



Original article

First multicenter survey on infectious keratitis following excimer laser surgery in Japan



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ABSTRACT

Purpose: To report the first multicenter survey in Japan on infectious keratitis after excimer laser surgery.

Methods: The laser *in situ* keratomileusis (LASIK) Safety Network (LSN) Committee sent questionnaires to 28 LSN member hospitals to assess the total number of laser corneal surgeries, the number of infection cases (including suspicious cases), and the postoperative follow-up rate during a 3-year period.

Results: Responses were obtained from 27 (96.4%) of 28 institutions. One phototherapeutic keratectomy infection case was reported among 22,415 excimer laser surgery cases, which equates to an incidence rate of 0.004%. The follow-up rate was 94.14% (67.2–100%), 80.11% (41.0–96.1%), 57.95% (11.5–93.0%), and 46.64% (4.7–93.0%) at 1 month, 3 months, 6 months, and 12 months of follow-up, respectively.

Conclusion: Infectious keratitis is a potentially devastating complication of excimer laser surgery. We did not see any infectious keratitis for refractive cases. This first multicenter survey in Japan on infectious keratitis provides important information on the safety of this therapy.

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1. Introduction

Excimer laser technology has evolved since it was first used in the early 1970s to etch silicone computer chips. Approximately 2 decades ago, the excimer laser began its evolution from a largely industrial cutting tool to the driving force behind precise, safe, and effective corneal refractive surgery. Excimer lasers are widely employed for laser *in situ* keratomileusis (LASIK), photorefractive keratectomy (PRK), and phototherapeutic keratectomy (PTK). This laser technology brought excimer laser surgery to the masses, and these laser surgeries are today the second most commonly performed ophthalmic procedure worldwide, after cataract surgery.

On February 25, 2009, the Japanese health authorities issued an alert that 70 (i.e., more than 10%) of 639 LASIK patients developed infectious keratitis—primarily nontuberculous mycobacterial

infections—after undergoing LASIK surgery between late September 2008 and mid-January 2009. Several outbreaks of post-LASIK mycobacterial infection have been reported.^{1–3} However, to our knowledge, this is the largest number of reported cases.⁴ This outbreak occurred surprisingly from a single private refractive surgery center in Tokyo, Japan. As of March 19, 2009, four of the 70 patients required hospitalization for intensive medical treatment; of these, two patients were believed likely to require corneal transplantation.

At the time, however, the precedent data on the incidence of infectious keratitis after excimer laser surgery had not been collected in Japan. Neither health authorities nor academic institutions in Japan conducted surveys on the subject. In fact, most academic university hospitals do not perform excimer laser surgeries on a regular basis. Because the number of patients undergoing these surgeries is increasing annually, the safety and efficacy of excimer laser surgery is a public health issue of considerable interest. We therefore established a network of physicians, the LASIK Safety Network (LSN), to collate these data. The prerequisites for joining this network were that the doctors should trust each

Conflicts of interest: The authors declare that they have no conflicts of interest.

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other and should be board certified. Furthermore, they should be trained in the cornea/refractive field and should follow their postoperative patients regularly.

The LSN Committee conducted a postexcimer laser surgery infectious keratitis survey to investigate the incidence of infectious keratitis after excimer laser surgeries among LSN institutions across Japan. This report presents the results of this survey.

2. Methods

In November 2010, the LSN Committee sent questionnaires to 28 LSN member hospitals to assess the previous 3-year-period (i.e., October 1, 2007 to September 30, 2010) concerning the total number of laser corneal surgeries, the number of infection cases

(including suspicious cases), and the postoperative follow-up rate at several time points (1 month, 3 months, 6 months, and 12 months) (Fig. 1). The definition of infectious keratitis in this report was the clinical appearance of a corneal ulcer and/or a positive culture result. The LSN members were asked to complete the questionnaire and send their responses back. No financial incentive was provided to the members for returning the questionnaire.

3. Results

We received responses from 27 (96.4%) of 28 institutions. One infection case was reported among 22,415 patients, which equates to an incidence rate of 0.004% (Table 1).

Questionnaire

TITLE: Survey on infectious keratitis following laser cornea surgeries

PURPOSE: The number of refractive surgeries has increased worldwide. However, in Japan there have been no multicenter surveys on the safety of laser corneal surgeries [e.g., laser *in situ* keratomileusis (LASIK), photorefractive keratectomy (PRK), epithelial LASIK (Epi-LASIK), laser epithelial keratomileusis (LASEK), and phototherapeutic keratectomy (PTK)]. We aim to report the manifestation of vision-threatening infectious keratitis after laser refractive surgeries.

METHOD: Each institution answered this questionnaire.

INCLUSION CRITERIA: All patients who underwent laser cornea surgery during the previous 3-year period (October 1, 2007 to September 30, 2010) and who were followed at least 1 month postoperatively.

EXCLUSION CRITERIA: Patients who received PTK for infectious keratitis (e.g., in some patients we performed PTK for cases of infectious keratitis such as *Acanthamoeba*).

Institution: _____

1. Total case number of laser cornea surgeries.

2. Total number of infectious keratitis (including suspicious cases).

3. Details on infectious keratitis (e.g., culture results, treatment, onset, slit lamp findings, visual acuity, etc.), if available.

(_____)

4. The follow-up rate at each time point:
 1 month cases (%)
 3 months cases (%)
 6 months cases (%)
 12 months cases (%)

Fig. 1. The questionnaire used for the survey. The questionnaire was originally written in Japanese. It has been translated into English for publication purposes.

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