ARTICLE

Outcomes of femtosecond laser-assisted cataract and refractive lens surgery in patients with prior radial keratotomy



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Purpose: To investigate outcomes of femtosecond laser (FL)assisted cataract surgery (FLACS) and refractive lens exchange (RLE) in patients with prior radial keratotomy (RK).

Setting: Single clinical practice.

Design: Retrospective observational case series.

Methods: All patients with prior RK undergoing FLACS- or FLassisted RLE surgeries over a 6-year period were reviewed. Inclusion criteria were diurnal stability and stable manifest refraction. Exclusion criteria were any other incisional corneal surgery, macular or glaucomatous pathology, or vision loss due to any other cause. Data collected included demographics, visual acuity, laser settings, and complications. Main outcome measures were intraoperative and postoperative complications and visual outcomes. Safety and efficacy indices were evaluated.

Results: 16 eyes of 9 patients were included. Mean age and follow-up time were 59.9 ± 9.9 years (range 44 to 75 years) and

3.3 ± 2.5 months, respectively. The mean number of RK cuts was 11.8 ± 5.3 (range 8 to 20). Mean preoperative uncorrected (UDVA) and corrected distance visual acuity (CDVA) were 0.9 ± 0.4 logMAR (Snellen 20/160) and 0.2 ± 0.3 logMAR (Snellen 20/30), respectively. 2 intraoperative anterior capsule tears were identified. 1 postoperative intraocular lens dislocation occurred. Postoperatively, the mean UDVA and CDVA were 0.2 ± 0.2 logMAR (20/30) and 0.1 ± 0.1 logMAR (20/25), respectively. The safety index was 1.6, and the efficacy index was 1.2.

Conclusions: FLACS- or FL-assisted RLE surgery in RK patients has a high risk for anterior capsule tear and should be avoided. Thickened incisional scars are potential sources of incomplete laser penetrance. Toric lens implantation in RK eyes provide unpredictable astigmatic correction and should also be avoided.

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Radial keratotomy (RK) was a refractive surgical procedure to treat myopia and astigmatism. Transepithelial radial incisions (90% depth) were made manually using a blade, numbering 4 to 12 in total. Additional arcuate incisions were created as needed for astigmatic correction leaving the cornea more altered, often with irregular astigmatism.¹ Many patients who undergo RK procedures are now of the age at which cataracts interfere with visual function. Cataract surgery in this group is challenging because of the possibility of intraoperative corneal perforation from dehiscence of old RK wounds, anterior chamber instability, and potential endothelial cell and iris damage.^{2–6} Dehiscence of RK wounds has even

been reported to occur after surgery in other routine cataract surgeries.⁷ In addition, good refractive outcomes can be challenging to achieve.

Optical coherence tomography (OCT)-guided femtosecond laser (FL)-assisted lens surgery was introduced in 2009; it can be used to perform precise capsulotomy, lens fragmentation, and corneal incisions. However, the laser's ability to perform these tasks depends on the transparency of the cornea and lens as well as the pupil diameter.^{8,9} The use of the FL in cases with penetrating corneal injury, capsular damage, zonular injury, and white traumatic cataracts has been reported.^{10–14} There is a paucity of data on the use of the FL in eyes with prior RK, with a single

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report limited to 3 patients.¹⁵ To our knowledge, the current study is the largest to review the outcomes of FL-assisted cataract surgery (FLACS) and FL-assisted refractive lens exchange (RLE) in patients with prior RK incisions.

METHODS

A single-center, retrospective observational case series of intraoperative and postoperative outcomes of consecutive RK patients who underwent FLACS or FL-assisted RLE between January 2015 and August 2020 was performed. This study received Research Ethics Board approval from the University of Toronto and was conducted in compliance with the tenets of the Declaration of Helsinki. All surgeries were performed by a single experienced surgeon (D.S.R.) and were not within the surgeon's first 150 cases performed.

Inclusion criteria were patients with prior RK with diurnal stability and stable manifest refraction who underwent FLACS or FL-assisted RLE. Exclusion criteria were any other prior incisional corneal surgery or transplant, macular or glaucomatous pathology, or vision loss due to any other cause. Data collected included patient demographics, preoperative and postoperative uncorrected (UDVA) and corrected distance visual acuities (CDVA), FL settings, lens thickness, intraocular lens (IOL) type, and intraoperative and postoperative complications. The main outcome measures were intraoperative and postoperative complications and visual outcomes. Safety and efficacy indices were also calculated.

