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RESEARCH STUDY

Keratorefractive lenticule extraction (KLEx) in patients with cardiac implantable electronic devices

Antonio Leccisotti[1,2,3*], Stefania V. Fields[1,3], Lorenzo Azzaro[1,3], Tara Moore[2] and Matteo Posarelli[1,3†]

[1]Department of Ophthalmology, Siena Eye Laser, Siena, Italy
[2]Department of Ophthalmology, School of Biomedical Sciences, Ulster University, Coleraine, UK
[3]Department of Ophthalmology, Centre for Research in Refractive Surgery, Siena, Italy

*__Correspondence:__
Antonio Leccisotti,
leccisotti@libero.it

†**ORCID:**
Matteo Posarelli
0000-0002-3983-0381

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Purpose: The use of an excimer laser in corneal refractive surgery generates an electromagnetic field that can interfere with cardiac implantable electronic devices (CIEDs); in addition, CIEDs may disturb the eye-tracking system of the laser machine, leading to potential errors in the surgical refractive correction plan. The recently introduced technique of keratorefractive lenticule extraction (KLEx) does not use an excimer laser, instead based upon the delineation of an intracorneal lenticule by a femtosecond laser, which does not interfere with CIEDs, but the evaluation of KLEx in the presence of a CIED has not been reported before.

Methods: We therefore presented in this study four eyes of two patients with a CIED for atrioventricular block and Wolf-Parkinson-White syndrome that underwent KLEx surgery for myopia and astigmatism correction. Subjects were both 37-year-old males, and the mean spherical equivalent error (SER) was -5.75 ± 0.50 D.

Results: The Surgeries were uneventful, and no interference between the femto-laser and the CIED was observed. At 6 months, both patients had a visual acuity of 6/6 with a mean residual SER of $+0.35 \pm 0.25$ D, and no issues related to their CEID function were detected.

Conclusions: In this pilot study we demonstrated that KLEx can be a good option in patients with CIEDs, as it does not require cardiological care and avoids interferences with an excimer laser.

Keywords: keratorefractive lenticule extraction (KLEx), myopia, cardiac implantable electronic devices (CIEDs), refractive surgery, femtosecond laser

Introduction

Corneal refractive surgery is performed by three fundamental techniques: (1) photorefractive keratectomy (PRK), using only an excimer laser to remodel the anterior surface of the cornea (1); (2) femtosecond laser in situ keratomileusis (femto-LASIK), using both a femtosecond laser to create a corneal flap and an excimer laser to reshape the cornea (2); (3) keratorefractive lenticule extraction (KLEx), using only a femtosecond laser to delineate an intracorneal lenticule, then extracted through a small incision (3).

Excimer lasers produce an electromagnetic field (4) and are therefore contraindicated by manufacturers in patients with cardiac implantable electronic devices (CIEDs), as the electromagnetic field may interfere with the CIED and cause arrhythmias, or the CIED can interfere with the eye-tracking mechanism (5, 6). A cardiologist may be required to shield the CIED with a magnet temporarily (7).

Femtosecond lasers do not produce a relevant electromagnetic field and can be safely used in the presence of a CIED. KLEx, in which only a femtosecond laser is used, could therefore be used as a safe technique of refractive surgery, not requiring the intervention of a cardiologist. However, while reports on LASIK and PRK in patients with CIED have been published (8), no analogous reports of KLEx exist.

We therefore evaluated the results of bilateral KLEx in two patients with CIED to assess refractive results and general health issues.

Patients and methods

A retrospective analysis of patients with CIED who underwent KLEx was done. The study was approved by our Institutional Review Board on February 10, 2025. The research adhered to tenets of the Declaration of Helsinki; patients provided a signed informed consent. We included in our study adult subjects aged ≥18 years, with a myopic or spherical equivalent (SE) refractive error ≥−1 D and ≤−12 D, a cylinder ≤3 D, and a postoperative follow-up of at least six months. We excluded patients with systemic diseases such as autoimmune diseases, collagen vascular diseases, heart failure, or poor general health status. In terms of ocular history, we included only subjects with no previous ocular surgeries, no history of lens alterations, macular diseases, or ocular hypertension, and patients with no dry eye symptoms or signs. All subjects had to have a corrected distance visual acuity (CDVA) better than or equal to 20/40 Snellen and a central corneal thickness ≥480 µm.

