Corneal Augmentation: SMILE – The Gate Opener

Majid Moshirfar, MD
Hoopes Vision

What is SMILE?

1. **Small Incision**
2. **Lenticular Extraction**

**STEP 1**
Lenticule Creation
A refractive lenticule and small incision are created inside intact corneas, all in one step.

**STEP 2**
Lenticule Removal
The lenticule is removed through the incision with only minimal disruption to the corneal biomechanics.

**STEP 3**
Corneal Curve Change
Removing the lenticule changes the shape of the cornea, thereby achieving the desired refractive correction.

FINANCIAL DISCLOSURES
NONE
What is SMILE?

**Small Incision Lenticular Extraction**

- **History**
  - Designed from developmental needs?
  - Could help with less epi-ingrowth
  - Could decrease nerve disruption compared to LASIK
  - Increased Refractive Correction Range
  - Etc.

- **Advantages**
  - No flap complications, less invasive, possibly less dry eye due to less nerve disruption

- **Disadvantages**
  - Greater surgical skill needed, some may have slower recovery
What do we do with these tissues?:
We throw them out.

**LASIK & HYPEROPIA**

- 14 million Americans have hyperopia
- For hyperopia > +5.0 D, LASIK is imperfect.
- Hyperopic ablations commonly result in worse optical regressions than myopic corrections due to epithelial hyperplasia.
- Complications of HOAs, loss of BCVA
- Two possible improvements: LIKE and sLIKE

**The Safety and Predictability of Implanting Autologous Lenticule Obtained by SMILE for Hyperopia**

Ling Sun, Peijun Yao, Meiyun Li, Yang Shen, Jing Zhao, Xingtao Zhou

- 5 patients (10 eyes) with 1 EYE MYOPIC and 1 EYE HYPEROPIC

Myopic SMILE → Hyperopic LIKE
The Safety and Predictability of Implanting Autologous Lenticule Obtained by SMILE for Hyperopia
Ling Sun, Peijun Yao, Meiyan Li, Yang Shen, Jing Zhao, Xingtao Zhou

- 5 patients (10 eyes) with 1 EYE MYOPIC and 1 EYE HYPEROPIC
- Performed SMILE procedure in MYOPIC EYE
- Used +LENTICULE removed from MYOPIC EYE and re-implanted into HYPEROPIC EYE under femtosecond flap.
- HYPEROPIC EYE did receive some treatment of excimer laser to compensate for what the implanted lenticule could not correct.
- Patients followed for 12 months

Results MYOPIC EYES

<table>
<thead>
<tr>
<th>Patient</th>
<th>PREOP UCVA</th>
<th>PREOP Refraction</th>
<th>PREOP BCVA</th>
<th>POSTOP UCVA</th>
<th>POSTOP Refraction</th>
<th>POSTOP BCVA</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>20/400</td>
<td>+3.00 -0.25 x</td>
<td>20/100</td>
<td>20/100</td>
<td>-2.00 -1.25 x</td>
<td>20/50</td>
</tr>
<tr>
<td>02</td>
<td>20/100</td>
<td>-4.75 -0.75 x</td>
<td>20/32</td>
<td>20/32</td>
<td>-1.00 -0.75 x</td>
<td>20/32</td>
</tr>
<tr>
<td>03</td>
<td>20/200</td>
<td>+5.25 -0.75 x</td>
<td>20/50</td>
<td>20/32</td>
<td>-0.75 -0.00 x</td>
<td>20/20</td>
</tr>
<tr>
<td>04</td>
<td>20/400</td>
<td>+8.25 -2.00 x</td>
<td>20/63</td>
<td>20/100</td>
<td>-2.00 -0.50 x</td>
<td>20/50</td>
</tr>
<tr>
<td>05</td>
<td>20/20</td>
<td>+3.50 -0.25 x</td>
<td>20/20</td>
<td>20/20</td>
<td>+1.50 -0.75 x</td>
<td>20/20</td>
</tr>
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• Lenticules were well centered
• Transparent with no haze
• No complications

Results HYPEROPIC EYES

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<tr>
<th>Patient</th>
<th>PREOP UCVA</th>
<th>PREOP Refraction</th>
<th>PREOP BCVA</th>
<th>POSTOP UCVA</th>
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<td>20/40</td>
<td>+8.25 -2.00 x</td>
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</tr>
</tbody>
</table>

What is LIKE?
Lenticular
Intrastromal
KERatoplasty
**What is LIKE?**

**Lenticular Intrastromal Keratoplasty**

**HARLI**
- Hyperopic
- Allogenic
- Refractive
- Lenticule
- Implantation

**LIKE (Lenticular Intrastromal Keratoplasty)**

- Developed by Dr. Theo Seiler
- First conceived of by Dr. Jose Barraquer

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**LIKE (Lenticular Intrastromal Keratoplasty)**

