Outcome of second surgery in LASIK cases aborted due to flap complications

Nada S. Jabbur, MD, Elliott Myrowitz, OD, Jeffrey L. Wexler, MD, Terrence P. O'Brien, MD

Purpose: To describe the technique and timing of second refractive surgery after aborted laser in situ keratomileusis (LASIK) due to intraoperative flap complication and determine the final visual outcome.

Setting: Outpatient ambulatory laser vision correction centers.

Methods: This retrospective noncomparative case series included 16 patients (16 eyes) who had a second refractive surgery after initial LASIK surgery was aborted because of a flap complication. Charts were reviewed with attention to initial preoperative data, intraoperative details of the aborted LASIK, postoperative examination, possible causes of the flap complication, timing and technique of second refractive surgery, and final visual outcome.

Results: Causes of the aborted LASIK were identified in 13 of 16 eyes (81.2%) and included eye squeezing (5 eyes), loss of suction or machine failure (5 eyes), steep corneas (2 eyes), and learning curve of the surgeon (1 eye). The mean time until the second surgery was 135 days (range 49 to 372 days). Repeat flaps were created deeper and larger than the initially attempted flaps when possible. No patient had a final uncorrected visual acuity (UCVA) worse than 20/30 after the second surgery. Two eyes (12.5%) lost 1 line of best spectacle-corrected visual acuity.

Conclusion: A planned delayed reoperation after sufficient corneal healing following an intraoperative flap complication can result in satisfactory recovery of UCVA.

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Laser in situ keratomileusis (LASIK) has become the most common method of refractive surgery performed in the United States. During the informed consent process, it is incumbent upon refractive surgeons to inform patients about the possibility of a flap complication as well as the possibility of an excimer laser ablation complication. Flap complications encompass a variety of irregularities in flap reconstruction related to size, shape, and thickness; all can result in a delay in initial visual recovery as well as considerable patient dissatisfaction. Reoperations are usually performed a few months after the initial surgery, and patients usually recover satisfactory albeit delayed visual acuity. We reviewed the records of patients who had an aborted LASIK procedure because of flap complication followed by a reoperation and discuss possible causes of suboptimal flap creation and the timing, techniques, and outcomes of second surgeries.

Patients and Methods

The surgical logs of 3 surgeons (T.P.O., N.S.J., J.L.W.) were retrospectively reviewed to identify patients who experienced an intraoperative flap complication necessitating postponement of laser vision correction followed by a delayed second refractive surgery.

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From the Refractive Surgery Center, The Wilmer Eye Institute, The Johns Hopkins University School of Medicine (Jabbur, Myrowitz, O'Brien), Baltimore, and Physicians Eye Care Center (Wexler), Columbia, Maryland, USA.

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Reprint requests to Nada S. Jabbur, MD, The Wilmer Eye Institute, The Johns Hopkins University School of Medicine, Green Spring Station, 10755 Falls Road, Suite 110, Lutherville, Maryland 21093, USA. E-mail: nsjabbur@jhmi.edu.

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Table 1. Summary of patient information.