Preoperative Workup and IOL Calculation

All patients received preoperative manifest refraction and were questioned about diurnal fluctuation. Only patients with diurnal stability and stable manifest refractions proceeded to lens-based surgery.

The IOL formula used for all lens calculations was the Barrett True-K or Barrett True-K Toric IOL calculator. For toric IOL calculation, the manifest refraction was compared against the Nidek OPD-Scan III (Nidek Technologies Srl) topographer for consistency. If there was a mismatch, or in cases in which the manifest refraction did not correct to 20/40 or better, a toric IOL was not used.

Laser Settings

For the capsulotomy, all patients received a 4.8 mm circular diameter capsulotomy (horizontal spot spacing 4 μ m, vertical line spacing 9 μ m, and pulse energy 4 μ J) with a total energy of 0.7 J. No side-port or primary incision cuts were made by the FL.

Surgical Technique

All procedures were performed in a sterile operating room. After docking the eye, 3D spectral domain OCT was performed and confirmed, followed by the laser treatment. All cases used the Catalys Precision Femtosecond Laser System (Optimedica, Johnson & Johnson Vision). Anterior capsulotomy was then followed by lens fragmentation. The eye was then undocked, and the patient moved to the operating microscope setup in the same room. The lens was removed by phacoemulsification using either the Infiniti system or Centurion system (Alcon Laboratories, Inc.) or the Whitestar Signature Pro (Johnson & Johnson Vision) phacoemulsification system. All cases were performed under topical anesthesia using preservative-free tetracaine hydrochloride 0.5% and oral sedation with 0.5 to 1 mg lorazepam for the FL component and then augmented with mild sedation using intravenous midazolam and fentanyl with intracameral preservative-free lidocaine 1% on entry into the eye.

One primary keratome incision (2.2 mm) and 1 side-port incision were made using metal blades, ensuring passage between the edges of the RK incisions. The laser was not used to make either incision because of our prior experience with laser-created incisions susceptible to swelling during phacoemulsification. A clear corneal incision location was selected at the surgeon's discretion, generally as close to the horizontal axis as possible. The anterior chamber was filled with viscodispersive ophthalmic viscosurgical device, and the capsule was depressed posteriorly in the center to determine the completeness of the capsulorhexis. The disc of the capsule was pulled toward the center of the lens to separate the disc from the surrounding peripheral capsule using Utrata forceps. Hydrodissection was used to free the lens nucleus and to soften the peripheral lens cortex. Lens segmentation, fragmentation, and aspiration were performed. Removal of the cortex was performed followed by Viscoat injection and lens implantation into the capsular bag. All ophthalmic viscosurgical devices were removed by irrigation/aspiration at the conclusion of the case, and the wounds were hydrated and tested for watertightness. No effort was made to aspirate underneath the IOL.

Postoperative Regime

Postoperative drops included moxifloxacin 0.5% four times daily for 1 week, dexamethasone 0.1% four times daily for 2 weeks then twice daily for 2 weeks, bromfenac 0.07% once daily or nepafenac 0.3% three times a day for 1 month, and preservative-free lubrication drops as needed for 1 month.

Any patients with final postoperative visual acuity worse than Snellen 20/30 who did not improve on further refraction or whose vision could not be explained by anterior segment pathology underwent macular OCT to exclude macular pathology.

Statistical Analysis

Data were recorded and analyzed in Microsoft Excel (Microsoft Corp., 2016). CDVA results were converted to the logMAR and decimal format. The efficacy index was defined as UDVA postoperatively/CDVA preoperatively. The safety index was defined as CDVA postoperatively/CDVA preoperatively.

RESULTS

One thousand fifty-seven FLACS or FL-assisted RLE surgeries performed by a single surgeon at a single center from 2015 to 2020 were reviewed for a history of RK. Two eyes that underwent DALK after RK and then cataract surgery were excluded. Sixteen eyes of 9 patients were included in the final analysis.

Of these 16 eyes, 11 were from male patients, and 9 were right eyes. The mean age was 59.9 ± 9.9 years (range 44 to 75 years). The mean follow-up time was 3.3 ± 2.5 months. Fourteen eyes underwent FLACS, and 2 eyes underwent FL-assisted RLE. In addition, 3 eyes had undergone photorefractive keratectomy after RK (both prior to cataract surgery). Of the data that were available, the mean number of RK cuts per eye was 11.8 ± 5.3 (range 8 to 20). Patient characteristics and visual outcomes are summarized in Table 1.