- Theo Seiler (Germany)
  - 7 eyes of 6 patients treated with LIKE
  - Hyperopia up to +6.50 D and Astigmatism up to -2.50 D
  - 3 eyes received Excimer Laser treatment on Lenticule at 1 month
  - 1 lenticule was replaced at 1 month due to undercorrection
  - No eyes lost more than 1 line of BCVA
  - 3 eyes gained 2 lines or more of BCVA
  - 4 eyes showed transient haze in the lenticule
  - 2 eyes had decentered lenticule which were recentered
LIKE – Hoopes Vision Case Report (1st in U.S.)

PREOP 6 MO POSTOP

<table>
<thead>
<tr>
<th></th>
<th>PREOP</th>
<th>6 MO POSTOP</th>
</tr>
</thead>
<tbody>
<tr>
<td>K-Readings Flat</td>
<td>39.9</td>
<td>46.2</td>
</tr>
<tr>
<td>K-Readings Steep</td>
<td>41.4</td>
<td>47.6</td>
</tr>
<tr>
<td>UCVA</td>
<td>20/25</td>
<td>20/40</td>
</tr>
<tr>
<td>Refraction</td>
<td>+6.00 -1.00 x 0.40</td>
<td>0.00 -1.25 x 0.71</td>
</tr>
<tr>
<td>BCVA</td>
<td>20/20</td>
<td>20/20</td>
</tr>
<tr>
<td>Corneal Thickness</td>
<td>597 (OCT)</td>
<td>816 (OCT)</td>
</tr>
</tbody>
</table>

Lenticule Information:
- Diameter: 7.0 mm
- Thickness: 157 microns
- Estimated Power: +7.00 D

2 Months Postop

- Eye Comfort normal
- Patient does experience some nighttime glare
- Patient wearing soft CL for residual refractive error
- Residual Rx may be enhanced with Lift Flap excimer enhancement or PRK when stable

sLIKE (small incision LIKE)

- Slight modification of LIKE
- Small incision access to stromal pocket
- Lenticule inserted into pocket
A Modified Small-Incision Lenticule Intrastromal Keratoplasty (sLIKE) for the Correction of High Hyperopia: A Description of a New Surgical Technique and Comparison to Lenticule Intrastromal Keratoplasty (LIKE)

Majid MOHEIRIFAR, MD, Tori I. SWEET, MD, Maha MAVIRO, ET, Tony FANNING, ET, Steven H. LINN, MD, and Vincente RONZELLIO, MD
Philip C. HOPEFS, MD
1. John A. Moran Eye Center, Department of Ophthalmology and Visual Sciences, School of Medicine, University of Utah, Salt Lake City, UT, United States
2. Utah Eye Institute, Sunnyvale, CA, United States
3. Moin Research Center, Sunnyvale, CA, USA
4. Department of Ophthalmology, University of Kansas Medical Center, Kansas City, KS, USA
5. University of Utah, Salt Lake City, UT, United States

ABSTRACT

Femtosecond laser-assisted keratectomy using microkeratomes can cause damage to the corneal stroma in the surgical zone. This study describes a new surgical technique that uses a smaller incision (sLIKE) for the correction of high hyperopia. The advantages and disadvantages of this technique are compared to LIKE in terms of safety, efficacy, and ease of surgery.

KEYWORDS

Small-Incision Intrastromal Keratoplasty (LIKE), Femtosecond laser-assisted intrastromal keratoplasty (FLIK), Lenticule Intrastromal Keratoplasty (LIKE), Lenticule Excision with Intrastromal Reshaping (sLIKE), Incision Intrastromal Keratoplasty (LIKE)

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Comparison of LIKE vs sLIKE for High Hyperopia Treatment

<table>
<thead>
<tr>
<th>ADVANTAGES</th>
<th>DISADVANTAGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>LIKE</td>
<td>sLIKE</td>
</tr>
<tr>
<td>• Surgical approach similar to LASIK</td>
<td>• Increased risk for epithelial ingrowth</td>
</tr>
<tr>
<td>• Easier centration</td>
<td>• Higher risk for dry eyes</td>
</tr>
<tr>
<td>• Simple &amp; straightforward enhancement (flap re-lift), if needed</td>
<td>• Significant weakening of corneal biomechanics</td>
</tr>
<tr>
<td>• Preliminary evidence shows efficacy and safety</td>
<td>• Higher risk for DLK</td>
</tr>
<tr>
<td>• Flap size of at least 10 mm is difficult to create on most FS platforms</td>
<td>• Other flap-related complications</td>
</tr>
</tbody>
</table>

sLIKE

• Less weakening of corneal biomechanics
• Less dry eye symptoms
• Less risk for epithelial ingrowth
• Less risk for DLK
• No flap