		Preoperative Data for First Surgery				Data for Second Surgery						Final Follow-up Since 2nd Surgery (Mo)
Patient	Age (Y)/ Sex	Manifest Refraction Before 1st Surgery	MRSE 1 (D)	BSCVA Before 1st Surgery	Keratometry Reading	Time Between 1st and 2nd Surgery (d)	Manifest Refraction Before 2nd Surgery	MRSE 2 (D)	BSCVA Before 2nd Surgery	Final UCVA	Final BSCVA	
1	54 M	–5.0 +0.25 × 50	−4.88	20/20	44.25/43.75	49	Same as initial	−4.88	20/20	20/20	20/20	11
2*	44 F	–7.75 +1.75 × 145	−6.88	20/20	42.0/43.0	65	–7.75 +2.0 × 145	−6.75	20/20	20/30	20/20	3
3	27 M	–3.25 +1.5 × 10	−2.50	20/15	43.5/43.75	72	Same as initial	−2.50	20/15	20/20	20/15	9
4*	47 M	–8.0 +1.25 × 85	−7.38	20/20	43.5/45.25	170	Same as initial	−7.38	20/20	20/20	20/20	2
5*	39 M	–5.0 +0.5 × 75	−4.75	20/20	45.25/45.75	96	–5.50 +0.50 × 50	−5.25	20/20	20/20$^+$	20/20$^+$	2
6*	40 F	–9.0 +0.25 × 35	−8.88	20/20	45.0/45.75	372	–7.50 +0.50 × 40	−7.25	20/25$^-$	20/25$^-$	20/25$^+$	4
7	37 M	–1.50 sph	−1.50	20/15	42.25/42.62	79	–1.50 +0.25 × 140	−1.38	20/15	20/15	20/15	9
8	54 F	–4.0 +0.50 × 120	−3.75	20/20	43.5/43.75	99	Same as initial	−3.75	20/20	20/30	20/20	3
9	30 M	–7.25 +3.50 × 90	−5.50	20/20	43.0/45.75	56	–6.50 +3.50 × 85	−4.75	20/20$^-$	20/25$^-$	20/20$^-$	9
10*	39 F	–4.25 sph	−4.25	20/20	43 sph	284	Same as initial	−4.25	20/20	20/30	20/20	7
11	49 F	–9.25 +1.75 × 75	−8.37	20/20	43.5/46.0	198	Same as initial	−8.37	20/20	20/30	20/20	10
12*	65 M	+1.50 sph	+1.50	20/20	42.5/43.12	172	+1.75 sph	+1.75	20/20	20/20	20/20	13
13*	40 F	–4.25 sph	−4.25	20/20	43.12/43.62	100	–4.0 sph	−4.0	20/20	20/20	20/20	2
14	55 F	–8.25 +1.5 × 75	−7.50	20/20	48.25/49.75	99	–8.50 +2.0 ×75	−7.50	20/20	20/30	20/20	2
15	36 M	–2.0 sph	−2.0	20/20	47.5/47.75	123	Same as initial	−2.0	20/20	20/30	20/25$^+$	11
16	44 M	–4.25 sph	−4.25	20/20	44.5/45.0	100	–4.25 +1.0 × 177	−3.75	20/20	20/25$^-$	20/20	7

BSCVA = best spectacle-corrected visual acuity; MRSE = manifest refraction spherical equivalent; NA = not available; sph = sphere; UCVA = uncorrected visual acuity
*Patient referred to T.P.O., N.S.J., or J.L.W after initial aborted LASIK

Two surgeons (T.P.O, N.S.J.) perform laser vision correction in an academic clinical practice at the Wilmer Eye Institute, The Johns Hopkins University School of Medicine, Baltimore, Maryland, and 1 surgeon (J.L.W.) practices refractive surgery at the Physicians Eye Care Center, Columbia, Maryland.

Sixteen medical records (16 eyes) were identified. Fifteen eyes had repeat LASIK and 1 eye, photorefractive keratectomy (PRK) after an initial aborted LASIK between September 1998 and December 2000. Seven of the 16 patients were referred to 1 of the 3 surgeons for a possible reoperation after initial complicated surgery performed elsewhere.

Chart information pertinent to the initial and second surgeries was recorded. This included age, sex, preoperative manifest refraction (MR), as well as best spectacle-corrected visual acuity (BSCVA), interval between first and second surgeries, and keratometry readings. Surgical details including keratome specifications (style, ring size, depth of cut), eye movement or machine failure during flap creation, and location and size of the abnormal flap were also recorded. Other recorded information was the presence of anterior basement membrane disease (ABMD) and diabetes mellitus (DM), the surgeon's LASIK learning curve, preoperative and intraoperative data, timing and technique of the reoperation, and final visual outcome.

Results

Preoperative Data

Age/Sex. Sixteen patients (16 eyes) were identified; 7 were women and 9, men. The mean age at the time of the first LASIK was 43.60 years (range 27 to 65 years) (Table 1).

Manifest Refraction and BSCVA Before Aborted LASIK. The refraction in the 1 hyperopic patient was +1.50 diopters (D). The mean myopia in the other 15 eyes was −5.45 D (range −1.5 to −9.0 D), the mean cylinder was +0.85 D (range +0.25 to +3.00 D), and the mean manifest refraction spherical equivalent (MRSE) was −5.02 D (range −1.50 to −8.37 D) (Table 1).

