Incidence of corneal infections after laser in situ keratomileusis and surface ablation when moxifloxacin and tobramycin are used as postoperative treatment

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PURPOSE: To assess the incidence, culture results, and visual outcomes of infectious keratitis after laser in situ keratomileusis (LASIK) and surface ablation when topical moxifloxacin was added to postoperative prophylaxis with tobramycin.

SETTING: Clínica Baviera, Instituto Oftalmológico Europeo, Bilbao, Spain.

DESIGN: Retrospective case series review.

METHODS: The medical records of 55 255 patients (108 014 eyes) who had LASIK and surface ablation were reviewed to identify cases of infectious keratitis. The incidence, risk factors, clinical course, days to diagnosis, treatment, and final visual outcomes were recorded. These data were compared with previously published data of 221 437 eyes that received postoperative tobramycin alone.

RESULTS: Post-LASIK infectious keratitis was diagnosed in 10 eyes (9 patients) and post-surface ablation infectious keratitis in 11 eyes (10 patients). The onset of infection was early in 40.00% of cases after LASIK and in 36.36% after surface ablation. Cultures were positive in 2 cases after surface ablation. Immediate flap lifting and irrigation with antibiotics were performed in all eyes after LASIK. The final corrected distance visual acuity was 20/20 or better in 7 cases after LASIK (70.00%) and 7 cases after surface ablation (63.64%) and 20/40 or better in all cases after LASIK or surface ablation.

CONCLUSIONS: The incidence of infectious keratitis decreased from 0.025% to 0.011% ($P < .001$) per procedure after LASIK and from 0.200% to 0.066% ($P < .001$) after surface ablation. Infectious keratitis was less frequent after LASIK than after surface ablation. The frequency of infection, mainly early-onset infection, was lower when the postoperative treatment was tobramycin and moxifloxacin rather than tobramycin alone.

Financial Disclosure: No author has a financial or proprietary interest in any material or method mentioned.

J Cataract Refract Surg 2015; 41:1210–1216 © 2015 ASCRS and ESCRS

Laser in situ keratomileusis (LASIK) continues to be the preferred method for surgical correction of refractive errors; however, surface ablation is increasingly used to prevent flap complications and lower the risk for other complications such as corneal ectasia and dry eye. Laser-assisted subepithelial keratectomy (LASEK), photorefractive keratectomy (PRK), and epithelial LASIK are also used. However, the incidence of postoperative corneal infections after surface ablation is higher than after LASIK.[1]

We previously reported the largest series of postoperative infectious keratitis after LASIK[1] and after surface ablation.[2] Routine prophylaxis of infection comprised topical application of tobramycin during the first week after surgery (or until the contact lens was removed in patients who had surface ablation).

http://dx.doi.org/10.1016/j.jcrs.2014.09.041
0886-3350

Topical moxifloxacin was approved in Spain in 2010, when it was incorporated into our routine. Since then, prophylaxis after LASIK and surface ablation has included both topical tobramycin and moxifloxacin. The aim of the present study was to determine whether the addition of moxifloxacin lowers the incidence of infectious keratitis after LASIK and surface ablation.

PATIENTS AND METHODS

This retrospective case series review comprised patients who had primary LASIK or enhancement surgery and patients who had primary surface ablation or enhancement surgery at Clínica Baviera between November 2010 and December 2013. More than 40 000 refractive procedures are performed each year at the clinic, a private ophthalmologic institution with 19 centers and 84 surgeons located throughout Spain. Data collection fulfilled Spanish legal requirements, and institutional review board approval was obtained. Given the retrospective nature of the research design, no informed consent was required.

Patients with a diagnosis of infectious keratitis within 6 months after LASIK were identified by an electronic search of medical histories using the key words *LASIK/surface ablation* and *infectious* or *LASIK/surface ablation* and *keratitis*. Diagnosis of infectious keratitis was based on symptoms, slitlamp findings, and/or microbiological results. Clinical diagnostic criteria included the presence of corneal infiltrates compatible with infectious keratitis and excluded other causes of noninfectious keratitis (diffuse lamellar keratitis, peripheral sterile infiltrates, multifocal lamellar keratitis, peripheral sterile infiltrates).

