Regulator of devices investigates complaints about multifocal lens

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The BMJ

The UK regulator of healthcare products is investigating reports that patients who had the intraocular lens Mplus X implanted have experienced problems with distance vision. Moorfields Eye Hospital in London has said that it has discontinued using the multifocal lens, which is used to treat nearsightedness, and has reported problems with “a very small number” of patients to the Medicines and Healthcare Products Regulatory Agency (MHRA). The agency later received reports about the lens from three other surgeons through its yellow card system.

A spokeswoman for the hospital said, “Two surgeons had used these lenses in a very small number of patients, but some of these cases developed visual problems and required replacement of the lens.

“In line with trust policy Moorfields reported concerns with this particular make of lens via the Medicines and Healthcare Products Regulatory Agency’s yellow card scheme. We understand the MHRA is investigating these concerns.”

The BMJ understands that two Moorfields surgeons used the lenses, manufactured by the German company Oculentis and marketed in the United Kingdom since January 2014, for a short period of time in private patients. Oculentis said that the three other yellow card reports, all in December 2014, complained of poor distance vision. The company added that the Mplus X lens was not faulty or defective in any way and that no regulator, independent scientific body, or expert had suggested otherwise.

An MHRA spokesman confirmed, “We are currently investigating and will take action if necessary.” He said that the Moorfields report, the first to be made, had now been closed but would not discuss the progress of the later notifications.

Oculentis said in a statement, “The first report, from Moorfields Eye Hospital, has already been closed by the MHRA. Three further reports were made very recently, in December 2014, and all lacked detail. We are currently investigating the facts behind these complaints, which are in very similar terms, basically relating to poor distance vision as the main complaint. We have not received a single incident report from any other competent authority in the EU.”

The company added, “Mplus X lenses are used throughout the world, and we are confident that they comply with all relevant safety and regulatory standards. As with any complex surgery, complications will arise for a small minority of patients.”

George Settas, a surgeon who worked for Optical Express, the UK’s leading corrective eye surgery business, for four years until December 2014, told The BMJ that he was one of the surgeons who made a yellow card report. He said that the lens caused more distance vision problems than its predecessor, the Mplus MF30, and a higher proportion required removal.

He pointed out that the Oculentis website rates the Mplus X as only “very good” for distance vision but “excellent” for near vision, while the Mplus MF30 is said to have “very good” near vision and “excellent” distance vision.

The website suggests that, rather than use the same lens for both eyes, surgeons could adopt a “mix and match” strategy with the Mplus X and another lens in the same family, the Mplus MF20. This is described as having excellent distance vision, very good intermediate vision, and good near vision.

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