Repairing failed SMILE procedures in the strongest way possible

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In a Nutshell

- **SMILE involves the creation of an intrastromal lenticule and removal tunnel with a femtosecond laser.**
- **With millions of SMILE surgeries performed globally, complications are rare, but fixing them is challenging due to the intrastromal location.**
- **SMILE complications – particularly partial removal or failure to remove the lenticule – can cause significant and permanent reduction of best spectacle-corrected vision through irregular astigmatism.**
- **We review the various complication types, and strategies for their repair.**
- **We present two cases of successful SMILE surgery repair using corneal wavefront-guided transepithelial photorefractive keratotomy (transPRK) using aberrometric data and corneal epithelial maps.**

Small Incision Lenticule Extraction (SMILE) is a laser refractive procedure that uses a femtosecond laser to create a lenticule within the cornea.[1] Started in 2008, SMILE has established itself successfully as an alternative to Laser in situ keratomileusis (LASIK) and photorefractive keratotomy (PRK) and by 2021, more than 5 million SMILE procedures have been performed globally.

The first two femtosecond laser cuts are intrastromal to create a refractive lenticule, that, when removed, provides the refractive correction. The third cut is a side incision from the corneal surface to the SMILE «cap» – the upper of the first two stromal incisions, to enable the lenticule to be removed. Because the laser is not able to completely separate the lenticule from the rest of the stroma, the surgeon is required to use a spatula to dissect the lenticule first, before extracting the lenticule with small through the tunnel. Although SMILE complications occur in less than 1 % of surgeries,[2] there are several potential points of failure.[3,4] The femtosecond laser requires suction to dock to the eye, and suction loss can result in cessation of laser energy delivery mid-cut. However, it is lenticule removal that presents the greatest challenge. If the lenticule is not completely detached, and some tissue is left behind, the patient will remain with significant irregular astigmatism. This leads to a massive decrease in best spectacle-corrected visual acuity and heavily reduced visual quality.

Since the introduction of SMILE, there have been several questions about how to perform a re-treatment if mistakes with the initial procedure have been made. A few approaches exist.[5–7]

Approaches to repair complicated SMILE

1. Re-SMILE

Cut a second lenticule from the bottom of the original SMILE cut. This is often the approach taken by surgeons in the immediate setting where suction is lost, or the procedure is aborted for any reason – to complete the procedure – or when a decentred or incorrect correction has been performed. The challenge with this approach is to identify the edge of the new lenticule and get the spatula under it to detach and remove it – especially if it is a small correction and a thin lenticule.

2. Wavefront-guided surface ablation (transPRK)

This approach has a number of advantages: wavefront-guided excimer laser ablation aims at reducing the aberrations caused by the incomplete lenticule removal. When performed, this approach must be combined with mitomycin C (MMC) application to prevent haze formation. Although some publications point to the fact that the excimer laser disrupts Bowman's membrane, which at least in theory, could reduce the biomechanical strength of the cornea, new laboratory investigations from our group show that Bowman's membrane does not play a role in corneal biomechanics.

3. Turn the SMILE cap into a LASIK flap and perform another ablation – the «Cap to flap» ablation

This involves extending the third incision made for instrument access and lenticule extraction to create a LASIK-like flap, opening the flap, and performing the ablation on the stromal bed. However, as SMILE is typically performed deeper in the cornea than LASIK, this intervention should result in a greater reduction of corneal biomechanical strength than LASIK, and increase the risk of postoperative ectasia.

Long-term stability of the cornea

One factor at the forefront of every refractive surgeon's thought is long-term refractive stability of the cornea. Surgeons, at all costs, want to avoid one of the most dreading complications in refractive laser surgery, postoperative ectasia. In our practice, we always want to leave patients with the strongest-possible cornea after the procedure. Through our research group at the University of Zurich and collaborations with excellent surgeons and researchers, we have been able to perform and publish a series of laboratory experiments to determine what SMILE means in terms of corneal biomechanics.