The medical histories were reviewed to collect the following data: age, sex, involved eye, procedure type (LASIK, LASEK, PRK, enhancement), time from surgery to presentation, preoperative and postoperative corrected distance visual acuity (CDVA), postoperative uncorrected distance visual acuity, risk factors, culture results, medical and surgical treatment, and complications. To obtain the mean postoperative CDVA, Snellen visual acuity was converted to its decimal equivalent to calculate the mean final visual acuity.

Clinical data files at the institution are computerized and contain a field labeled "indication," which includes the type of surgery each patient had. The 2 options available for laser corneal refractive surgery are LASIK and surface ablation, the latter of which includes PRK and LASEK. Epithelial LASIK is not performed at the institution.

Surgical Technique and Postoperative Protocol

Patients had a complete ophthalmologic examination before surgery following a standard protocol to determine whether they were suitable candidates for corneal refractive surgery. Written informed consent was obtained before surgery in each case. All procedures were performed according to standard protocols. The surgical suite met the criteria for ophthalmologic laser procedures, and all instruments were autoclaved before surgery. Patients were instructed to perform lid hygiene during the 3 days before surgery.

Laser in situ keratomileusis was performed using the Moria LSK-1 microkeratome (Microtech, Inc./Moria). In bilateral cases, the same microkeratome blade was used in both eyes. Lamellar keratectomy was always performed first in the left eye and then in the right eye.

Debridement of the epithelium in surface ablation was performed mechanically using a hockey knife or was assisted with exposure to 20% alcohol for 20 seconds, depending on the surgeon's preference.

Laser ablation was performed first in the right eye and then in the left eye using the Technolas 217C, 217-Z-100 excimer laser (Bausch & Lomb), the Mel 80 excimer laser (Carl Zeiss Meditec AG), or the Wavelight Allegretto laser (Alcon Surgical, Inc.).

A bandage soft contact lens was fitted after surface ablation. Once the contact lens was removed, the patient received a tapering regimen of fluorometholone 0.1% eyedrops and preservative-free artificial tears for 1.5 months.

Before 2010, all patients received a topical combination of tobramycin 3 mg/mL and dexamethasone 1 mg/mL (Tobradex) after surgery. This regimen was prescribed 4 times a day for 1 week together with preservative-free artificial tears. In November 2010, topical moxifloxacin 5 mg/mL (Vigamox) was added to the regimen (4 times a day for 1 week).

All patients were examined 12 hours, 7 days, and 1 and 3 months after surgery unless complications required more frequent visits.

The outcome measures of the study were the incidence of infectious keratitis within 6 months after surgery, culture results, response to treatment, and visual outcome.

Statistical Analysis

Outcomes reported in the clinical records were compiled in an Excel spreadsheet (Microsoft Corp.). Data were analyzed using Stata statistical software (release 11, Statacorp LP). To compare differences in the incidence of infections between the time periods, a 2-sample test of proportions was used.

RESULTS

During the study period, 91 340 LASIK procedures (primary LASIK or enhancement) and 16 674 surface ablation procedures (primary surface ablation or enhancements) were performed in 45 755 patients and 9500 patients, respectively. The mean patient age was 37.70 years ± 15.42 (SD) (range 21 to 70 years)

Submitted: June 3, 2014.
Final revision submitted: September 10, 2014.
Accepted: September 13, 2014.

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in the LASIK group and 41.09 ± 12.85 years (range 21 to 58 years) in the surface ablation group.

Infectious keratitis was detected in 10 eyes of 9 patients (overall rate, 0.011% per procedure) within 6 months after LASIK and in 11 eyes of 10 patients after surface ablation (overall rate, 0.066% per procedure). Five infections (50.00%) were in the right eye and 5 (50.00%) in the left eye after LASIK, and 7 infections (63.64%) were in the right eye and 4 (36.36%) in the left eye after surface ablation. Infection was bilateral in 1 patient after LASIK and in 1 after surface ablation. All infections presented after primary procedures except for 1 infection, which appeared after LASIK enhancement by flap lift. Two infections appeared after treatment of LASIK flap folds (Table 1).