The mean preoperative UDVA and CDVA were 0.9 ± 0.4 logMAR (Snellen 20/160) and 0.2 ± 0.3 logMAR (Snellen 20/30), respectively. The mean preoperative spherical and cylindrical errors were 1.9 ± 5.3 diopters (D) and -1.8 ± 1.7 D, respectively. The mean central corneal thickness was 560.7 μ m \pm 40.4 mm, the lens thickness was 4.5 ± 0.3 mm, and the anterior chamber depth (from the endothelium) was 3.5 ± 0.4 mm. The mean pupil diameter was 7.1 to 7.7 mm, and the white-to-white distance measured 11.6 \pm 0.6 mm.

		Preop		Intraop		Postop				
		UDVA	Manifest	CDVA	Toric		UDVA	Manifest	CDVA	
Age ^a	RK cuts	(Snellen)	refraction	(Snellen)	IOL	Complication	(Snellen)	refraction	(Snellen)	Complication
62	8	20/80	+4.25/-6.00 × 102	20/50	Yes	AC tear	20/50	+3.25/-4.75 × 80	20/40	Late IOL dislocation
										requiring suturing
54 ^b	N/A	20/80	+2.75/-2.75 × 127	20/20	No		20/20	+0.75/-1.25 × 142	20/20	
54 ^b	N/A	20/150	+5.75/-0.50 × 115	20/20	No		20/20	+1.00/-0.75 × 105	20/15	
44	18	20/150	-8.5	20/70	No		20/40	+2.25/-2.00 × 105	20/25	
44	20	20/400	-7.50/-1 × 75	20/50	Yes		20/100	+3.75/-2.00 × 166	20/50	
55	N/A	20/200	+5.50/-1.25 × 60	20/15	Yes		20/20	0	20/20	
55	N/A	20/300	+5.25/-2.00 × 122	20/15	Yes		20/25	+1.25/-0.50 × 180	20/20	
75	N/A	20/60	+0.25/-1.75 × 66	20/50	No		20/30	-0.50/-0.75 × 90	20/30	
75	N/A	20/50	+1.5	20/30	No		20/25	-0.50 sphere	20/20	
64	8	20/70	0	20/70	No		20/25	-0.25 × 15	20/20	
64	8	20/200	0	20/200	No		20/25	-0.25/-0.5 × 53	20/20	
53	N/A	CF	+8.25/-0.75 × 110	20/20	No	AC tear	20/40	+1.00/-0.50 × 115	20/20	
53	N/A	20/400	+7.50/-1.25 × 100	20/25	Yes		20/50	-1.00/-1.25 × 90	20/25	
70	16	20/50	+2.00/-0.25 × 90	20/30	No		20/25	0	20/25	
70	8	20/100	-2.25	20/30	No		20/20	0	20/20	
67	8	20/300		20/200	No		20/50	+1.50/-1.25 × 18	20/30	

N/A = not available; RK = radial keratotomy

In cases 2 and 3, refractive lens exchange was performed. All other cases were cataract extractions.

^aAge at the time of surgery

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The refractive target was plano for all cases except 1 patient who opted for monovision in 1 eye (aiming for -2 D and resulting in a spherical equivalent of -0.88). A monofocal IOL was used in all cases. The mean spherical power of the lens was 23.8 ± 6.5 D (range 11.0 to 31.5 D). IOL types and characteristics are summarized in Table 2.

Intraoperatively, there were no Descemet detachments, zonular dialyses, or rupture along any RK incision. There were 2 cases of anterior capsular tears. The first anterior capsule tear extended toward the equator of the lens but did not result in a posterior capsule tear, and a single-piece IOL was successfully implanted within the bag. The second tear appeared stable. There were no dropped nuclei.