Corneal cross-linking to improve corneal biomechanics

Corneal cross-linking (CXL) involves the application of riboflavin (vitamin B_2) to

the cornea under UV illumination. This causes a photochemical reaction that covalently cross-links together the molecules of the stroma (collagen), thereby strengthening it. CXL is the only known means to stop ectasia after laser surgery and was first described in 2007.[8]

In the past 5 years, our research group at the ELZA Institute and the University of Zurich, together with Sabine Kling from the ETH Zurich and SMILE pioneer Walter Sekundo from the Philipps University of Marburg investigated the biomechanical properties of SMILE. We wished to understand what amount of corneal weakening is induced by different SMILE re-treatment options (1) and to investigate the potential of CXL to help restore the original corneal stress resistance.[5,9–12]

Laboratory experience

Our laboratory research group at the University of Zurich utilized porcine eyes (n = 96) which were split equally into the following experimental groups:

- Control corneas (no refractive intervention)
- Control corneas + CXL (9 mW/cm², 10 minutes)
- SMILE -11 D + PRK -3 D
- SMILE -14 D
- FLEX -14 D (cap-and-flap)
- FLEX -14 D + CXL

As we were interested only in the biomechanical impact of the surgery, and not the intricacies of the surgery, we created -14 diopters (D) SMILE lenticules in one step, rather than two, for the SMILE and FLEX groups. The initial SMILE refractive correction was -11 D, with an enhancement (second procedure) of -3 D, for a total correction of 14 D. This might seem excessive, but porcine corneas are considerably thicker than human corneas; 14 D in pigs is the equivalent of 10 D in humans.

After the refractive and cross-linking procedures were performed, corneal buttons (that contained the region of laser ablation and cross-linking at the centre) were removed, and underwent stress-strain measurements to assess the elastic modulus of the cornea – in other words, the cornea's ability to resist biomechanical stress after surgery.

Compared with the control corneas (no laser ablation, no CXL), re-SMILE and PRK enhancements had little effect on the elastic modulus; LASIK enhancement – cap and flap – produced the weakest cornea; and CXL treatment significantly increased the elastic modulus. In general, refractive surgery decreased the overall elastic modulus by 7 %, whereas CXL increased it by 20 %. When it comes to re-treatments to patients who have undergone SMILE, Re-SMILE and PRK enhancements affect corneal biomechanical integrity less than LASIK – but the extent of corneal weakening thanks to laser refractive surgery is small, relative to the stiffening effect of CXL.[5]

"Refractive surgery decreased the overall elastic modulus by 7 %, whereas CXL increased it by 20 %."

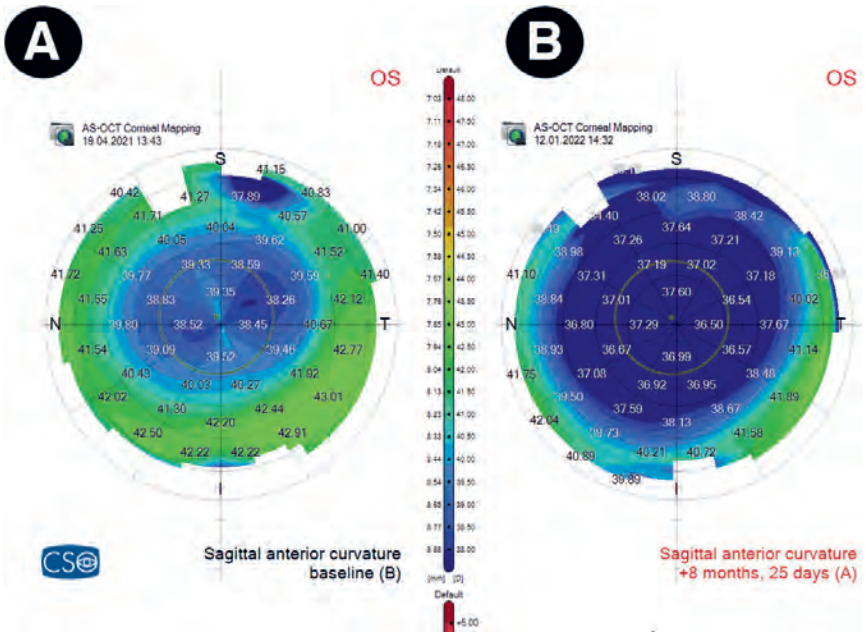

Fig. 1 Left eye of a 32-year-old male patient. Small optical zone after complicated SMILE (A) and enlarged optical zone at 8 months after corneal wavefront-guided transPRK (B).

