A Japanese LASIK surgeon is facing criminal charges following an outbreak of infectious keratitis at his clinic in Tokyo, Japan.

The epidemic first came to light when ophthalmologists in Tokyo began to see patients coming into their clinics with mycobacterial corneal infections, all within a narrow time period. Mycobacterial keratitis is an otherwise very rare occurrence in Japan, Hiroko Bissen-Miyajima MD, PhD, director, Department of Ophthalmology, Tokyo Dental College Suidobashi Hospital, told EuroTimes.

“We saw such a patient, and then another. One common finding was they had recently undergone LASIK. We sent out a request to 12 hospitals in the Tokyo area for information on any similar cases they might have encountered. Sure enough, cases were starting to appear at an alarming rate,” she said.

Subsequent investigations revealed that all of the patients had undergone LASIK at a single LASIK centre in Tokyo. Japanese health authorities visited the clinic after being alerted by Dr Bissen-Miyajima and colleagues. Their investigation revealed inadequate facilities for mandatory sterile operating conditions.

The authorities first shut down the operating room and then the clinic. The founder and sole proprietor of the clinic was arrested recently on suspicion of professional negligence resulting in injury. This is the first time a LASIK surgeon in Japan has faced criminal charges related to surgery. He is also facing several malpractice lawsuits, including a class action suit by 50 patients.

Some of the problems discovered by the authorities included inadequate facilities and poor hygiene protocols. Interviews with staff revealed that the surgeon had allegedly not followed standard hygiene protocols, reportedly not always sterilising microkeratomes between cases, and not prepping patients adequately. Other problems included no sink in the operating room, and a malfunctioning autoclave.

“We have learned that this doctor didn’t wash his hands between procedures, that he smoked in the laser room, and that he probably used the same blade on more than one patient, and the autoclave was not working well. It is really a pity what happened here in Japan, because it was just one surgeon doing bad things, but it gave a bad impression to the public about laser refractive surgery,” Dr Bissen-Miyajima commented.

The clinic in question was a freestanding LASIK clinic run by a single surgeon, which is something of an anomaly in Japan. Most patients are treated either at a handful of high-volume LASIK centres or in University clinics. Most of these centres have moved towards the all-laser LASIK approach for most patients. The clinic had run ads offering LASIK at far below market prices.

When refractive laser surgery first became available in Japan some 15 years ago it was often performed by cosmetic surgeons and other non-opthalmologists. However, the Japanese Ophthalmology Society stepped in and mounted a campaign insisting that qualified corneal surgeons should be doing this kind of surgery. Currently the majority of LASIK in Japan is performed by ophthalmic surgeons.

This was the first outbreak of this kind in Japan. Dr Bissen-Miyajima compiled information on 30 patients and reports her findings in a research article now in press in the Journal of Cataract and Refractive Surgery. She details information on 39 eyes in 30 patients who developed infectious keratitis over a period of five months.

All of the patients had undergone bilateral simultaneous LASIK procedures utilising a microkeratome. The average time between surgery and infection was about nine days, ranging from one to 50 days. Presentations included granular opacities beneath the flap, multiple infiltrations, and epithelial defects. Clinical examinations showed conjunctival hyperaemia, corneal oedema, anterior chamber inflammation and hypopyon.

Upon referral to corneal specialists, patients were treated with a variety of topical and systemic antibiotics including amikacin, arbekacin, erythromycin, clarithromycin, imipenem, fourth generation quinolones, and topical antifungal agents (voriconazole, fluconazole).

Patients presented with visual acuities ranging from worse than 0.1 to 1.0 or better. More than half presented with acuities of 0.5 or worse. Most responded well to treatment, but two eyes were still worse than 0.1, and five were 0.5 or worse after treatment.

Some cases were quite serious. 10 eyes required flap amputation because of flap necrosis. Five eyes were considered candidates for keratoplasty because of severe corneal scarring and poor visual acuity.

Subsequent laboratory analyses of corneal scrapings from 29 eyes confirmed the role of Mycobacterium in 31 per cent of cases. Mycobacterium Chelonae was identified in all but one of those cases. Those samples were shown to be resistant to treatment with several standard treatments including isoniazid, rifampicin and streptomycin. Lab studies failed to identify causative organisms in 62 per cent of cases.

The outbreak took the Japanese ophthalmology community by surprise, notes Dr Bissen-Miyajima. Patients involved in the outbreak presented at different times and in different centres, so it took some time to recognise that an outbreak was under way. This experience also shows a lack of standardisation in the treatment of post-LASIK infectious keratitis. She notes that the lessons learned from the epidemic should lead to more awareness of the potential for mycobacterial keratitis, and should prompt discussion on the best way to manage such cases.

“I’m also concerned about the effect this outbreak has had on the public perception of LASIK in Japan. This story got a lot of media attention in Japan. The problem is, the media did not report that it was a rare situation involving just one surgeon. This created an impression among the public that LASIK was very dangerous. LASIK volume was already down because of economic conditions, but it wouldn’t surprise me if this hadn’t also had an effect,” she added.