Corneal Augmentation

• Hyperopia
• Presbyopia
• Keratoconus
• Corneal Wounds
• Etc.
Corneal Reaction to Foreign Substances (inlays)

Corneal Healing Response

- **MAN MADE MATERIALS**
  - PMMA inlays
  - Hydrogel inlays (HEMA/MMA)
  - PVDF (polyvinylidene fluoride) inlay

- **DONOR CORNEAL TISSUE**
  - Stroma
  - Bowman’s Membrane
  - Full-Thickness Cornea

“The use of biological inlays could be a method to address the problems related to the tissue reaction resulting from the insertion of synthetic inlays.” - Soosan Jacobs, MS, FRCS, DNB

Types of Tissue:
- **Autogenic**: tissue from the same individual
- **Allogenic**: tissue from the same species
- **Xenogenic**: tissue from a different species

Corneal Augmentation for Keratoconus
Keratoconus

- A difficult condition to treat
- Penetrating keratoplasty (PK) and deep anterior lamellar keratoplasty (DALK) for advanced cases come with difficulties and complications.
- Wound-healing problems, allograft rejection, and persistent irregular astigmatism are a few problems with the current treatment paradigm.
- LIKE or sLIKE using a minus-shaped lenticule with collagen cross-linking could be less a troublesome therapeutic alternative.

Bowman layer transplantation using a femtosecond laser

- For progressive and advanced keratoconus
- Hypothesis:
  - Flatten corneal curvature
  - Halt progression
  - Increase Contact Lens tolerance

- Bowman layer prevents excessive bulging of the cornea.
- In keratoconic eyes, it suffers multiple changes that can be seen under electronic microscopy.
- Discontinuities, sharply edged defects, ruptures, gaps, and scars were all found in the Bowman layer of keratoconic eyes.

Bowman layer transplantation using a femtosecond laser

- Study / Procedure
  - Transplantation of an isolated donor Bowman layer within the mid-stroma of a keratoconic (KCN) cornea
  - 2 patients, stage IV KCN
  - Donor cornea prepared by removing epithelium
  - 360 degree dissection of Bowman’s layer with a 30-gauge needle
  - Mechanical removal of Bowman’s layer with forceps
  - Femtosecond creation of stromal pocket in KCN cornea at 50% depth
  - Pocket dissection and Bowman’s layer insertion and unfolding
Bowman layer transplantation using a femtosecond laser
Gonzalo García de Oteyza, Laura A. González Dibildox, Kristian A. Vázquez-Romo, Andre Tapia Vazquez, Jesus H. Davila Alquisiras, Blanca E. Martínez-Baez, Ana M. García-Albissa, Manuel Ramírez, Everardo Hernández-Quintela

- Bowman’s layer removal from donor cornea

Table 1. Results 3 months after Bowman layer transplantation using a femtosecond laser.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Case 1 Preop</th>
<th>Case 1 1 W Postop</th>
<th>Case 1 1 Mo Postop</th>
<th>Case 1 3 Mo Postop</th>
<th>Case 2 Preop</th>
<th>Case 2 1 W Postop</th>
<th>Case 2 1 Mo Postop</th>
<th>Case 2 3 Mo Postop</th>
</tr>
</thead>
<tbody>
<tr>
<td>UDVA</td>
<td>CF 20/200</td>
<td>20/400</td>
<td>20/800</td>
<td>20/1000</td>
<td>CF 20/200</td>
<td>20/400</td>
<td>20/800</td>
<td>20/1000</td>
</tr>
<tr>
<td>CDVA</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>CL balance</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>VA w/ CL</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>K1 (D)</td>
<td>65.7</td>
<td>65.6</td>
<td>61.6</td>
<td>61.6</td>
<td>61.1</td>
<td>61.6</td>
<td>61.5</td>
<td>61.5</td>
</tr>
<tr>
<td>K2 (D)</td>
<td>72.3</td>
<td>66.5</td>
<td>65</td>
<td>65.1</td>
<td>71.9</td>
<td>72.1</td>
<td>71.1</td>
<td>71.1</td>
</tr>
<tr>
<td>COT (μm)</td>
<td>390</td>
<td>358</td>
<td>515</td>
<td>454</td>
<td>371</td>
<td>458</td>
<td>425</td>
<td>420</td>
</tr>
<tr>
<td>TCT (μm)</td>
<td>350</td>
<td>357</td>
<td>510</td>
<td>452</td>
<td>371</td>
<td>450</td>
<td>421</td>
<td>420</td>
</tr>
</tbody>
</table>

