European Journal of Ophthalmology / Vol. 13 no. 2, 2003 / pp. 139-146

Complications of laser *in situ* keratomileusis (LASIK)

K.F. TABBARA[1,2], H.F. EL-SHEIKH[1], C.L. VERA-CRISTO[1]

[1] The Eye Center and The Eye Foundation for Research in Ophthalmology, Riyadh
[2] Department of Ophthalmology, College of Medicine, King Saud University, Riyadh - Saudi Arabia

PURPOSE. *To report major complications associated with laser* in situ *keratomileusis (LASIK).*
METHODS. *Twenty-four eyes of 23 patients who underwent LASIK in different centers in Saudi Arabia were included. There were 9 women and 14 men. The age range was from 20 to 65 years. Nineteen of the 23 patients had been referred to the Eye Center for management. All patients had a complete ophthalmologic examination, refraction, corneal topography and pachymetry.*
RESULTS. *The 24 eyes of 23 patients had complications consequent to LASIK. Thirteen were intraoperative complications, and 11 postoperative. Ten (44%) of the 23 cases were related to the corneal flap, two (9%) with intraocular perforation with the microkeratome. Three (13%) had photoablation-related complications. Postoperative complications included three (13%) cases of infections, four (17%) stromal-interface related problems, one (5%) who developed interface vascularization, and one (5%) with non-ischemic central retinal vein occlusion.*
CONCLUSIONS. *Although LASIK is a safe and effective procedure, a small number of patients may suffer serious complications that can even lead to visual loss. The procedure must be carefully performed by qualified surgeons. (Eur J Ophthalmol 2003; 13: 139-46)*

KEY WORDS. *Laser* in situ *keratomileusis (LASIK), Excimer laser, Cornea, Automated lamellar keratectomy (ALK), Myopia*

Accepted: July 15, 2002

INTRODUCTION

Laser *in situ* keratomileusis (LASIK) has proved to be a safe and effective procedure for the treatment of myopia, hyperopia and astigmatism. Barraquer developed a procedure known as keratomileusis designed to preserve Bowman's layer and the overlying epithelium by creating a central lamellar disc of the cornea which was freeze-dried and cryolathed in its deep surface to achieve the correction of the refractive error (1). Luiz Ruiz developed an automated micro keratome so the refractive cut could be made by a second pass of the microkeratome on the exposed corneal stroma rather than on the back of the lamellar disc (2). This procedure was referred to as automated lamellar keratoplasty or ALK, but suffered from certain limitations such as lack of accuracy and irregular astigmatism created by the microkeratome. Burratto subsequently pioneered a technique whereby a 300 micron thick corneal cap was removed and the back surface was ablated with the excimer laser to correct the error (3). The cap was later repositioned and sutured with a continuous 10-0 nylon suture. This procedure evolved to the creation of a lamellar flap with the subsequent ablation of the underlying stromal bed with the excimer laser by Pallikaris who developed a technique with a nasally-hinged corneal flap that could be repositioned more accurately into the cornea without sutures

1120-6721/139-08$04.00/0

(LASIK) (4, 5). This had the advantage of reducing the risk of flap damage or loss as well as helping to prevent dessication of the interface or contamination with debris.

In Saudi Arabia, ophthalmologists have performed LASIK procedures for several years (6-8). Initially, the Chiron automated corneal shaper was used to create the flap, and more recently the Hansatome with a superior-hinged flap has proved a welcome advance on the automated corneal shaper. Fortunately, there is only a low incidence of vision-threatening complications in LASIK but some of these can lead to loss of vision. It is therefore important that we continue reporting such complications in order to devise effective means for their prevention.

PATIENTS AND METHODS

A total of 24 eyes of 23 patients that had undergone LASIK by eight ophthalmologists in Saudi Arabia. Nineteen of them were referred to the cornea clinic at the Eye Center in Riyadh, Saudi Arabia and four had their LASIK procedures at the Eye Center. All underwent complete ophthalmologic examination including visual acuity, intraocular pressure, corneal topography, refraction, keratometry and pachymetry. Whenever indicated, the ophthalmologist who had performed the procedure was contacted and the type of complication was verified as far as possible. All patients underwent Excimer laser photoablation of the stromal bed with the Chiron Keracor 117C or NIDEK EC 5000 after creating a corneal flap with the microkeratome. Seventeen cases had a 160 µm corneal flap made with a nasal hinge, using the automated microkeratome (Chiron), and six cases had a superior hinge of the flap using the Hansatome or Moria microkeratome.