Keratometry Measurement. The mean preoperative keratometry measurement at the time of the initial LASIK was 44.44 D (range 42.50 to 49.0 D) (Table 1).

History of ABMD or DM. No patient had a history of ABMD or DM.

Surgeon Learning Curve. Seven of the 16 patients were self-referred or referred by external surgeons; only 1 of the complicated flaps was associated with a novice refractive surgeon. Each of the 3 surgeons who experienced the other 9 complicated flaps and/or carried out the second surgery had performed at least 1000 refractive procedures.

Interval Between Initial and Second Refractive Procedures. The mean time between the aborted LASIK and the second surgery was 135 days (range 49 to 372 days) (Table 1).

Table 2. Surgical details of the first and second surgeries.

	First Surgery			Second Surgery					
Patient	Keratome	Depth of Cut (μm)	Ring Size (mm)	Keratome	Depth of Cut (μm)	Ring Size (mm)	Description of Abnormal Flap	Presumed Cause for Flap Complication	Use of BCL After First Surgery
1	H	160	8.5	H	180	8.5	Incomplete 2/3 flap size	Failure of keratome to advance	n
2*	H	160	9.5	H	180	9.5	Incomplete 2/3 flap size	Failure of keratome to advance	n
3	H	180	9.5	A	180	9.5	Incomplete 1/2 flap size	Failure of keratome to advance	y
4*	H	na	na	H	180	9.5	Incomplete 1/3 flap size, temporal cut	Unknown	
5*	A	160	8.5	H	180	8.5	Central small free flap	Loss of suction	y
6*	H	160	8.5	H	180	8.5	Incomplete flap with buttonhole	Learning curve of surgeon and loss of suction	y
7	H	160	9.5	H	180	9.5	Incomplete 2/3 flap size	Squeezed eye	n
8	H	160	8.5	A	180	9.5	Thin inferior 1/2 flap size	Squeezed eye	n
9	A	180	9.5	A	180	9.5	Central thin free flap	Squeezed eye	y
10*	na	na	na	H	180	8.5	Incomplete 2/3 flap size	Unknown	na
11	H	180	8.5	H	160	9.5	Incomplete 1/2 flap size	Squeezed eye	n
12*	H	na	na	A	180	9.5	Thin inferior 1/2 flap size	Unknown	y
13*	H	160	9.5	H	180	8.5	Incomplete 1/2 flap size inferotemporal	Loss of suction, learning curve of surgeon, and keratome caught on lip and drape	y
14	H	180	8.5	PRK	NA	NA	Normal size flap with buttonhole	Steep keratometry	y
15	M	130		H	180	8.5	Buttonhole	Steep keratometry	y
16	H	180	9.5	H	180	9.5	Incomplete 1/3 flap size	Squeezed eye	n

A =Amadeus; BCL = bandage contact lens; H = Hansatome; M = Moria; n = no; na = not available; NA = not applicable; PRK = photorefractive keratectomy; y = yes
*Patient referred to T.P.O., N.S.J., or J.L.W. after initial aborted LASIK

The aborted LASIK surgery occurred in the first eye in 10 of 16 eyes. In 1 of the 10 patients, the second-eye surgery was performed without complication in the same surgery session. In the other 9 patients, the second-eye surgery was deferred to a later time, immediately after the reoperation in the first eye. No bilateral complications were encountered.

Intraoperative Data

Microkeratome Specifications and Flap Description in Both Surgeries. All flap complications resulted in abnormal size, shape, or thickness of the flap. No corneal epithelial abrasions were included in the study. No patient had excimer laser ablation at the time of the initial surgery.

Details of the microkeratomes used in both surgeries as well as the shape of the flap obtained at the time of the initial LASIK are summarized in Table 2. Twelve of the initial flaps were created using the Hansatome® microkeratome (Bausch & Lomb). Two were created using the Amadeus microkeratome (Advanced Medical Optics) and 1, using the Moria model M2 unit. In 1 case (#10), the microkeratome used initially could not be identified.

Fifteen of the 16 reoperations were LASIK procedures. Eleven were performed using a Hansatome microkeratome; 10 were at a depth different from that of the initial surgery. Nine of the 15 reoperations were performed using a larger suction ring than that used initially. Four of the 15 were performed with a different microkeratome than that used in the initial surgery (Table 2).