COT = central corneal thickness; CDVA = corrected distance visual acuity; CF = counting fingers; CL = contact lens; K1 = minimum keratometry; K2 = maximum keratometry; TCT = thinnest corneal thickness; UDVA = uncorrected distance visual acuity; VA = visual acuity.
Bowman’s Intrastromal Transplant for Keratoconus

What about sLIKE for Keratoconus?

sLIKE for Keratoconus

sLIKE for Keratoconus
sLIKE for Keratoconus OCT

sLIKE for Keratoconus

- Flattens cornea
- Reinforces periphery
- Refractive outcomes unknown
- Preliminary trials necessary to measure outcomes

Intacs for Keratoconus - made of PMMA

Possible Complications:

- Segment migration
- Stromal thinning
- Corneal melt
- Infectious keratitis
- Neovascularization
Corneal Allogenic Intrastromal Ring Segments (CAIRS) Combined With Corneal Cross-linking for Keratoconus

Soosan Jacobs, Shaila Patel, Amar Agarwal, Arvind Ramalingam, John Michael Raj

• Study / Procedure
  • 24 eyes of 20 patients, stage 1-4 KCN
  • Donor cornea cut into ring with double trephine
  • Divided into 2 equal half segments, then soaked in riboflavin
  • Receiving cornea channels made by femtosecond laser @ 50% depth
  • Segments then implanted into receiving cornea using PMMA intacs segment as “threading needle”
  • Corneal Cross-Linking performed

The segments were not visible on naked eye examination in any patient.
All segments remained well positioned and no case of melt or corneal necrosis was encountered.
No other major intraoperative or postoperative complication were seen.

AVERAGES PREOP POSTOP
UDVA 20/100 20/50
CDVA 20/30 20/25
Spherical Equivalent (SE) -5.35 -1.28
Steepest K value 57.61 D 52.55 D

*12 Month Follow-up
*24 eyes of 20 patients
Biological corneal inlay for presbyopia, derived from small incision lenticule extraction (SMILE)
Yu-Chi Liu, Ericia Pei Wen Teo, Heng Pei Ang, Xin Yi Seah, Nyein Chan Lwin, Gary Hin Fai Yam, Jodhbir S. Mehta

• Study Design:
  - 10 primate eyes
  - Received Autogenic & Xenogenic lenticules
  - Removed -3.00 D convex-shaped lenticule from myopic SMILE procedure using femtosecond laser.
  - 3 mm diameter stroma section cut from central portion of lenticule
  - 7.5 mm intrastromal pocket was created in receiving eye at 120 micron depth using a femtosecond laser.

Study Results:
• "In this study, the implanted lenticule, derived from a SMILE procedure, acted as a shape-altering inlay to induce a corneal hyper-prolate change, by increasing the central corneal radius of curvature."
• "The procedure had good biocompatibility and was not associated with adverse effects such as corneal haze or keratolysis."

Soosan Jacobs, MS, FRCS, DNB

Donor Cornea – SMILE created lenticule
Lenticule cut to size
Presbyopic Lenticule implanted into recipient
Excimer Laser Shaped Allograft Corneal Inlay for Presbyopia: Initial Clinical Results
Aylin Kihic, Merve Ozbek, Burcu Nurozler Tabakci, David Muller, Michael Mrochen

- Study Design:
  - 12 eyes of 12 patients (average age 52)
  - Received allogenic lenticules in non-dominant eye.
  - Tissue buttons from Eyebank were cut with 3 mm trephine
  - Button was then formed by excimer laser to desired shape.
    - Dia: 3mm Thickness: 20 microns
  - Femtosecond created flap was created in receiving eye at 110 micron depth
  - Stromal inlay was placed and centered over pupil, then flap replaced
  - Patients were followed for 3 months.

Study Results:
- 9 out of 12 were satisfied with outcome
- Average Uncorrected NEAR VA increase by 5 lines
- 2 eyes lost 1 line of Uncorrected Distance VA
- 2 eyes lost 2 lines of Uncorrected Distance VA
- Mild corneal haze was seen in 2 patients but disappeared after 3 months

Conclusion
- Corneal augmentation with allogenic tissue is a promising method for corneal reshaping and strengthening.
- Prophylactic corneal collagen cross-linking of lenticule/segments after implantation may help reinforce cornea, reduce optical regression, and improve visual outcomes.

THANK YOU
QUESTIONS?