The mean follow-up was 302 ± 236 days (range 50 to 700 days) after LASIK and 352 ± 246 days (range 40 to 1008 days) after surface ablation. All patients attended visits until the infection resolved; thus, none was lost to follow-up.

The mean time from LASIK to the onset of the initial symptoms was 40.80 ± 59.30 days (range 1 to 165 days); onset was early (within 7 days after surgery) in 4 eyes (40.00%; mean 1.50 ± 1.00 days; range 1 to 3 days) and late (>7 days after surgery) in 6 eyes (60.00%; mean 67.00 ± 65.35 days; range 10 to 165 days). No clusters of cases were detected. The following risk factors were identified: blepharitis, health professional, dry eye, and incomplete eyelid closure (Table 2).

The mean time from surface ablation to the onset of the initial symptoms was 20.55 ± 25.94 days (range 2 to 86 days); onset was early (within 7 days after surgery) in 4 eyes (36.36%; mean 2.50 ± 0.58 days; range 2 to 3 days) and late (>7 days after surgery) in 7 eyes (63.64%; mean 30.86 ± 27.93 days; range 8 to 86 days). No clusters of cases were detected. The following risk factors were identified: blepharitis, dry eye, floppy-eyelid syndrome, and working as a farmer (Table 3).

Table 1. Demographics of infectious keratitis patients.

Characteristic	LASIK	SA
Age (y)		
Mean ± SD	37.70 ± 15.42	41.09 ± 12.85
Range	21, 70	21, 58
Sex, n (%)		
Male	3 (33.33)	5 (50.00)
Female	6 (66.67)	5 (50.00)
Type of surgery, n (%)		
Primary	9 (90.00)	10 (100)
Reoperation	1 (10.00)	0

LASIK = laser in situ keratomileusis; SA = surface ablation

Clinical symptoms were reported by all patients except 1 surface ablation patient, who was asymptomatic at a routine postoperative checkup. Pain was reported in 7 post-LASIK infection patients (70.00%), decreased vision in 6 patients (60.00%), and red eye in 8 patients (80.00%). Photophobia was reported in 3 cases (30.00%) and tearing in 3 cases (30.00%). Pain was reported in 8 patients with post-LASIK infections (72.73%), decreased vision in 3 patients (27.27%), and red eye in 7 patients (63.64%). Photophobia was reported in 1 case (9.09%).

Corneal infiltrates were detected in all cases. In the LASIK group, 1 infiltrate was found in 7 eyes, 2 in 1 eye, 4 in 1 eye, and more than 5 in 1 eye. The infiltrates were located at the interface, and adjacent stroma without epithelial involvement was observed in 6 cases; involvement was superficial in 5 cases, with epithelial defects over the stromal abscesses. In the surface ablation group, 1 infiltrate was found in 6 eyes, 2 in 1 eye, 3 in 1 eye, 4 in 1 eye, and more than 5 in 2 eyes.

Samples were taken for microbiological analysis in all post-LASIK cases before treatment (flap-lifting procedure), and the interface was subsequently irrigated with fortified vancomycin. Nine of the samples were negative, and 1 was positive for *Pseudomonas aeruginosa*. After surface ablation, samples were taken for microbiological analysis in 7 cases. Five of the samples were negative, and 2 were positive (*Staphylococcus epidermidis* and *Candida tropicalis*) (Tables 2 and 3).

Tables 4 and 5 show the antibiotic treatment regimen. Oral doxycycline was added after LASIK in 6 cases and after surface ablation in 3 cases.

Tables 4 and 5 also show the visual outcomes. The mean postoperative CDVA after LASIK was 0.93 ± 0.15 (range 0.70 to 1.20). Seven cases maintained CDVA. The final CDVA was 20/20 or better in 7 cases (70.00%) and 20/40 or better in all cases (100%). Visual rehabilitation procedures after resolution of infection included wearing spectacles (2 cases) or contact lenses (1 case).

The mean postoperative CDVA after surface ablation was 0.93 ± 0.09 (range 0.75 to 1.00). Nine eyes maintained their CDVA. The final CDVA was 20/20 or better in 7 cases (63.64%) and 20/40 or better in all cases (100%). Clinically significant residual corneal scars were recorded in 3 eyes after LASIK and 1 eye after surface ablation. Visual rehabilitation procedures after resolution of infection included spectacle correction (3 cases).