Surgical Observations and Associations During First Surgery. Causes of aborted LASIK were identified in 13 of 16 eyes (81.2%). Five patients were noted to squeeze their eyes after the flap cut was initiated with a resultant loss of suction. In 3 eyes, there was an apparent loss of suction without observed squeezing. Machine failure (jamming of the microkeratome) was experienced in 3 other eyes. The steep corneas in 2 eyes and the learning curve of 1 referring surgeon whose Hansatome got caught by the lid and drape were possibly implicated in the other flap complications. In 3 eyes, no cause of flap complication could be identified (Table 2).

Description of Abnormal Flaps. Incomplete flaps occurred in 10 eyes (62.5%). The edge and/or hinge of 8 of the 10 flaps was within the area overlying the

entrance pupil. The 2 remaining eyes had small, peripheral incomplete flaps.

Thin flaps and/or free flaps occurred in 3 eyes. Two were central (involving the area overlying the entrance pupil), and 1 was thin and peripheral.

Buttonhole flaps occurred in 3 eyes. One occurred within a normal-sized flap and 1 as part of a two-third-sized flap; 1 was an isolated small free flap in a central location. All were located within the area overlying the entrance pupil. Two of the buttonholes were associated with steep keratometry readings (higher than 47.5 D) (Table 1).

Therapeutic Bandage Contact Lens Use. A bandage contact lens (BCL) was placed on 8 of 16 eyes (50%) at the conclusion of the initial LASIK surgery. These covered thin, free, and buttonhole flaps (Table 2) and were kept in situ for 1 to 5 days postoperatively.

Surgical Observations During Second Surgery. One patient (#6) experienced significant flap striae that required flap repositioning after the second surgery. The final uncorrected visual acuity (UCVA) improved without visual sequelae. No other complication such as epithelial ingrowth and diffuse lamellar keratitis were noted after either surgery.

Postoperative Data

Postoperative MR and MRSE Before and After Aborted LASIK. Seven of 16 eyes (43.75%) had similar MRs after the aborted LASIK compared with the preoperative measurements. In 1 additional eye, the refraction was essentially unchanged, with similar SEs postoperatively and preoperatively (Table 1).

Preoperative BSCVA Compared with Postoperative BSCVA After Initial Aborted LASIK. One patient (#6) lost 1 line of BSCVA after the initial LASIK surgery and before proceeding with the reoperation. The patient's MR changed after the initial surgery (Table 1).

Final UCVA and BSCVA After Second Refractive Surgery and Loss of BSCVA. The mean follow-up time after the second surgery was 8.3 months (range 2 to 13 months). In all patients, the final UCVA was equal to or better than 20/30. Fourteen of 16 eyes (87.5%) retained the BSCVA. Two eyes (12.5%) lost 1 line of BSCVA: One (#15) had a central buttonhole flaps; the final UCVA and BSCVA were 20/30+ and 20/25, respectively. The other patient (#6) lost 1 line of BSCVA after the abnormal flap. He had the highest degree of preoperative myopia in the series (Table 1).

Photorefractive Keratectomy After Aborted LASIK. One patient (#14) had a 1.5 mm buttonhole in the center of an otherwise adequate-sized flap. Ninety-nine days after the initial surgery, photoastigmatic refractive keratectomy was performed using the Visx Star S3 excimer laser system. This was performed in a transepithelial approach starting with 40 μm of epithelial ablation followed by an anterior stromal ablation, according to the nomogram-adjusted MR.

Discussion

The incidence of intraoperative flap complications varies depending on the type of complication and the learning curve of the surgeon. Corneal abrasions are reported to occur in about 5% of LASIK cases[1] and can be associated with ABMD,[2] dry eyes,[3] increased age,[3] and DM.[4] Even though the occurrence of intraoperative corneal abrasions may be reduced with newer microkeratome designs (eg, zero-compression model Hansatome), intraoperative epithelial injury is possible in an individual patient with any microkeratome design.

Intraoperative abrasions usually result in good final visual acuity, and therefore many surgeons may opt to proceed with laser ablation at the time of the initial surgery.

Flap complications that cut through Bowman's layer are less common but tend to be more serious, especially if the abnormal flap involves or extends through the area overlying the entrance pupil, as this can cause more qualitative visual symptoms.