RESULTS

There were nine women and fourteen men. The age range was 20 to 65 years with a mean age of 26.2 years. Table I sets out the main pre- and post-operative data, complications, and final outcome among the 23 patients. Ten (44%) eyes presented with complications related to flap creation, eight (35%) (cases 1-8) without perforation and two (9%, cases 9 and 10) with corneal perforation. In three (13% - cases 1, 2, 3) the corneal flap was lost. Their postoperative best-corrected visual acuity (BCVA) ranged from 20/40 to 20/60. In two (8%) (cases 4 and 5), the corneal flap was incomplete and the procedure had to be aborted after replacing the flap over the stromal bed. The postoperative BCVA was not seriously affected. In case 6, the surgeon produced an incomplete flap and immediately proceeded to create a new flap, resulting in a bifurcated small flap with the cut line running from 5 o'clock to 11 o'clock, bisecting the papillary zone. The final outcome was residual myopia and irregular astigmatism due to an irregular corneal surface as shown by the corneal topographic changes, with two lines lost in BCVA (Fig. 1). Two cases (8%), 7 and 8, had a doughnut-shaped flap (buttonhole) causing interruption of the procedure and replacement of the flap, with two lines loss in BCVA. Two patients, 9 and 10, had perforation of the cornea because the depth plate was not placed in the microkeratome. The cornea was sutured with interrupted 10-0 nylon sutures. In case 9, the iris was cut, resulting in superior and inferior iridectomies (Fig. 2); postoperative BCVA was 20/50. Case 10 suffered perforation and lens injury for the same reason. The cornea was sutured and cataract extraction was done, with IOL implantation. The patient ended up with high myopia and astigmatism, and his BCVA was 20/25 with a hard contact lens.

Three (13%) eyes had photoablation-related complications. Case 11 underwent myopic LASIK followed later by an enhancement procedure that resulted in marked central corneal thinning with a significant increase in myopia, and astigmatism, and marked loss of BCVA. Case 12 showed overcorrection after the LASIK procedure for hyperopia, with significant astigmatism and myopic shift, and the BCVA decreased markedly. The surgeon reported a surge in the energy of the equipment he was using (NIDEK EC 5000) during the operation. Case no. 13 had hyperopic LASIK, resulting in a very steep cornea. Postoperatively, vision with glasses was 20/120, but was corrected to 20/30 with hard contact lenses. Figure 3 shows the pre- and post-operative corneal topography.

Four (17%) eyes (patients 14, 15 and 16) presented with significant postoperative corneal haze. Case 14 (bilateral case) and case 15 developed corneal thinning with scar and over-correction of the myopia, resulting in hyperopic shift and loss of 4, 3 and 5 lines

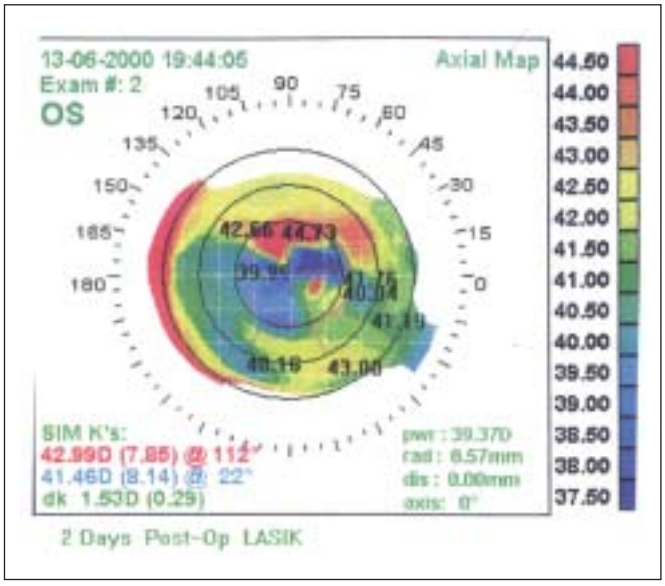

Fig. 1 - *Post-operative corneal topography of case no. 6 with a bifurcation of the corneal flap.*

