extraction.

Abstract

Journal of Cataract & Refractive Surgery 2012 Aug, Riau AK, Angunawela RI, Chaurasia SS, Tan DT, Mehta JS

Optical zone

Corneal power distribution and functional optical zone following Small Incision Lenticule Extraction for myopia.

Abstract


Incision size

Two millimeter micro incision lenticule extraction surgery with minimal invasion: a preliminary clinical report.


Nomogram

Predictors for the outcome of Small-incision Lenticule Extraction for myopia.

Abstract


Vector analysis of low to moderate astigmatism with small incision lenticule extraction (SMILE): results of a 1-year follow-up.

Full text


Correction of myopic astigmatism with Small Incision Lenticule Extraction.

Abstract

Surgical techniques

Pocket irrigation

Effect of intraoperative corneal stromal pocket irrigation in Small Incision Lenticule Extraction.  

Alternative surgical techniques

Development of the continuous curvilinear lenticulerrhexis technique for Small Incision Lenticule Extraction.  

Rescue instruments

New instruments for Lenticule Extraction in Small Incision Lenticule Extraction (SMILE).  
PLOS One 2014 Dec, Liu YC, Pujara T, Mehta JS

SMILE enhancement

Preliminary evidence of successful enhancement after a primary SMILE procedure with the sub-cap-lenticule-extraction technique.  

Comparison of four different VisuMax circle patterns for flap creation after Small Incision Lenticule Extraction.  
Journal of Refractive Surgery 2013 Apr, Riau AK, Ang HP, Lwin NC, Chaurasia SS, Tan DT, Mehta JS
Possible complications

“SMILE had acceptable safety. Although 1.5% of eyes had reduced CDVA by 3 months, visual acuity was restored in the long term. Likewise, patient satisfaction was high.”
Ivarsen et al, Ophthalmology 2014

**Safety & complications**

Safety and complications of more than 1500 Small-Incision Lenticule Extraction procedures.  
Ophthalmology 2014, Ivarsen A, Asp S, Hjortdal J

**Suction loss**

Incidence and management of suction loss in refractive lenticule extraction.  
Journal of Cataract & Refractive Surgery 2014 Dec, Chee Wai Wong, Cordelia Chan, Donald Tan, Jodhbir S. Mehta

Implications and management of suction loss during Refractive Lenticule Extraction (ReLEx).  
Journal of Refractive Surgery 2013 Jul, Sharma R, Vaddavalli PK

**SMILE and forme fruste keratoconus**

Corneal ectasia after femtosecond laser-assisted small-incision lenticule extraction in eyes with subclinical keratoconus/forme fruste keratoconus.  
Journal of Cataract & Refractive Surgery 2015 Jul, Remy M, Kohnen T

Bilateral ectasia after femtosecond laser-assisted small-incision lenticule extraction.  
Journal of Cataract & Refractive Surgery 2015 Jun, Mastropasqua L

Corneal ectasia 6.5 months after small-incision lenticule extraction.  

**Diffuse lamellar keratitis**

Diffuse lamellar keratitis after small-incision lenticule extraction.  
“The VisuMax readout lenticule depth was found to be 8μm thicker than the achieved stromal change. This can be partly explained by alignment errors between preoperative and postoperative scans.”
Reinstein et al, Journal of Refractive Surgery 2013 Oct

VisuMax laser cut quality and accuracy

Surface quality of human corneal lenticules after SMILE assessed using environmental scanning electron microscopy. Abstract

Surface quality of human corneal lenticules after femtosecond laser surgery for myopia comparing different laser parameters. Full text
Graefe’s Archive for Clinical and Experimental Ophthalmology 2011 Sep, Kunert KS, Blum M, Duncker GJ, Sietmann R, Heichel J

Accuracy and reproducibility of cap thickness in Small Incision Lenticule Extraction. Abstract
Journal of Refractive Surgery 2013 Oct, Reinstein DZ, Archer TJ, Gobbe M

Accuracy and precision of cap thickness in small incision lenticule extraction. Full text