Two patients were finally identified and included in the study. Uncorrected distance visual acuity (UDVA) and CDVA were measured by a trained optometrist, and the surgeon (A.L.) repeated the manifest refraction and assessed cycloplegic refraction (after instillation of dilating drops) the day before surgery (9). All subjects underwent a full slit-lamp examination, intraocular pressure measurement with a Goldmann applanation tonometer (10), and dilated retinal and optic nerve evaluation. Tear function was evaluated with Schirmer test type 2 after instillation of anesthetic drops and with noninvasive tear breakup time using anterior segment optical coherence tomography (AS-OCT) MS-39 (CSO, Firenze, Italy). Cornea thickness, epithelial thickness, and pupillography were assessed with Placido topography and AS-OCT tomography MS-39. MS-39 combines spectral domain optical coherence tomography (SD-OCT)-based anterior segment tomography and Placido-disk corneal topography, and it is also able to create a map of the corneal epithelium. An 840 nm superluminescent light source is used to create corneal images with an axial, transverse, and depth resolution of 3.5 nm, 35 nm, and 7.5 mm, respectively (11). After calibration, three consecutive scans of subjects' eyes were acquired, and images with the best resolution for each eye were selected by an experienced ophthalmologist (M.P.). Biometric measures, as well as corneal thickness, were assessed with the built-in software of the machine. For contact lens users, soft contact lenses were stopped 30 days before the surgery, and rigid contact lenses 90 days before surgery. Informed written consent was obtained from all subjects.

Surgical technique of KLEx

Our technique for KLEx with the corneal lenticule extraction for advanced refractive correction (CLEAR) application has been published (12). A Ziemer Z8 femtosecond laser was used, characterized by a 1,045 nm wavelength, a pulse repetition rate of 10,000 kHz, a pulse duration of 250 fs, and a pulse energy of 0.1 mJ.

Briefly, sphere and cylinder manifest values were set in the machine software. Cap thickness, defined as the corneal tissue in front of the dissected lenticule, was customized to 120 µm. We used only one superotemporal incision of 2.5 mm to dissect the lenticule. Laser power and cut velocity were set to achieve a smooth pattern of cut and to reduce the risk of opaque bubble layer (OBL) formation.

After we applied a drop of oxybuprocaine anesthetic and a drop of preservative-free 0.2% sodium hyaluronate, the Ziemer Z8 handpiece (Ziemer Ophthalmic Systems) was docked, suction was activated, and the treatment zone was centered according to patients' Purkinje reflex.

Once lenticule delineation was completed, the incision created in the supero-temporal quadrant was scored and the lenticule separated with a Reinstein Lenticule Separator (Malosa MMSU1297S). Straight, fine-tip tying forceps (Malosa MMSU1414CS) were used to extract the lenticule.

Patients' postoperative treatment included dexamethasone 0.1% and netilmicin 0.3% eye drops to be used for 14 days according to a tapering regime. Lubricant drops and gel were prescribed to be used as needed. Patients were assessed at day 1, week 1, day 90, and day 180.

Case reports

Case 1 (male, 37 years old)

The patient, using a CIED for atrioventricular block, underwent KLEx for a refraction of OD −4.75 −1.25 × 15°, with CDVA 6/6^{-}; LE −4 −0.75 × 170°, with CDVA 6/6. Mean corneal thickness was 530 µm for the right eye and 535 µm for the left. Slit lamp examination showed unremarkable anterior and posterior segment status, and intraocular pressure (IOP) was within normal limits in both eyes. Expected cap thickness was set to 130 µm, with an optical zone of 6.8 mm and an expected residual stromal thickness greater than 290 μm. Surgery was uneventful, with a regular functioning of the laser and no subjective cardiological symptoms. At postoperative day 1 (POD1), visual acuity was 6/9 in both eyes, with a clear cornea. At 6 months, uncorrected visual acuity (UCVA) was 6/6 in both eyes, with a residual refractive error of $+0.25 \times 35^\circ$ in the right eye and $+0.25 + 0.25 \times 80^\circ$ in the left.