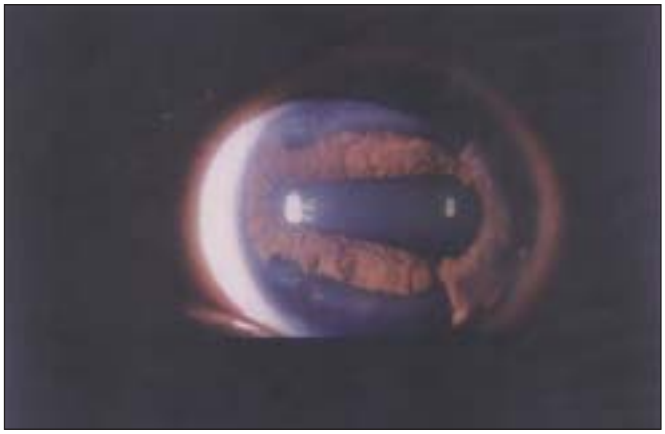

Fig. 2 - *The right eye of case no. 9. This patient had corneal perforation and anterior chamber penetration with horizontal iridectomies superiorly and inferiorly. The plate of the automated corneal shaper was missing during the procedure.*

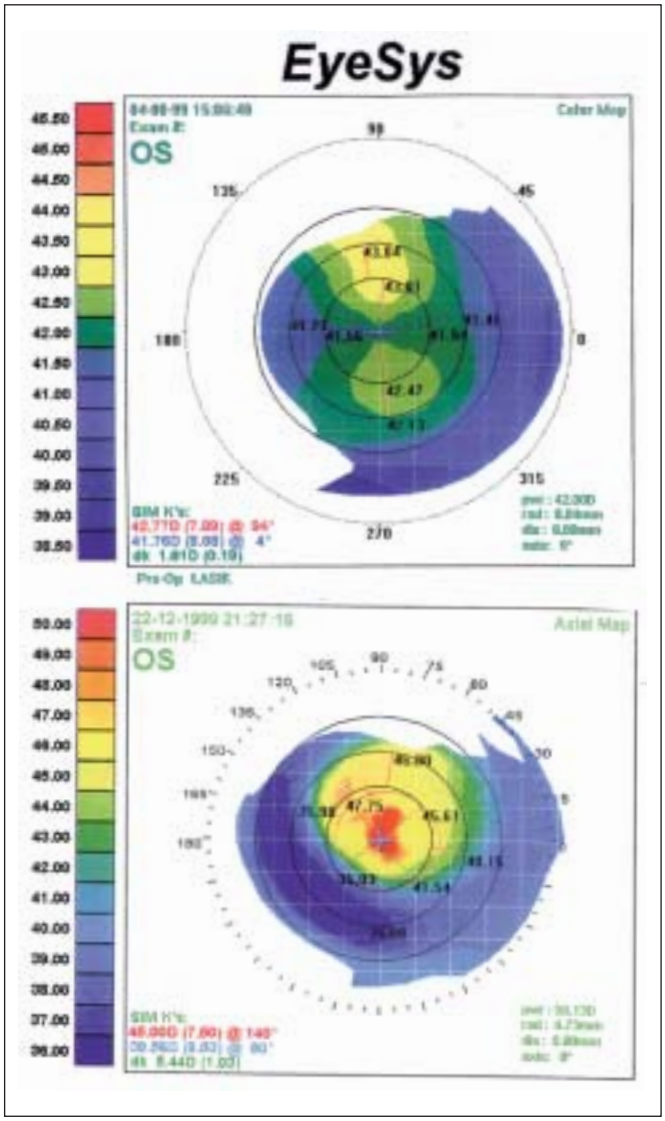

Fig. 3 - *Pre- and post-operative corneal topography of case no. 13. Note the excessive postoperative central steepening. The ablation appears decentered.*

in BCVA. One patient (no. 16) received topical steroids for four months and developed cataract. He underwent phacoemulsification with posterior capsule rupture in the same institution. Anterior vitrectomy was done and an IOL was placed in the sulcus. Two months later, he developed a retinal detachment which was repaired. Subsequently, he developed glaucoma and underwent trabeculectomy with mitomycin C. Two months after this procedure, he presented with a herpetic keratitis that healed with topical and systemic antiviral agents. His final BCVA was 20/400.