Thin flaps occur in 0.3% to 0.75% of cases, buttonhole flaps in 0.2% to 0.56%, and incomplete flaps in 0.3% to 1.2%.[5–7] In these cases, the surgeon should be cautious and abort LASIK surgery if the area for stromal ablation is insufficient for the diameter of the ablation.[8,9] The surgeon can return later, after corneal healing, and proceed with a second surgery to achieve a better final visual outcome. Predisposing factors leading to thin and buttonhole flaps include flat (less than 42 D) or steep (greater than 47 D) corneas,[10] loss of suction (deep orbit, conjunctival chemosis, surgeon's learning curve, eye movement),[11] failure of synchronized keratome movement with oscillation of the blade,[11] and damaged blade.[12] Failure of the microkeratome can be due to

obstruction of the microkeratome path by any debris including lashes, lid margin, skin, or drape material. In addition, regular maintenance for the motor of the microkeratome is essential to ensure proper functioning and avoid failure. With improvements in microkeratome design and safety features, the possibility of a serious, full-corneal-thickness flap complication can be eliminated.[13] The availability of suction rings of different sizes provides the surgeon with better choices when faced with flat or steep corneas.[14]

In our series, the most commonly identified predisposing factor was eye squeezing and loss of suction despite the surgeon's constant reassurance of the patient at the time of surgery. Squeezing the eyelids is a known possible undesired reaction of the anxious LASIK patient that is usually encountered during the application of suction to the eye. It can be caused by several phenomena, and these can be eliminated if the surgeon is aware of them and prepares the patient. First, patients may feel pressure from the increased suction around the limbus and cornea. This may be compounded in patients who have shallow orbital anatomy. Second, patients may be startled by the disappearance of the fixation light at the time of intraocular pressure (IOP) rise from suction during flap creation. Finally, depending on the particular microkeratome design, lashes and/or the lid margin may be engaged by the microkeratome at the beginning of the pass (eg, Hansatome) or at the end of the forward pass (eg, Automated Corneal Shaper® [Bausch & Lomb]). It is imperative to alert patients preoperatively as to the sequence of events to reduce anxiety. It is also important to provide a continuous, calm dialogue with instructions during the procedure to improve compliance with the surgeon's recommendations.

The steps of the retreatment procedure were carefully reviewed with the patients in our series to avoid a negative result similar to that in the initial surgery. In some instances, a mild oral sedative agent (eg, diazepam [Valium®], 5 to 10 mg) was provided preoperatively for additional relaxation and reduction of anxiety. Care must be taken to avoid oversedation, which can reduce patient cooperation.

In rare instances, one can obtain false conjunctival suction rather than true scleral suction. It is essential to ensure a proper increase in IOP by asking the patient for verbal confirmation of the disappearance of the microscope lights; by direct measurement with the applanation tonometer to verify that when in contact with the cornea, the indentation ring appears smaller than the ring on the tonometer; and by visualization of pupil dilation. Finally, one needs to be familiar with the location of the fenestration(s) for the suction on the back of the suction ring to ensure it is well apposed to the sclera.

Three of the eyes in our study had buttonhole flaps; 2 were associated with steep corneas and 1, with normal keratometry (45.37 D). Leung et al.[15] describe 6 cases of buttonhole flaps in eyes with a mean keratometry of 44.2 D. In our series, 2 of the 3 patients also experienced a 1-line loss of BSCVA. Two of the patients had repeat LASIK and 1, transepithelial PRK.

After obtaining an incomplete, partial, or buttonhole flap, the LASIK surgeon should inspect the abnormal lamellar section and carefully replace and reposition the abnormal corneal tissue to achieve the best realignment. Excimer laser ablation should usually be deferred at the time of a flap complication that results in an irregular, incomplete flap. Placement of a therapeutic BCL is recommended to protect the irregular flap of corneal tissue from the action of the eyelids as well as to promote healing of the abnormal corneal tissue. Adjunctive pharmaceutical agents to optimize corneal wound healing including topical antibiotics, corticosteroids, nonsteroidal antiinflammatory drugs, and preservative-free artificial tears are recommended.