CDVA improved in all eyes. Preoperatively, 0% of eyes had UDVA better than or equal to 20/40, and 56.3% (n = 9) of eyes

Table 2. IOL Characteristics and Femtosecond Laser Settings.								
Lens and laser characteristics								
Aspheric lens power (D)								
Mean ± SD	23.8 ± 6.5							
Range	11.0, 31.5							
Lens type								
TECNIS PCBOO	6							
TECNIS ZCBOO	3							
TECNIS ZCT	5							
Rayner 600C	1							
Envista MX60	1							
Mean CDE value (s)	2.7							
Vacuum time (min)	2:07 ± 0.01							
Mean total laser time (s)	29.1 ± 4.4							
Mean total fragmentation laser time (s)	25.8 ± 3.2							
Mean total fragmentation energy (J)	12.0 ± 2.1							

CDE = cumulative dissipated energy

had CDVA better than or equal to 20/40. Seventy-five percent (n = 12) of postoperative eyes attained UDVA better than or equal to 20/40, and 93.8% (n = 15) attained CDVA better than or equal to 20/40. Postoperatively, the mean UDVA was 0.2 \pm 0.2 logMAR (Snellen 20/30), and the mean residual refraction was spherical +0.8 \pm 1.3 D with a cylinder of -1.0 \pm 0.6 D. Mean CDVA was 0.1 \pm 0.1 logMAR (Snellen 20/25). With respect to refractive targets using the Barrett True-K formula, 43.8% (n = 7) were within \pm 0.5 D, 81.3% (n = 13) were within \pm 1 D, 87.5% (n = 14) were within \pm 1.5 D, and 93.8% (n = 15) were within \pm 2D.

The cohort requiring toric IOLs (n = 6) had a baseline mean cylinder of -2.33 ± 1.98 D. Preoperative UDVA and CDVA were 0.72 ± 0.31 logMAR and 0.13 ± 0.23 logMAR, respectively. One of these patients was targeted for monovision (-2 D). The mean IOL cylinder power placed was -5 ± 4 D. The postoperative UDVA and CDVA were 0.1 ± 0.2 logMAR and 0.1 ± 0.1 D logMAR, respectively (n = 5). The mean postoperative spherical equivalent was $0.4 \pm$ 0.5 D (n = 5).

Postoperatively, there were no cases of cystoid macular edema, retinal detachment, epiretinal membrane, or prolonged inflammation. One case of posterior capsular opacification developed, but it did not require treatment. The second of the anterior capsule tears was judged to be stable enough at the time of surgery to support a singlepiece Rayner toric IOL within the bag; however, there was a late IOL dislocation at 3 weeks, and this required additional suturing through the haptic with 9.0 Prolene suture and capsular tension ring placement. The safety index was found to be 1.6, and the efficacy index was 1.2.

DISCUSSION

This study evaluated the outcomes of FLACS or FL-assisted RLE in patients with prior RK surgery. There were 2 cases of

^bRK cuts

anterior capsular tears, one of which led to a subluxated IOL requiring a second reparative surgery. This is, to our knowledge, the largest study of RK eyes treated with an FL for lens surgery.

Dehiscence along the prior RK incisions is the most common site of rupture in these patients.¹⁶ Intraoperative wound opening causes anterior chamber instability, making cataract surgery more challenging. Corneal sutures may be required to close the wound before progressing with surgery. In addition, wound dehiscence does not seem to be related to clear corneal incision wound size.¹⁷ In our study, we used manual clear corneal incisions positioned at the surgeon's discretion because of difficulty with wound predictability and intraoperative edema with FL incisions. The wound size was 2.2 mm. There were no cases of intraoperative or postoperative RK wound dehiscence. This may be attributable to complete FL-assisted capsulotomy and lens fragmentation, resulting in less manipulation of the corneal wounds. Wound dehiscence has been reported during the postoperative course although this is rare.

The literature reports increased precision and reproducibility of anterior capsulotomy with laser-assisted cataract surgery over conventional cataract surgery; however, a recent meta-analysis of 3,554 cases found that risks for incomplete capsulotomy, anterior capsulotomy tags, and anterior capsule tears were significantly higher with FLACS in routine cases.¹⁸⁻²¹ The FEMCAT trial (nearly 1500 eyes) found no significant difference in overall clinical outcome between routine phacoemulsification and FSassisted methods, including complication rates in routine eyes, which was further supported by a recent meta-analysis reporting that both methods are safe and effective with no difference in mid-term visual acuity.^{22,23} We report, however, 2 (12.5%) anterior capsule tears, which is higher than expected compared with larger studies reporting anterior capsule tear rates of 0.5% to 1.84% or incomplete capsulotomy rates of 3.6%.^{21,24,25} One of the anterior capsule tears partially extended radially but did not preclude successful placement of a single-piece lens within the bag. The other anterior capsule tear developed at the 2 o'clock position where FL application was subsequently found to be incomplete on the capsulorhexis (despite an apparently complete laser capsulotomy process). This coincided with one of the RK incision scars. The capsule appeared stable enough to support an IOL in the bag at the time of surgery; however, 3 weeks later, the IOL subluxated, requiring suturing with a 9.0 Prolene suture and capsular tension ring placement. The final UDVA in both eyes was logMAR 0.3 (20/40).