Case 2 (male, 37 years old)

The patient, using a CIED for Wolf-Parkinson-White syndrome, underwent KLEx for a refraction of OD $-6-0.25 \times 80^\circ$, with CDVA 6/6; LE $-7-0.50 \times 70^\circ$, with CDVA 6/6. Corneal thickness was 555 μm in both eyes, and clinical examination showed normal anterior and posterior segments and IOP. Expected cap thickness was 110 μm, with an optical zone of 6.5 mm and an expected residual stromal thickness greater than 290 μm. Surgery was uneventful also in this case. At POD1, visual acuity was 6/6 in both eyes, and corneas were clear. At 6 months, both eyes showed a visual acuity of 6/6, with a refraction of +0.50 sphere and $+0.50\ +0.25 \times 10^\circ$ in the right and left eyes (LE), respectively.

Discussion

In this study, we showed that KLEx represents a safe method to correct the refractive error in patients with CIED that cannot undergo excimer laser. In our two cases surgery was uneventful and perfectly tolerated by the patients, with no general or ocular side effects. A good refractive result was achieved. Cardiologic assistance during the procedure was not required.

The excimer laser is based upon the excitement of dimers by an electron beam (13), whereas the femtosecond laser is a solid-state, low-energy source, generating a very feeble electromagnetic field (14). The effect of an excimer laser and two different neodymium-doped yttrium aluminum garnet (Nd:YAG) lasers has been evaluated *in vitro* on CIEDs; their electromagnetic interference did not affect the CIEDs function (15). However, CIED manufacturers have previously discouraged the use of excimer lasers without a magnetic shield (7). Furthermore, the interference between the excimer laser and the CIED might modify the surgical settings, leading to cardiac stimulation, body shaking, and alterations in the capability of the CIED to restore the cardiac rhythm in case of severe arrhythmias (4). In a laboratory model of CIED, Sher et al. (15) evaluated the effect of ophthalmic laser electromagnetic interference on this cardiac device. This *in vitro* work showed that ophthalmic lasers can be used in patients with CEID because most of the energy produced by the excimer laser is absorbed by the cornea and attenuated by the tissues around the eye. However, this study has some limitations, such as the fact that the authors tested only a specific laser brand and the *in vitro* nature of the work that might differ from data produced by an *in vivo* setting. A retrospective study demonstrated no effects of excimer laser on 13 patients who undergone LASIK and PRK, with a ventricular arrhythmia occurring at two months considered unrelated to laser exposure (8). However, it is difficult to say if the cardiac event that happened two weeks later might or might not be related to the surgery and if the electromagnetic field generated by the excimer laser has damaged the CEID. Indeed, Skaff et al. reported a case of CEID that was disabled by a magnet implanted with a breast tissue expander in a patient that had undergone a left mastectomy (16). The woman did not experience any serious adverse event, but she underwent breast implant exchange with a magnet-free model to restore CEID function. Another issue with CIEDs is that a shock administered by the device during eye laser surgery can cause unexpected eye movements, loss of suction during applanation, and loss of eye tracking. These events might lead to uncompleted flap or lenticule creation and unexpected residual refractive error (17). If it is true that suction loss can happen in both KLEx and LASIK surgery, KLEx centration does not require an eye-tracking system (12), which could be disturbed by the CIED, reducing the risk of complications related to loss of pupil tracking. In some cases, surgeons can use a magnet to deactivate the CIED and proceed with LASIK surgery. However, this might arm the patients by avoiding the device to deliver a shock and restore the normal cardiac sinus rhythm (17). Thus, although in some cases LASIK surgery might be performed on these patients, we think that clinicians should consider patients safety over refractive error correction. Our work demonstrates that KLEx surgery can represent an effective method to correct refractive errors in patients with CIED. Further studies are needed to confirm these preliminary results.

Conclusion

In myopic candidates for refractive surgery with a CIED, KLEx can be considered a good alternative to excimer laser-based procedures such as PRK and LASIK, as the femtosecond laser employed in KLEx does not interfere with the CIED and needs no eye-tracking system that could be, in turn, be affected by the CIED. The limitations of this study are the small case series and the lack of a control group; these conditions were; however, not easy to fulfill because of the relative rarity of the situation and for ethical reasons.

Data availability statement

Upon request, authors can provide data used for this study.

Author contributions

AL: Conception and design, Draft review, Final approval. SVF: Conception and design, Draft review, Final approval. LA: Data analysis, Draft review, Final approval. MP: Data analysis, Draft review, Final approval. TM: Data analysis, Draft review, Final approval.

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Conflict of interest

The authors have no conflict of interest.

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