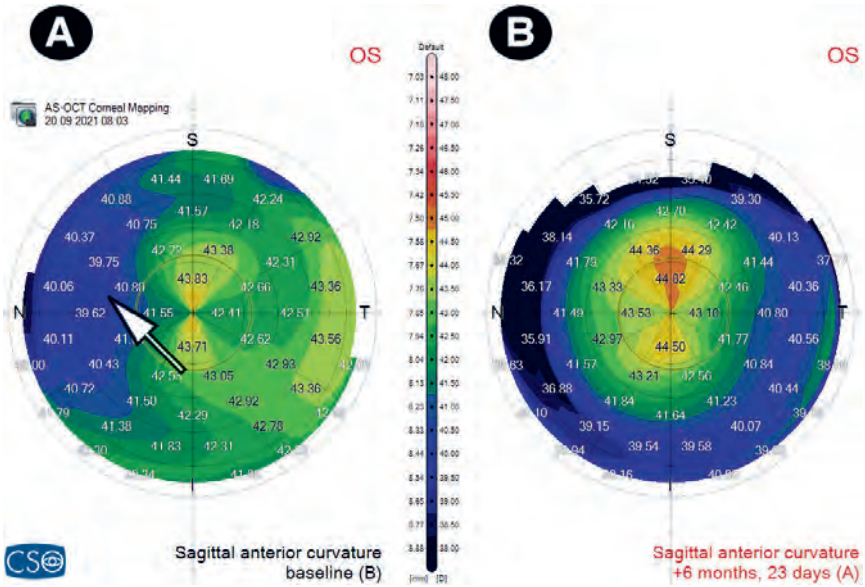

Fig. 2 Left eye of a 26-year-old female patient. Scarring of the interface in difficult lenticule extraction in primary complicated SMILE. Note the massive flattening of the cornea on the nasal area (blue, arrows) (A). Following a corneal wavefront-guided transPRK at ELZA, major regularization of the topography at 6 months after repair (B).

Clinical experience

Fixing a failed refractive laser surgery is far more demanding than performing the original surgery. In many cases, we can improve on the situation by reducing the irregular astigmatism and the higher order aberrations. Still, sometimes normalization of vision remains very challenging. Surgeons aim to give the patients the best visual quality possible with a residual refractive correction that can be corrected with glasses.

Fixing SMILE surgery complications

Case 1

Small optical zones are not limited to old laser surgeries; here we present a case of a 32-year-old patient who presented to our clinic reporting good photopic vision (small pupil) but had significant issues under mesopic and scotopic conditions (twilight and night-time, large pupil). The patient had previously undergone SMILE surgery that resulted in a complication with a small optical zone.

We performed a corneal wavefront-guided transepithelial photorefractive keratotomy (transPRK) using epithelial maps and corneal and ocular aberrometric data. Our aim was to enlarge the optical zone to improve visual quality and recover much of what the patient lost with the failed SMILE surgery (Fig. 1 A, B). The patient now is at an unaided visual acuity of 1.0 binocularly, both during daytime and at night.

Case 2

As described earlier, an incomplete extraction of the SMILE lenticule might lead to major irregular astigmatism that cannot be corrected with glasses. Here, we show such a case in the left eye of a 27-year-old female patient that had been treated for myopia with SMILE. The surgeon had difficulties removing the lenticule on the nasal part. Removal attempts led to major scarring and irregular astigmatism (Fig. 2 A) (blue area, arrows). A corneal wavefront-guided transPRK was performed to improve corneal topography (Fig. 2 B). •

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ESCRS Best Poster Award

Unter den Best Posters am Jahreskongress 2022 der European Society of Cataract and Refractive Surgeons (ESCRS, Mailand, 18.09.2022) aus dem Bereich Refractive Surgery waren zwei Studien zum Thema SMILE. Das ELZA Institut teilte mit, dass zum vierten Mal seit 2019 ein ESCRS Best Poster Award an einen Mitarbeitenden des Instituts ging: In 2022

wurde ELZA-Postdoktorand Dr. Nan-Ji Lu ausgezeichnet. •

Lu NJ, et al. Combining Spectral-Domain OCT and Air-Puff Tonometry Analysis to Diagnose Keratoconus. J Refract Surg. 2022 Jun;38(6):374-380.