Proposed mechanisms for anterior capsule tears include inadvertent aspiration of unseen anterior capsule tags or the stress and stretch of the continuous curvilinear capsulorhexis when aspirating the subincisional cortex, suggesting the influence of FL-introduced biomechanical weakness rather than surgeon-related factors. The other relevant factor is the reduction in media transparency with RK corneal scarring. FL-assisted lens surgery is contraindicated in cases of severe corneal opacification, as scars reduce effective laser penetration. In general, RK incisions are neither dense nor confluent over large areas, and intraoperative anterior segment OCT imaging can penetrate through RK scars. This, and the fact that the capsulotomy laser parameters may be modified in terms of position, depth, and energy, if necessary, increases the likelihood of successful and complete capsulotomy. Our capsulotomy parameters were not modified from our usual practice (horizontal spot spacing 4 μ m, vertical line spacing 9 μ m, and pulse energy 4 nJ) for a 4.8 mm capsulotomy. However, this could be considered to improve the chances of complete capsulotomy. No tags or incomplete capsulotomies were noted at the time of creation of the capsulotomy. However, in our 2 cases of anterior capsule tears, the tears were suspected to be present after the anterior capsule was removed and then confirmed during phacoemulsification against the improving red reflex. We believe that this most likely occurred because of interference with laser absorption during the capsulotomy process, secondary to opacity of the RK scar. If incisions are thick, translucent, or have epithelial inclusions within the interface, the use of an FL should be reconsidered.

Although we did not use trypan blue to stain the anterior capsules, in light of our findings, we agree with the recommendation made by Rocha et al. to carefully inspect the capsulotomy under high magnification in all tags and suspected incomplete ablation cases. We speculate that the use of trypan blue may reduce the chances of complications in cases in which there is a suspicion of incomplete capsulorhexis or peripheral microtears.²⁶

Achieving good refractive outcomes in RK patients can be challenging. The normal anterior curvature and anterior-posterior corneal curvature relationship are altered in a manner different from laser refractive surgery.²⁷ Optical zones are frequently less than 3.0 mm, meaning that standard keratometry includes the transition zone between incised and indirectly flattened corneas, resulting in corneal power overestimation and subsequent risk for hyperopic outcomes with standard IOL formulas. Scarring, irregularly healed anterior surfaces, and poor ocular surface stability also contribute to difficulties with preoperative IOL calculations. The Barrett True-K formula has been found to be comparable to the ORA aberrometer (Alcon Laboratories, Inc.) and other established formulas, with significantly more eyes within half a diopter of target compared with formulas SRK/T, Hoffer Q, and Holladay 1 formulas.²⁸

Our use of the Barrett True-K (no history) for our cohort found that over 40% of eyes (n = 7) were within ± 0.5 D and a further 37.5% (n = 6) within ± 1 D. This is lower than the results reported by Turnbull et al. (69.2% within ± 0.5 D of target) but consistent with those reported by Wang et al. (43.2% within ± 0.5 D).^{29,30} Our patients came from referral sources elsewhere, and past refractive history was not available; thus, having this information available may have improved refractive results.²⁹ The standardized figures for reporting refractive outcomes are provided in Figure 1.

94%

75%

20/40

63%

20/32

56%

20/25

31

20/20

Cumulative Snellen Visual Acuity (20/x or better)