Our patients were managed with topical fluoroquinolone (ciprofloxacin 0.3%, ofloxacin 0.3%, and levofloxacin 0.3%), preservative-free ketorolac tromethamine 0.5%, fluorometholone 0.1%, and preservative-free artificial tears for 7 to 10 days. In the patient who had PRK, the fluorometholone was initiated 4 times a day and tapered to cessation over 4 weeks. Systemic agents such as oral doxycycline to inhibit the action of induced collagenases and vitamin C to help promote new collagen synthesis in the injured cornea are also suggested by some refractive surgeons. No patient in our series was given these adjunctive agents. The therapeutic BCL remained in place until the irregular, incomplete flap was observed to adhere and reepithelialization was complete (range 1 to 5 days). The refractive power of the BCL was adjusted to reduce the effects of anisometropia if the complication occurred in the second eye after successful laser vision correction with near emme-

tropia in the first eye. This allowed more useful visual function while waiting for adequate healing of the laser vision correction.

The techniques of reoperation after an abnormal flap include repeat LASIK using conventional keratomes, PRK, or possibly treatment with a femtosecond laser.[16] With repeat LASIK, it is critical to avoid the initial lamellar interface and a free roll of stromal tissue after the second cut. To prevent this complication, we selected a different microkeratome suction ring and/or plate to cut a larger, deeper, and more temporal or inferior edge of the new flap (Table 2).

In the case of buttonhole (or donut-shaped) flaps, we found it best not to treat the patient primarily with the laser even if there were an occult buttonhole resulting in a small mound of epithelium above Bowman's layer and no hole in the remaining epithelium in the flap. We have observed that it is not uncommon to develop mild stromal haze in that central area. Therefore, recutting a flap may not be the optimal solution as it will not solve the problem of superficial haze.

In the patient who had PRK, it was our recommendation to proceed 4 to 6 weeks later using combined phototherapeutic and refractive keratectomies (PTK/PRK) to smooth the surface and eliminate the original interface over the central 5.0 to 6.0 mm of the cornea. In this case, waiting up to a year was not ideal as we were worried that the cornea might heal with more adhesion and develop greater amounts of haze. The PTK/PRK method was selected to monitor epithelial fluorescence to decide when to switch from PTK to PRK.[17–19] The risk for haze secondary to ablating over a flap is small if the residual refractive error and required corrective ablation is small. The application of topical mitomycin C should not be routine in the treatment of smaller residual refractive errors (less than −6.0 D) because of the narrow therapeutic index for this agent and the potential for excessive, unnecessary toxicity.

In the case of a flap complication secondary to flat or steep corneas when central scarring is not anticipated, it would be possible to use a conventional keratome to recut a flap or perhaps a femtosecond laser to create a customized second flap.[16]

Although the recommended timing of PTK/PRK after buttonhole flaps is 4 to 6 weeks and has been performed as early as a few weeks,[20] it is generally advisable to wait longer with other flap complications. Waiting at least 3 months before repeat LASIK flap creation with a microkeratome[21] is advisable, as the original flap is likely to be more adherent, which allows safe recutting.

In our series, all patients recovered a UCVA of at least 20/30. We speculate that the satisfactory outcomes may be due to the lack of preoperative monocular diplopia, the lack of central haze in buttonhole flaps, and the preservation of good BCVA before the second surgery. No conclusions about complication rates with the various manufacturers can be drawn from our small observational case series. We also speculate that the refractive surgeon should have lower expectations in free flaps or buttonhole flaps due to possible misalignment and scarring. In the patient who had a free central flap, there was a change in MR after the first surgery, which might have been the result of flap misalignment at the end of the case or striae contributing to irregular astigmatism. However, this resulted in the loss of only 1 line of BSCVA. Thus, placement of a mark on the corneal surface to aid careful realignment of a free cap under these circumstances remains a beneficial practice.

All our patients were subjectively satisfied with the results of the repeat surgery, and no additional retreatments were needed.

Conclusion

Laser in situ keratomileusis flap complications may occur even in the hands of experienced surgeons. Delay of the excimer laser ablation is prudent depending on the severity of the flap complication. Proper handling of the irregular, incomplete flap with careful repositioning of corneal tissue followed by placement of a therapeutic BCL is essential. In our series, the second surgeries were performed a few months later after an adequate period of corneal wound healing and resulted in good visual recovery with high patient satisfaction.

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