Infectious Keratitis in 204 586 LASIK Procedures

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Purpose: To investigate the incidence, culture results, risk factors, and visual outcomes of infectious keratitis after LASIK, and examine treatment strategies.

Design: Retrospective study.

Participants: We included 107 613 patients who underwent LASIK at Clínica Baviera (Instituto Oftalmológico Europeo, Spain) from September 2002 to May 2008.

Methods: The medical records of post-LASIK patients (204 586 eyes) were reviewed to identify cases of infectious keratitis. Incidence, risk factors, clinical course, days to diagnosis, medical and surgical treatment, and final visual outcomes were recorded.

Main Outcome Measures: Incidence of post-LASIK infectious keratitis, culture results, response to treatment, and visual outcome.

Results: Post-LASIK infectious keratitis was diagnosed in 72 eyes from 63 patients. Onset of infection was early (within 7 days after surgery) in 62.5% of cases. Cultures were positive in 21 of 54 cases in which samples were taken. The most frequently isolated microorganism was *Staphylococcus epidermidis* (9 cases). Immediate flap lifting and irrigation with antibiotics was performed in 54 eyes; late flap lifting was subsequently required in 10 out of 18 cases initially treated with topical antibiotics alone. One case required flap amputation owing to flap necrosis. Final best spectacle-corrected visual acuity (BSCVA) was ≥20/20 in 38 cases (52.7%) and ≥20/40 in 67 cases (93.05%); final BSCVA was <20/40 in 5 cases (6.94%).

Conclusions: The incidence of post-LASIK infectious keratitis was 0.035% per procedure. Infectious keratitis after LASIK is a potentially vision-threatening complication. The appearance of infections in asymptomatic patients highlights the need for a proper schedule of follow-up appointments. Prompt and aggressive management of this LASIK complication with early flap lifting, scraping, culture, and irrigation with antibiotics is strongly recommended. Proper management can result in preserving useful vision.

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LASIK is currently the preferred method for the surgical correction of refractive errors, and thousands of procedures are performed worldwide every year. The procedure provides rapid recovery of visual acuity with a low incidence of complications.[1] However, microbial keratitis after LASIK has become an increasingly recognized, sight-threatening complication of refractive surgery.[2–4] The incidence of infection is unknown, and in most cases, it is difficult to determine the origin. Predisposing factors include a history of corneal surgery, breaks in the epithelial barrier, excessive surgical manipulation, intraoperative contamination, delayed postoperative reepithelialization of the cornea, and use of topical corticosteroids.[4,5]

The occurrence rate of post-LASIK keratitis remains difficult to estimate and can vary widely depending on the source of the data.

Two retrospective case series from 2 institutions have found an incidence of 2 infections in 1062 eyes[6] and 1 infection in 1019 eyes[7]; however, the small number of cases prevents an integrated analysis of the data from being performed and conclusions drawn on diagnosis and management. The largest series reported to date analyzed 15 eyes from 13 patients,[5] although it included cases of infection referred to the Bascom Palmer Eye Institute from several parts of Florida, thus making it difficult to draw conclusions about incidence.

In a comprehensive review of the literature on post-LASIK infections, Chang et al[4] state that incidence can vary widely (0%–1.5%). However, many cases of infection are probably not reported, and these numbers might underestimate the true incidence of infection. Conversely, atypical or worse cases could be reported more frequently, thus biasing results on incidence and outcome.

Further information about the incidence of infection and its more common etiologies has been obtained from surveys performed by the American Society of Cataract and Refractive Surgery (ASCRS), with a calculated incidence of 1 case in 2919 procedures[2] and 1 case in 2131 procedures.[3] Nevertheless, this estimation is not conclusive, because it is subject to the nonresponse bias of surveys with a response rate of <66%.[8]

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Because the frequency of post-LASIK infection is low, the analysis of a large series from a single center could reveal more data on several clinically relevant parameters and provide a better understanding of the presentation, etiology, and management of these infections. Series from a single center have the advantage of offering information about incidence in a setting in which most of the possible variables are controlled, because uniform protocols are followed by patients and surgeons before, during, and after surgery. However, given the low incidence of the condition, large numbers of patients would be needed to obtain meaningful conclusions, and such a high number is difficult to recruit from a single center. The largest series until the present study from a single center—10 cases of nonviral infection in 10 477 eyes—was recently published.[9]

We report the largest series to date of post-LASIK infectious keratitis, with all procedures carried out in the same institution. Cases were retrospectively reviewed to provide information on onset, etiology, clinical course, risk factors, and treatment, with the aim of improving our understanding of the prevention, diagnosis and management of this entity.