Lenticule thickness readout for Small Incision Lenticule Extraction compared to Artemis three-dimensional very high-frequency digital ultrasound stromal measurements. Abstract
Journal of Refractive Surgery 2014 May, Reinstein DZ, Archer TJ, Gobbe M

The Morphology of corneal cap and its relation to refractive outcomes in femtosecond laser Small Incision Lenticule Extraction (SMILE) with anterior segment optical coherence tomography observation. Full text

Changes to cornea curvature and power

Assessing the corneal power change after refractive surgery using Scheimpflug imaging. Abstract
Ophthalmic & Physiological Optic 2015 May, Gyldenkerne A, Ivarsen A, Hjortdal JØ
Safety related investigations

“The centration of the treatment zone as measured by the Pentacam was better for patient-controlled fixation during SMILE than active eye tracker-assisted FS-LASIK.”
Lazaridis et al, Journal of Refractive Surgery 2014 Oct

Wound healing/inflammatory response


Effect on endothelial cells


Effect on the ocular posterior segment

Experimental applications

SMILE and lenticule re-implantation

“Based on the initial clinical outcome it appears that SMILE Xtra may be a safe and feasible modality to prevent corneal ectasia in susceptible individuals.”


The safety and predictability of implanting autologous lenticule obtained by SMILE for hyperopia.  

Tailored stromal expansion with a refractive lenticule for cross-linking the ultrathin cornea.  

LASIK following Small Incision Lenticule Extraction (SMILE) lenticule re-implantation: A feasibility study of a novel method for treatment of presbyopia.  
PLOS One 2013 Dec, Lim CHL, Riau AK, Lwin NC, Chaurasia SS, Tan DT, Mehta JS

Femtosecond laser-assisted keyhole endokeratophakia: correction of hyperopia by implantation of an allogeneic lenticule obtained by SMILE from a myopic donor.  

Reversible femtosecond laser-assisted myopia correction: A non-human primate study of lenticule re-implantation after refractive lenticule extraction.  
PLOS One 2013 Jun, Riau AK, Angunawela RI, Chaurasia SS, Lee WS, Tan DT, Mehta JS

Cryopreservation of extracted corneal lenticule after small incision lenticule extraction for potential use in human subjects.  
Cornea 2014 Dec, Ganesh S, Brar S, Rao PA

Cornea lenticule viability and structural integrity after refractive lenticule extraction (ReLEx) and cryopreservation.  

SMILE with collagen cross-linking

Femtosecond intrastromal lenticular implantation combined with accelerated collagen cross-linking for the treatment of keratoconus – initial clinical result in 6 eyes.  
Cornea 2015 Oct, Ganesh S, Brar S

Clinical outcomes of Small Incision Lenticule Extraction with accelerated Cross-Linking (ReLEx SMILE Xtra) in patients with thin corneas and borderline topography.  

SMILE with keratoplasty/keratotomy

Small Incision Lenticule Extraction after Deep Anterior Lamellar Keratoplasty.  

Full-thickness astigmatic keratotomy combined with Small-Incision Lenticule Extraction to treat high-level and mixed astigmatism.  
Cornea 2015 Sep, Kim BK, Mun SJ, Lee DG, Kim JR, Kim HS, Chung YT
Future development

Hyperopia correction

“This pilot study confirms that the improved lenticule’s design with a large optical and transition zone can achieve good centration and acceptable results for spherical hyperopia using FLEx.”
Sekundo et al, Lasers in Medical Science 2016 May

Improved lenticule shape for hyperopic femtosecond lenticule extraction (ReLEx® FLEx): a pilot study. Abstract
Lasers in Medical Science 2016 May, Sekundo W, Reinstein DZ, Blum M

Femtosecond lenticule extraction (ReLEx®) for correction of hyperopia - first results. Abstract
Graefe’s Archive for Clinical and Experimental Ophthalmology 2013 Jan, Blum M, Kunert KS, Voßmerbäumer U, Sekundo W
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