The comparison of the incidence of post-LASIK infectious keratitis between postoperative prophylaxis with tobramycin and the combination of tobramycin

Table 2. Summary of infectious keratitis cases after LASIK between 2010 and 2013.

Case	Age/Sex	Eye	Risk Factors	Day to Presentation	Culture Samples Taken	Organism
1	28/M	R	None	126	Yes	Negative
2	38/F	L	Dry eye, healthcare worker	165	Yes	*P aeruginosa*
3	50/M	L	None	14	Yes	Negative
4	23/F	R	Incomplete eyelid closure	20	Yes	Negative
5	21/F	R	None	3	Yes	Negative
6	37/F	L	Healthcare worker	10	Yes	Negative
7	70/F	R	None	67	Yes	Negative
8	29/F	R	Blepharitis	1	Yes	Negative
9	29/F	L	None	1	Yes	Negative
10	52/M	L	None	1	Yes	Negative

P aeruginosa = *Pseudomonas aeruginosa.*

and moxifloxacin showed a decrease (Table 6); the decrease was statistically significant ($P < .001$). The incidence of post-surface ablation infectious keratitis also decreased significantly, from 0.209% to 0.066% ($P < .001$) (Table 7). The reduction in the incidence of both early-onset and late-onset infections after LASIK and early-onset infections after surface ablation was statistically significant (Tables 6 and 7).

DISCUSSION

Chung et al.[3] analyzed the antibiotic susceptibility of conjunctival bacterial isolates from patients who had refractive surgery. The microorganisms isolated were coagulase-negative staphylococci (85.0%), *S aureus* (2.3%), *S pneumoniae* (1.2%), and gram-negative rods (4.8%). The most effective antibiotic agents against these bacteria were moxifloxacin, gemifloxacin, and gatifloxacin. None of these drugs was available in Spain before 2010. We began to use topical moxifloxacin in combination with tobramycin as standard postoperative prophylaxis as soon as moxifloxacin became available in Spain. Although moxifloxacin has a wide spectrum of action and covers most organisms, it might not be effective against *P aeruginosa*, which is a common pathogen in contact lens users; therefore, we decided to combine tobramycin and moxifloxacin as opposed to using moxifloxacin as a monotherapy.

The incidence of infectious keratitis after surface ablation might be higher than the incidence of infectious keratitis after LASIK. The actual incidence of infectious keratitis after surface ablation and LASIK varies widely depending on the data source and has been reported to be 0.2% (1 case in 500) after surface ablation and 0.035% after LASIK in 2 large series of infectious keratitis by our group.[1,2] The true incidence depends on the completeness of follow-up. In our experience, most patients attend all scheduled visits. Moreover, these visits were included in the cost of the procedure. Because ours is a private ophthalmology institution with 19 centers throughout Spain,

Table 3. Summary of infectious keratitis cases after surface ablation between 2010 and 2013.

Case	Age/Sex	Eye	Risk Factors	Day to Presentation	Culture Samples Taken	Organism
1	45/F	R	Dry eye	86	No	—
2	32/M	R	Farmer	10	Yes	*S epidermidis*
3	21/M	R	None	17	No	—
4	52/M	R	None	3	Yes	Negative
5	58/F	R	Blepharitis, floppy-eyelid syndrome	3	Yes	Negative
6	53/F	L	Dry eye	34	Yes	*C tropicalis*
7	36/F	R	None	2	Yes	Negative
8	36/F	L	None	2	Yes	Negative
9	26/M	L	None	46	Yes	Negative
10	58/F	L	None	15	No	—
11	35/M	R	None	8	No	—

C tropicalis = *Candida tropicalis; S epidermidis* = *Staphylococcus epidermidis*

Table 4. Surgical/medical treatment and clinical outcomes of infectious keratitis cases after LASIK between 2010 and 2013.