Three eyes (13%) had immediate postoperative infection (cases 17-19) caused by *Staphylococcus aureus*. One patient (case 17) had an abscess with severe loss of BCVA; the other two developed severe infiltration of the interface with loss of 2 and 4 lines of BCVA. All three had irrigation with antibiotics under the flap and topical antibiotics. In addition, case 18 received systemic antibiotics and the other two received subconjunctival antibiotics as adjunctive therapy. Two eyes (8%) developed epithelial ingrowth in the interface, which was removed six months after

TABLE I - MAJOR COMPLICATIONS OF LASIK AMONG 23 PATIENTS

Case No.	Age/Sex/Eye	Microkeratome	Sph. Equival. Preop	Sph. Equival. Postop	BCVA Preop	BCVA Postop	Excimer laser	Complication	Final Outcome
1	28/M OD	ACS	-5.00	+4.50	20/20	20/40	N	Free cap loss	Hyperopia
2	44/M OS	ACS	-4.00	+3.50	20/20	20/50	N	Free cap loss	Hyperopia
3	22/M OS	Moria	-5.0		20/20	20/60		Free cap loss and central scar	Hyperopia
4	28/M OD	ACS	-2.25	-2.00	20/16	20/25	N	Patient moved during the procedure and corneal flap was partially amputated and replaced Procedure postponed	Flap replaced Procedure postponed
5	37/M OS	ACS	-8.00	-0.50	20/15	20/20	C	Incomplete flap, replaced (Procedure postponed)	Re-operated (3 months later)
6	32/M OS	Hansatome	-4.5	-2.0	20/20	20/35		Incomplete corneal flap, new flap was attempted in the same session resulting in a bifurcated flap	Myopic Astigmatism with irregular corneal surface
7	49/M OS	ACS	-5.50	-1.25	20/16	20/30	C	Central buttonhole Re-operated (PRK)	Induced astigmatism
8	26/M OS	ACS	-11.0	-1.50	20/25	20/40	C	Buttonhole Procedure aborted Wrong plate serial number Re-operated (four months later)	Residual error
9	26/F OD	ACS	-5.50	-6.00	20/20	20/50	N	Ocular perforation iris tissue cut	Cornea sutured horizontal iridotomies
10	27/M OD	ACS	-6.0	-8.0	20/20	20/25	N	Ocular perforation and lens injured	Cornea suture and cataract extraction with IOL implantation High myopia and astigmatism
11	22/M OD	ACS	-4.50	-12.00	20/20	20/200	N	Enhancement procedure Flap striae Central thinning	LASIK-induced Keratoconus (K 63D) High myopia

to be continued

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Case No.	Age/Sex/Eye	Microkeratome	Sph. Equival. Preop	Sph. Equival. Postop	BCVA Preop	BCVA Postop	Excimer laser	Complication	Final Outcome
12	48/F OS	Hansa	+4.00	-12.50	20/20	20/120	N	Small corneal flap (7.0 mm) energy surge	High myopia with astigmatism Interface haze
13	20/F OS	Hansa	+7.0	+3.00	20/20	20/120	C	Excessive steepening of central cornea	Corrected by hard contact lens achieved 20/30
14	27/M OU	Hansa	-3.50 -3.50	+5.00 +3.50	20/20 20/20	20/60 20/50	N N Nidek EC 5000?	Interface haze (overcorrection) Central corneal thinning (bilateral)	Interface haze Corneal thinning OD 320 µm OS 300 µm
15	24/M OD	ACS	-5.50	+2.00	20/20	20/70	N	Irregular corneal flap with subepithelial scar	Corneal scar Stromal thinning
16	32/M OS	ACS	-8.50		20/20	20/400	N	Small corneal flap Interface haze treated with four months' steroid therapy	Cataract (Phaco with PC rupture with PC-IOL) Retinal detachment (vitrectomy) Glaucoma (trabeculectomy) Herpetic keratitis
17	22/F OD	ACS	-4.50	-1.50	20/15	20/100	C	Abscess in interface *Staphylococcus aureus*	Partial melting of flap Corneal haze
18	28/F OS	ACS	-6.00	+1.00	20/15	20/30	N	*Staphylococcus aureus* infection	Corneal haze
19	24/F OD	ACS	-5.00	-1.25	20/15	20/50	N	*Staphylococcus aureus* infection	Corneal scarring
20	43/M OS	ACS	+5.00	+1.00	20/20	20/30	C	Epithelial ingrowth outside visual axis	Irrigation under flap - Argon laser
21	29/F OD	ACS	-3.50	-0.75	20/20	20/25	N	Epithelial ingrowth under the flap	Irrigation, scraping
22	38/F OS	ACS	-9.50	-2.00	20/35	20/30	C	Interface vascularization	Interface vascularization
23	65/M OS	Hansa	+2.50	plano	20/20	20/200	C	Non-ischemic central retinal vein occlusion developed 4 days after LASIK	Cystoid macular edema

