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Incidence and outcome of suction loss during corneal lenticule extraction with the femtosecond laser application CLEAR

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ABSTRACT

A femtosecond laser creates an intrastromal lenticule while the eye is immobilized by vacuum in refractive corneal lenticule extraction to correct myopia. Suction loss has a 0.72% overall incidence and may result in an incomplete cut; the procedure can then be completed using the same or different techniques. While previous laser platforms used corneal suction, the recent lenticule extraction (CLEAR) application for the Ziemer Z8 femtosecond laser (Ziemer Group, Port) uses scleral suction; studies on suction loss with this vacuum system are lacking. A total of 652 eyes from 357 CLEAR patients were thus included in a consecutive, single-institution, retrospective study. Suction loss occurred in three patients' left eyes (0.46%) due to a strong involuntary eyelid contraction. After an early suction loss in patient #1, the procedure was successfully repeated with the same parameters. Suction loss occurred after the completion of the posterior cut and at 44% of the anterior cut in patient #2. The laser procedure appeared to have been completed in patient #3, but the lenticule had not been delineated temporally due to false suction on the conjunctiva. Thin flap femtosecond laser in situ keratomileusis (LASIK) was used to complete the refractive procedure in patients #2 and #3. Uncorrected distance visual acuity was 20/20 or better in all three eyes at 6 months. Finally, suction loss during CLEAR was uncommon and had a favorable prognosis. Repeat lenticule extraction or femtosecond LASIK can be performed on the same day to complete the treatment.

Key words: myopia; LASIK; corneal lenticule extraction; suction loss.

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Introduction

Lenticule extraction is a well-established technique for the correction of myopia and myopic astigmatism, in which, while the eye is maintained firm by suction, a femtosecond laser creates an intrastromal lenticule, then extracted through a small incision.[1] Suction loss may occur at any time during the laser delineation of the lenticule, thus causing an incomplete cut: the procedure can then be completed by the same technique or by other procedures, including laser in situ keratomileusis (LASIK) or photorefractive keratectomy (PRK).[2-4]
However, all the literature about suction loss during lenticule extraction is based upon the experience with the Zeiss VisuMax femtosecond laser (Carl Zeiss, Jena), using a curved applanation glass and corneal suction, the only existing platform until 2020. Since then, a new application for lenticule extraction (called CLEAR) has been approved for the Ziemer Z8 femtosecond laser platform (Ziemer Group, Port), with an entirely different vacuum mechanism, based upon corneal applanation and scleral suction with a double control;[5] studies on suction loss during lenticule extraction by CLEAR are lacking. We therefore report the incidence and clinical outcome of suction loss during the CLEAR procedure.

Materials and Methods

A retrospective, consecutive, non-comparative case series study was designed, including consecutive patients undergone lenticule extraction with the CLEAR application between June 2020 and January 2023, in a single-institute series. Surgeries were performed by 2 of the authors (A.L. and G.D.B). The Institutional Review Board provided approval on May 21, 2020 (#11/20). The research followed the tenets of the Declaration of Helsinki.
Inclusion criteria were: treatment of myopia or compound myopic astigmatism with spherical equivalent (SE) -2 to -12 dioptres (D); age between 21 and 55 years; absence of collagen vascular disease, no pregnancy; no previous eye surgery; absence of scars or epithelial irregularities; absence of macular or lens abnormality; absence of dry eye symptoms, non-invasive tear film break-up time ≥10 seconds (MS-39, Costruzione Strumenti Oftalmici, Firenze), lacrimal fluid osmolarity ≤300 mOsm/l (I-PEN, Imedpharma, Saint-Laurent); corneal features on anterior segment optical coherence tomography (AS-OCT) and Placido topography (MS-39): central pachymetry ≥480 µm; regular posterior elevation, anterior and posterior tangential topography; no signs of ectasia; minimum follow-up: 6 months from treatment.
Our technique for lenticule extraction with the CLEAR application has been published in detail.[5] An adequate suction ring is chosen depending on the average corneal curvature and the horizontal corneal diameter (white-to-white), measured by AS-OCT. A curvature >45 dioptres (D) is approached with an 8.5 mm ring; a curvature between 42.5 and 45 D with a 9 mm ring, a curvature <42.5 with a 9.5 mm ring; these options can be adjusted in the presence of particularly large or small white-to-white measurements. An eyelid speculum is applied and the laser handpiece with the applanation glass is laid upon the cornea; when a complete applanation is apparent on the operating microscope and on the laser screen, suction is started. When a steady vacuum is built, as shown by the values on the laser screen, the treatment can be started. The total time of vacuum is between 40 and 60 seconds. If the vacuum significantly decreases, the treatment will automatically stop.
Our standard technique for femtosecond Lasik has been published:[6] it entails flap creation with the femtosecond laser Ziemer Z8 and refractive treatment with the Technolas 317 Teneo excimer laser.

Results

A total of 652 eyes of 357 patients were included. Suction loss occurred in the 3 left eyes of 3 patients (0.46%; Table 1). In all cases, the right eye had just completed the CLEAR procedure and, in the left eye, suction loss followed a strong involuntary eyelid contraction. None of the 3 cases took place during the surgeon learning curve, all happening after the first 100 cases.
In patient #1, the suction loss occurred at the very beginning of the procedure, with only 3% of the posterior cut performed, consisting of the sole peripheral rim. After 15 minutes, the procedure was successfully repeated with the same parameters. The post-operative course was unremarkable. At 6 months, uncorrected distance visual acuity was 20/20, with a refraction of +0.25 +0.25 x 36°.

Table 1. Pre-operative features of eyes experiencing suction loss during lenticule extraction with the CLEAR application. Refraction and curvature are in diopters.