25%

94%

Postop UDVA

Preop CDVA

20/80

20/100

20/63

100%

100%

20/200





Uncorrected Distance Visual Acuity

0% 0% 0%

20/12.5

20/16

16 eyes (plano target) 3 months postop

А

Cumulative % Of Eyes

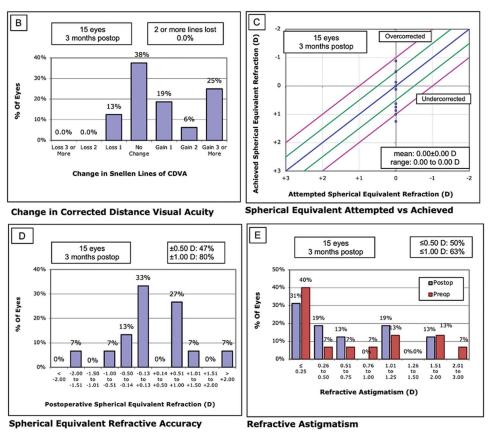
100%

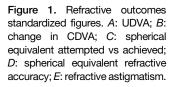
80%

60%

20%

0%





Good toric outcomes can also be more challenging to achieve in these eyes. At our refractive practice, the indication for consideration of toric IOL insertion is when the cornea demonstrates regular astigmatism on topography or tomography, their preoperative manifest refraction is 20/40 or better, and the patient is still preferentially seeking spectacle independence. In a similar vein, Cao et al. found that the ideal candidates for toric IOL implantation in eyes with prior refractive surgery were eyes with regular bowtie astigmatism across the central 3 mm zone, with 0.75 D or less difference in corneal astigmatism magnitude between differing biometers and with 15 degrees or less difference in astigmatic meridians, but this study did not include RK eyes.³¹ The same group found that 69% of RK eyes meeting these criteria attained a residual astigmatism of 0.5 D or less (Canedo ALC, Wang L, Koch DD, unpublished data, October 2019).

Overall, our toric outcomes achieved good functional UDVA and CDVA with a mean residual astigmatism of -1.0 ± 0.6 D. However, our results do show that at least 3

toric IOLs had no or low effect at astigmatism reduction, 1 patient had increased astigmatism, and another patient experienced an IOL dislocation requiring suturing and was left with residual astigmatism of 4.75 D. In light of this, toric IOL implantation may not be a good indication in these eyes that have higher potential for intraocular complication, and selection of a spherical IOL may be more appropriate. Furthermore, toric IOL implantation for low dioptric powers also did not seem to reduce astigmatism in 3 cases. Small amounts of residual refractive error in this scenario may be better treated with spectacles and contact lenses on stabilization of postoperative refraction.

A strength of our study is that RK eyes are well described to undergo initial hyperopic overshoot after lens surgery because of swelling and subsequent corneal flattening, followed by a period of partial myopic regression.³² This usually stabilizes by 3 months, so our mean follow-up time of 3.2 months should reflect this. Even if the eyes at this point were still more emmetropic or hyperopic, the continuation of additional myopic regression was better tolerated by patients than remaining hyperopic.

Limitations of our study include its retrospective nature, lack of a control group, a small cohort size of limited power to examine safety outcomes, and the lack of long-term follow-up. In particular, some patients were followed up elsewhere or did not return for follow-up after their first week visit, which may have skewed the results of our visual outcomes. However, given the small numbers and scarcity of RK eyes treated with FL in general, these patients were kept in the study for analysis. Another potential limitation of this study was the inclusion of 2 eyes for some of the included patients. However, as this study provided descriptive statistical analyses and did not provide inferential statistics, there was no need for unique statistical analysis accounting for the inclusion of 2 eyes in some of the included patients.

Despite safety and efficacy indices of 1.6 and 1.2, respectively, our preliminary findings suggest that FL capsulotomies should be avoided in this group until larger studies confirm safe ways of performing this technique. Investigating the role of trypan blue and higher magnification is one such avenue; however, identification of capsular irregularities does not guarantee avoidance of peripheral extension.

In summary, this is the largest study to date demonstrating the use of FLACS- or FL-assisted RLE surgery in patients with RK. Avoidance of this technique is recommended because RK incisional scars or opacities, especially those with epithelial inclusions, are potential sources of incomplete laser penetrance leading to higher rates anterior capsular tears. The use of high magnification and trypan blue staining could be studied in the future to investigate improvements in the detection of capsular abnormalities. The insertion of toric IOLs should also be avoided in these cases because of unpredictable visual outcomes and a spherical option chosen instead, using spectacles or contact lenses to treat postoperative residual astigmatism.

WHAT WAS KNOWN

- The femtosecond laser (FL) can be used in lens surgery for cataract surgery and refractive lens exchange in radial keratotomy (RK).
- To our knowledge, rates of intraoperative and postoperative complications in RK patients undergoing FL-assisted cataract or refractive lens surgery have not been studied.

WHAT THIS PAPER ADDS

- Anterior capsular tears seem to occur at a higher frequency in patients with prior RK.
- RK incisional scars or opacities, especially inclusive of epithelial plugging, are potential sources of incomplete laser penetrance.
- Avoidance of using the FL in this group of patients is recommended.

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