ACS = Chiron Automated Corneal Shaper; Hansa = Hansatome; C = Chiron Technolas 117C or 116; SE = Spherical equivalent; VA = Visual acuity; N = NIDEK; BCVA = Best corrected visual acuity; BUVA = Best uncorrected visual acuity

the procedure in case 20, and four months after the procedure in case 21. One eye (4%) developed interface vascularization that did not affect his postoperative vision (case 22). Case 23 was a 65-year-old male with hyperopia. His BCVA was 20/20 in both eyes on the first and third postoperative days. Four days after surgery, he complained of decreased vision in the left eye. Fundus examination showed a picture of non-ischemic central retinal vein occlusion (CRVO). His final BCVA was 20/200.

Loss of preoperative BCVA in these 23 of 24 cases (95.8%) amounted to between 1 and 2 lines in 8 (33.3%); between 2-4 lines in 8 (33.3%); ≥ 5 lines in 7 (29.1%). Calculating the total number of patients operated in Saudi Arabia during the period from January 1998 to December 2001, the general incidence of these major complications was around 0.2%. The incidence of these major complications among our patients in the Eye Center was four eyes out of 3000 (0.1%). These were cases 4, 5, 8 and 23.

DISCUSSION

We studied 23 cases of major postoperative LASIK complications. Ten eyes (44%) were related to failures during creation of the flap with the microkeratome. There is probably a significant learning curve in the use of the microkeratome since the incidence of complications was significantly lower in the second series of patients than in the first (9). This learning curve can be modified by careful training, and by taking detailed records of every operation and analyzing the problems or complications that may occur. In three of the cases referred to us, the cap was lost, with secondary healing and re-epithelialization over the stroma. Postoperative BCVA was better than expected. This suggests that the resulting scar may be less damaging than might be feared. It is interesting to note that these cases developed a hyperopic postoperative shift. A free cap can occur with an incidence of up to 10%; it may result from low intraoperative intraocular pressure and large flat corneas (1). With today's microkeratome, the risk of free cap is high in eyes with a large flat cornea. With a flat cornea, a small amount protrudes through the ring, so the blade engages late in its passage across the cornea and exits early, making for a smaller flap and hinge and increasing the risk of a free cap. Changing the size or height of the corneal ring according to K readings is a good preventive measure. In most cases of free caps, the LASIK can be continued; the cap is recovered from the blade-platform space and appositioned to adhere to the stromal bed. A therapeutic contact lens may be placed for 48 hours. Marking the flap before the lamellar dissection allows it to be repositioned in the proper direction. However, cases 4 and 5 had incomplete caps that were replaced, aborting the procedure but resulting in satisfactory healing with good postoperative BCVA. In case 6, the surgeon got an incomplete flap and tried another cut in the same session, resulting in a bifurcated flap. In contrast to the other two cases, the final outcome was residual myopia with irregular astigmatism.

This case highlights the importance of aborting the procedure in cases of incomplete cut and rescheduling them after a minimum of three months. In two cases (7 and 8) a buttonhole was noted in the flap which caused the procedure to be aborted. Four months later, both patients were operated again with a loss of two lines in BCVA, a decrease that can be attributed to scar formation in the medial paracentral zone with astigmatism as a result of healing of the buttonhole. In cases where the flap is thin, buttonholing may occur and may lead to scar formation. Adequate pressure may reduce the risk of a thin flap. Confirmation of the recommended pressure before passing the microkeratome is recommended. Thin flaps (less than 100 micrometers) may be difficult to handle and may adhere to the underlying stroma in an irregular manner, giving rise to striae or folds. If detected during the procedure, they should be flattened. If folds are detected several days after the procedure, the flap can be lifted and pulled perpendicular to the direction of the fold and replaced back down.