Patients and Methods

This retrospective case-series review comprised 204 586 eyes from 107 613 patients who underwent primary LASIK or enhancement surgery consecutively at Clínica Baviera between September 2002 and May 2008. More than 40 000 refractive procedures are performed each year at the clinic, a private ophthalmologic institution with 19 centers and 84 surgeons throughout Spain. 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 and infectious or LASIK and keratitis. Diagnosis of infectious keratitis was based on symptoms, slit-lamp findings, and/or microbiological results. Clinical diagnostic criteria included the presence of corneal infiltrates compatible with infectious keratitis, excluding other causes of noninfectious keratitis (diffuse lamellar keratitis, peripheral sterile infiltrates, multifocal lamellar keratitis).[9,10] The medical histories were reviewed to collect the following data: age, gender, involved eye, procedure type (primary versus enhancement), time from surgery to presentation, preoperative and postoperative best spectacle-corrected visual acuity (BSCVA), postoperative uncorrected visual acuity, risk factors, culture results, medical and surgical treatment, and complications. To obtain the average postoperative BSCVA, we converted Snellen visual acuities to their decimal equivalent to calculate mean final visual acuity. 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 needed.

Operative Technique

Patients underwent 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 LASIK surgery. Patients were instructed to perform lid hygiene during the 3 days before surgery. LASIK was performed using the Moria LSK-One microkeratome (Microtech Inc., Moria, France). In bilateral cases, the same microkeratome blade was used in both eyes. The lamellar keratectomy was always performed first in the left eye and then in the right eye, and was followed by laser ablation first in the right eye and then in the left eye using the Technolas 217C, 217-Z-100 excimer laser (Bausch & Lomb, Claremont, CA) or the Mel 80 excimer laser (Carl Zeiss Meditec Inc., Jena, Germany). After surgery, a topical combination of tobramycin 3 mg/ml and dexamethasone 1 mg/ml (TobraDex, Alcon Laboratories, Barcelona, Spain) was prescribed 4 times a day for 1 week together with preservative-free artificial tears. All patients were examined 12 hours, 7 days, 1 month, 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 LASIK, culture results, response to treatment, and visual outcome.

Results

During the study period, 204 589 procedures (primary LASIK or enhancement) were performed on 107 613 patients. We identified 72 eyes from 63 patients (28 women, 44 men) with infectious keratitis (overall rate, 0.035% per procedure) within 6 months after LASIK. Mean age was 38.5 ± 10.08 years (range, 22–65). Thirty-four (47.22%) infections involved the right eye and 38 (52.77%) involved the left. Infection was bilateral in 9 patients. Sixty-eight (94.44%) infections presented after primary procedures and 3 infections appeared after an enhancement procedure (2 cases) or after lifting and ironing of flap folds (1 case; Table 1). Mean follow-up was 5.48 months (range, 1–42), and >6 months in 26 cases. Twelve cases did not complete the scheduled routine visit at 3 months (most of them were cases of early onset and rapid resolution). All patients attended visits until complete resolution of the infection so that no patient was lost to follow-up.

Time from surgery to the appearance of the initial symptoms was 16 ± 31 days (range, 1–180); onset was early (within 7 days after surgery) in 45 eyes (62.5%; mean, 3.5 ± 1.8; range, 1–7) and late (>7 days after surgery) in 27 eyes (37.5%; mean, 35.7 ± 43.7; range, 8–180). No clusters of cases were detected.

We detected the following risk factors: blepharitis (3 cases), intraoperative epithelial defect (6 cases; a bandage contact lens was applied in 3), dry eye (1 case), health professional (2 cases), and veterinarian (1 case).

Clinical symptoms were reported by 54 patients, whereas 9 were asymptomatic. In the asymptomatic patients, infection was diagnosed at one of the routine postoperative checkups. Thirty (41.6%) of the symptomatic eyes presented pain, 25 (34.72%) had

Table 1. Patient Demographics

Characteristic	Total
No. of eyes	72
No. of patients	63
Age (yrs)	
Mean ± standard deviation	38.51 ± 10.08
Range	22–65
Gender	
Female	28 (38.38%)
Male	44 (61.11%)
Type of surgery	
Primary	69 (95.83%)
Reoperation	3 (4.16%)