Case	Medical Treatment	Surgical Treatment	FU (D)	Preop CDVA	Postop UDVA	Postop CDVA
1	Vanc + cefta + coric	FLI w/vanc	257	20/20	20/25	20/20
2	Vanc + amik + moxi + doxy	FLI w/vanc	339	20/20	20/25	20/25
3	Moxi + tobra	FLI w/vanc	700	20/20	20/50	20/20
4	Amik + moxi + tobra + doxy	FLI w/vanc	661	20/20	20/100	20/30
5	Vanc + FT	FLI w/vanc	121	20/25	20/20	20/20
6	Vanc + amik + doxy	FLI w/vanc	50	20/20	20/20	20/20
7	Amik + moxi + doxy	FLI w/vanc	72	20/20	20/25	20/25
8	Cefazo + moxi + doxy	FLI w/vanc	240	20/20	20/20	20/20
9	Cefazo + moxi + doxy	FLI w/vanc	240	20/20	20/20	20/20
10	Vanc + tobra + moxi	FLI w/vanc	295	20/20	25/20	25/20

Amik = amikacin 35 mg/mL; CDVA = corrected distance visual acuity; Cefazo = cefazoline 50 mg/mL; Cefta = ceftazidime 50 mg/mL; Doxy = oral doxycycline 100 mg; FLI w/ = flap lifting and irrigation with; FT = tobramycin 13.5 mg/mL; FU = follow-up; Moxi = moxifloxacin 5 mg/mL; Tobra = tobramycin 3 mg/mL; UDVA = uncorrected distance visual acuity; Vanc = vancomycin 50 mg/mL; Voric = voriconazole

visits are easy to organize. Therefore, we believe that the incidence we calculated seems reasonably accurate. The incidence we report is similar to that in a study by Machat[4] and de Oliveira et al.[5] However, it is 10-fold higher than the 0.019% reported by Wroblewski et al.[6] and Leccisotti et al.[7]

Postoperative prophylaxis with the combination of tobramycin and moxifloxacin considerably reduced the incidence of infectious keratitis after LASIK and surface ablation. Compared with the incidence recorded with tobramycin alone, use of the combination decreased the incidence from 0.035% to 0.011% after LASIK and from 0.200% to 0.066% after surface ablation. Our previously reported rate of infection after LASIK is 5.7 times lower than the incidence after surface ablation. The use of the combination lowered the incidence of infectious keratitis after surface ablation and after LASIK, and the incidence after LASIK remained lower than the incidence after surface ablation. The institution, protocols, operating room, and surgeons were the same; thus, in the absence of other unknown variables, the only factor that could account for the difference in the infection rate is the type of procedure. The increased risk in surface ablation procedures might be the result of the epithelial defect, extended use of a bandage contact lens,[8,9] and the use of topical corticosteroids for a longer period than after LASIK.

Infectious keratitis after LASIK is usually classified as early onset (occurring within 1 to 2 weeks after surgery) and late onset (occurring after 1 or 2 weeks to 3 months after surgery).[10] In a literature review performed by Chang et al.,[10] symptoms appeared within 7 days of the LASIK procedure in 49.4% of cases and more than 10 days after surgery in 50.6%. Consistent with studies by other authors,[5–7,10] early onset was more frequent when tobramycin was used alone; however, early-

Table 5. Medical treatment and clinical outcomes of infectious keratitis cases after surface ablation between 2010 and 2013.

Case	Medical Treatment	FU (D)	Preop CDVA	Postop UDVA	Postop CDVA
1	Vanc + cefta + moxi	40	20/20	20/20	20/20
2	Vanc + cefta	204	20/25	20/20	20/20
3	Vanc + cefta + tobra	247	20/20	20/20	20/20
4	Vanc + amik + moxi	186	20/20	20/20	20/60
5	Vanc + cefazo	111	20/25	20/25	20/25
6	Nata + ampho + fluc	486	20/20	20/25	20/50
7	Vanc +amik + doxy	1008	20/20	20/20	20/50
8	Vanc +Amik + doxy	1008	20/20	20/20	20/20
9	Amik + Moxi + doxy	178	20/20	20/20	20/20
10	Amik + oflox	84	20/20	20/25	20/25
11	Vanc + oflox	322	20/20	20/20	20/20

Ampho = amphotericin; Amik = amikacin 35 mg/mL; CDVA = corrected distance visual acuity; Cefazo = cefazoline 50 mg/mL; Cefta = ceftazidime 50 mg/mL; Doxy = oral doxycycline 100 mg; Fluc = oral fluconazole; FU = follow-up; Moxi = moxifloxacin 5 mg/mL; Nata = natamycin; Oflox = ofloxacin 3 mg/mL; Tobra = tobramycin 3 mg/mL; UDVA = uncorrected distance visual acuity; Vanc = vancomycin 50 mg/mL

Table 6. Comparison of the incidence of post-LASIK infectious keratitis with tobramycin as postoperative prophylaxis versus tobramycin and moxifloxacin.