Age, gender, eye	Refraction	CDVA	Curvature	White-to-white	Suction ring used	Moment of suction loss
33, male, left	-5 -0.75×23°	20/20	44.2	11.85 mm	9 mm	3% of posterior interface
37, female, left	-1.75 -0.5×0°	20/16	42.9	11.98 mm	9 mm	44% of anterior interface
32, female, left	-7.5 -1.5×172°	20/20	43.	12.76 mm	9.5 mm	Beginning of procedure (partial suction)

CDVA, corrected distance visual acuity; Curvature, mean central corneal curvature on Placido tangential topography; White-to-white: horizontal corneal diameter on Placido tangential topography.

In patient #2, the suction loss occurred after a completed posterior cut and at 44% of the anterior cut. After 30 minutes and the complete resorption of intracorneal plasma bubbles, femtosecond LASIK with a 90 m flap was performed. The postoperative course was unremarkable. At 6 months, uncorrected distance visual acuity was 20/16, with a refraction of +0.25 (Figure 1).
In patient #3, the laser procedure was completed, with no signs of suction loss except for an early "click" sound at the eye level, while the suction control reported adequate vacuum during the whole procedure. However, when the handpiece was removed, the lenticule had not been delineated in the temporal 2 mm. After 45 minutes, femtosecond LASIK with a 95 m flap was performed. The post-operative course was unremarkable. At 6 months, uncorrected distance visual acuity was 20/20, with a plano refraction (Figure 2).

Discussion

The incidence of suction loss during lenticule extraction with the CLEAR application (0.46%) was similar to that observed with previous laser platforms, which ranged between 0.20%[7] and 6%,[8] with an overall incidence of 0.72%.[9] Contrary to previous studies, in which the most commonly affected eye was the first treated,[3,10] our 3 cases always occurred during the treatment of the second eye. In patients #1 and #2, the vacuum decreased and the treatment was automatically stopped, whereas in patient #3 vacuum did not decrease, but the applanation glass lost contact with the temporal cornea, where a conjunctival intrusion might have caused a good suction.
The treatment could be completed soon after the primary procedure: in patient #1, by repeating lenticule extraction exactly with the same parameters, and in patients #2 and #3 by thin-flap femtosecond LASIK. In all eyes, the visual outcome was excellent and without complications. No eye-lost lines of visual acuity.

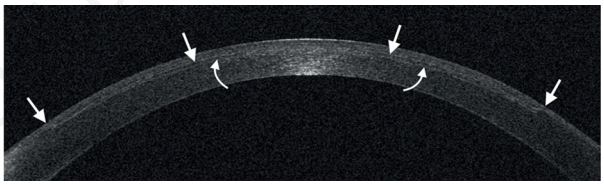

Figure 1. Patient #2, post-operative anterior segment optical coherence tomography (AS-OCT) at day 1. After a suction loss during the creation of the cap interface for lenticule extraction, laser in situ keratomileusis (LASIK) was carried out. The straight arrows indicate the edge and the interface of the LASIK flap. The curved arrows indicate the completed posterior lenticule interface.

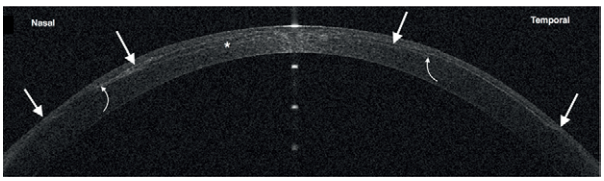

Figure 2. Patient #3, post-operative anterior segment optical coherence tomography (AS-OCT) at day 1. A partial suction loss during lenticule extraction caused an incomplete delineation of the lenticule on the temporal side. The lenticule was therefore not removed and laser in situ keratomileusis (LASIK) was performed. The straight arrows indicate the edge and the interface of the LASIK flap. The curved arrows point at the edges of the lenticule, complete on the nasal side and incomplete on the temporal side. The asterisk indicates the lenticule interface.

The options to complete the refractive treatment after suction loss during lenticule extraction are varied. Repeat lenticule extraction can be carried out, continuing the procedure with the same or different parameters, depending on the moment of suction loss,[4] on the same day[7] or postponed.[11] The advantage of repeating lenticule extraction is represented by maintaining the pre-operative plan; the disadvantages are complications related to the dissection of incomplete or intersecting cutting planes. PRK is an alternative method to complete the treatment, with the transepithelial PRK offering a technically easy solution with no suction and no creation of new planes;[2] however, PRK can be followed by pain, haze, and delayed visual recovery. A further alternative is femtosecond LASIK,[9] which has the advantage of fast visual recovery with minimal discomfort and can be performed at a more superficial depth than the lenticule. The disadvantages of LASIK are the loss of the biomechanical peculiarities of lenticule extraction and higher stromal consumption.[12]
The main limitation of this paper is the small sample, justified, however, by the rarity of the event.

Conclusions

In conclusion, suction loss during lenticule extraction with the CLEAR platform was relatively rare and carried a very good final prognosis. The treatment can be completed on the same day by repeat lenticule extraction (only with very early suction loss) or by thin flap femtosecond LASIK.

Conflict of interest: the authors declare no potential conflict of interest, and all authors confirm accuracy.

Ethics approval and consent to participate: the subject has given written informed consent to publish the case, including the images. The study has been granted an exemption from requiring ethics approval by the Institutional Review Board at Siena Eye Laser. Ethical approval is not required for this study in accordance with national guidelines.

Contributions: AL, concept, drafting, final approval; SVF, interpretation of data, drafting, final approval; GDB, analysis of data, revising, final approval; CC, concept, analysis of data, final approval.

Availability of data and materials: all data generated or analyzed during this study are included in this published article.

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