The most severe complications reported here were corneal perforation and penetration of the anterior chamber (cases 9 and 10) due to failure to place the depth plate in the microkeratome. The new generation of microkeratomes have a built-in platform which prevents anterior chamber penetration. The high incidence of flap-related complications stresses the importance of this step in LASIK. Flap complications were more common with the automatic corneal shaper microkeratome than the Hansatome or Moria Corriazo-Barraquer microkeratome. Case 11 had LASIK-induced

keratoconus after enhancement. The patient developed ectasia with an increase in curvature of the central cornea. The corneal thickness should be measured and corneal topography done before considering enhancement procedures.

In the case of marked overcorrection for hyperopia (case 12), the unexpected surge in laser power during the ablation reported by the surgeon may have contributed to the outcome. In general, over or undercorrection may be caused by stromal desiccation or overhydration during the procedure.

The second most common complication in this study was interface haze (17%) which occurred in four eyes of three cases, resulting in central thinning, flattening and hyperopic shift. This followed diffuse interface keratitis. The appearance of diffuse haze at the interface is known as "diffuse interface keratitis" or "Sahara sands syndrome", and it is non-infectious (9-11). Interface contaminants, including meibomian gland secretions and bacterial endotoxins, are possible causes (10, 11). Another is microkeratome oil (personal observation, KFT). Adequate irrigation of the stromal surface with balanced salt solution (BSS) may prevent this complication. The use of topical steroids in case 16 may have been the cause of the cataract, glaucoma and other complications (herpetic keratitis).

The incidence of immediate postoperative infection was 13%. *Staphylococcus aureus* was recovered from all three cases, and they all responded to treatment. Case 17, which had a corneal abscess, suffered a marked decrease in BCVA. Cases 18 and 19 developed corneal opacity but the final BCVA was better than the case with corneal abscess. This stresses the importance of doing LASIK under rigorously aseptic conditions and giving prophylactic antibiotics after surgery to avoid this serious, sight-threatening complication.

Epithelial ingrowth (cases 20, 21) is another problem probably due to lack of proper approximation of the corneal flap at the edges (12). Epithelial cells may proliferate and encroach on the visual axis; they can be washed away by simply irrigating the interface with BSS using a 30- gauge cannula and disconnecting the epithelial islets from the interface. One of our cases (case 20) had recurrence of the epithelial islets. This patient was treated later with the argon laser (100 w, 100 spots, 0.1 sec.), and the cells disappeared in a few days and BCVA improved to 20/30.

We do not know how to explain the case of interlamellar vascularization (no. 22). However, it is interesting to record it and the fact that the final BCVA was not affected.

One patient developed non-ischemic CRVO four days after LASIK. The vacuum ring applies suction greater than 65 mmHg to stabilize the globe and provides mechanical support while the corneal flap is being created. The intraocular pressure may increase to 120 mmHg while the flap is being cut; of course the role of increased pressure during creation of the flap may be causal, circumstantial, or incidental. The patient also had systemic hypertension and hyperopia which may have contributed to the development of CRVO.

In conclusion, LASIK is an elective procedure considered to be a safe and effective surgical approach for the correction of refractive errors. In a small percentage of cases, however, serious complications may arise. Our aim was to highlight some of these complications seen during the first four years of LASIK in Saudi Arabia. The risks of these complications should be explained to patients before they undergo the procedure. They must also be kept in mind by the surgeons performing the procedure in order to minimize their incidence and to pave the way for their management.

ACKNOWLEDGEMENTS

The authors would like to acknowledge the help and support of the Administrator of the Eye Center, Mrs. Najwa Tabbara, and the secretarial assistance of Vangie Ontoria. The authors also appreciate with gratitude the assistance of the Eye Center nursing staff.

This study was supported in part by the Eye Center and the Eye Foundation for Research in Ophthamology, Riyadh, Saudi Arabia.

Reprint requests to:
Khalid F. Tabbara, MD
P. O. Box 55307, Riyadh 11534
Saudi Arabia
k.tabbara@nesma.net.sa.
www. eyecenter.com.sa
www.kftabbara.com

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