Infections	Tobramycin	Tobramycin + Moxifloxacin	*P* Value*
Total (n)	72	10	<.001
Incidence (%)	0.067	0.011	
Early onset (n)	45	4	<.001
Late onset (n)	27	6	.00014

*Two-sample test of proportions

Table 7. Comparison of the incidence of post-surface ablation infectious keratitis with tobramycin as postoperative prophylaxis versus tobramycin and moxifloxacin.

Infections	Tobramycin	Tobramycin + Moxifloxacin	*P* Value*
Total (n)	39	11	<.001
Incidence (%)	0.209	0.066	
Early onset (n)	28	4	<.001
Late onset (n)	11	7	.48

*Two-sample test of proportions

onset infectious keratitis after LASIK and surface ablation was less frequent after the addition of moxifloxacin. Early-onset cases accounted for 62.50% of the total after LASIK and 71.80% of the total after surface ablation; in the current series, 40.00% of early-onset cases were after LASIK and 36.36% after surface ablation.

As in our previous studies, the present study is limited by the high rate of negative cultures, which could be the result of technical issues, such as the low number of samples, alteration of samples during transport to the reference microbiology laboratory, and previous growth-inhibiting antibiotic therapy.

The potential risk factors for keratitis after surface ablation and LASIK reported in the literature include blepharitis, contact lens manipulation, and being in a healthcare environment.[6,11,12] We identified blepharitis, dry eye, floppy-eyelid syndrome, and working as a farmer to be possible risk factors after surface ablation. Two of our LASIK patients were health professionals who might have also be susceptible to methicillin-resistant *Staphylococcus aureus* (MRSA) infections,[12] although we did not isolate MRSA. One of the post-LASIK cases had incomplete eyelid closure, and another had blepharitis.

One patient developed bilateral infections after surface ablation and 1 after LASIK. The LASIK blade is not routinely changed between eyes. Some clinicians recommend performing monocular surgery or using separate instruments when performing bilateral surgery,[13] although this is not the practice of the members of the Cornea Clinical Committee of the American Society of Cataract and Refractive Surgery.[14]

The recommended approaches for the management of post-surface ablation and post-LASIK infectious keratitis include use of aggressive antibiotic agents, addition of gram-positive coverage, and removal of the soft contact lens in cases of surface ablation.[5,6,11] Chang et al.[10] found that flap lifting performed within 3 days of the onset of symptoms might be associated with a better visual outcome after post-LASIK infectious keratitis. The flap was lifted in all LASIK eyes in our series. This involved irrigation with antibiotics.

Visual acuity results in the current series are reasonably satisfactory and similar to those published in other studies.[5,6,11] All eyes in our series responded to medical therapy.

In summary, infectious keratitis after surface ablation was recorded in 0.066% of cases, which is 6 times higher than after LASIK (0.011%). Infectious keratitis after LASIK and surface ablation is a potentially vision-threatening complication. Antibiotic prophylaxis with tobramycin and moxifloxacin should be preferred to tobramycin alone.

WHAT WAS KNOWN

- The incidence of postoperative corneal infections after surface ablation is higher than after LASIK.
- Early-onset infectious keratitis is more frequent when tobramycin is used alone.

WHAT THIS PAPER ADDS

- Postoperative prophylaxis with the combination of tobramycin and moxifloxacin considerably reduced the incidence of infectious keratitis after LASIK and surface ablation compared with tobramycin alone.
- The incidence of postoperative corneal infections after surface ablation remained higher than after LASIK despite the addition of moxifloxacin.
- Early-onset infectious keratitis after LASIK and surface ablation became less frequent after the addition of moxifloxacin.

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