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Warning

# Concerns about prion disease spotlight surgical safety risks

## Ophthalmic surgery leaders urge increased safety-engineered instrumentation

By Cheryl Guttman
Reviewed by Francis Mah, MD, Randall J. Olson, MD, and Henry Perry, MD

Ophthalmic surgeons need to be better educated about the risk of sharps injuries and to adopt available safety measures designed for their prevention in light of the mounting concerns about prion disease, concluded a panel of leading corneal and refractive surgeons.


Dr. Mah


Dr. Olson


Dr. Perry

Issues relating to ophthalmic surgery safety were reviewed in a safety conference moderated by Randall J. Olson, MD, and attended by Francis Mah, MD, and Henry Perry, MD. The potential for transmission of diseases caused by prions was a major focus of their discussion.

Prions are the non-viral, non-bacterial infectious proteins that are the cause of Creutzfeldt-Jakob disease (CJD), bovine spongiform encephalopathy, and a new variant of CJD carried by deer and elk that appears to manifest in humans with a rapidly fatal course.

"Western states have been identified as a high-risk area for deer and elk prion disease, but problems with this type of transmissible spongiform encephalopathy appear to be more widespread because it has also been documented in animals from various states in the Midwest and very recently in New York. There are very few cases of transmission to humans so far, but recent increases in mad deer and mad elk disease are worrisome because they may pose the potential for a future epidemic," said Dr. Olson, who is The John A. Moran Presidential Professor and Chair of Ophthalmology and Visual Sciences, and Director, John A. Moran Eye Center, University of Utah School of Medicine, Salt Lake City.

Exposure to prion-mediated disease is particularly relevant to ophthalmic surgery because the eyes, along with the brain and spinal cord, are considered high-infectivity tissues.

In addition, persons infected with prions may remain asymptomatic for years, and currently there are no tests available to diagnose infection. For those reasons, any person needs to be considered as potentially infected. Moreover, unlike bacteria and viruses, it is unclear whether prions contaminating medical instruments can be destroyed using recommended sterilization techniques.

"The potential for contracting bloodborne infections, such as HIV or hepatitis C, as a result of a sharps injury has provided reason enough to implement universal safety precautions, but the potential risk of transmission of prion-mediated disease adds another layer of concern and reinforces the importance of adopting solutions for protection," said Dr. Perry, chief, cornea service, Nassau County Medical Center, East Meadow, NY and senior founding partner, Ophthalmic Consultants of Long Island.

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>
> Henry Perry, MD

"Instrument injuries pose definite concerns with potentially devastating outcomes for surgeons and even more so for the ancillary staff assisting with ophthalmic surgery, and the problems are expected to escalate in the future commensurate with an increased risk level of prion disease in the population of patients who will be coming to cataract surgery," said Dr. Mah, who is assistant professor of cornea, external disease and refractive surgery, department of ophthalmology, University of Pittsburgh. "Everyone involved in this specialty needs to be aware of these issues and of the technology designed to address the risks."

### Safety solutions

The panel members agree that recently introduced single-use, shielded blades offer an important step forward in sharps injury protection. Becton, Dickinson and Co. (BD) is marketing such products, although other ophthalmic instrument manufacturers are expected to follow suit in introducing new safety-oriented blades. The BD line of patented, safety-engineered, single-use incision products features an integrated retractable shield to protect the blade and prevent sharps injuries during instrument use and handling. The shield remains in place, covering the blade to make inadvertent injury impossible, until it is retracted by fingertip activation of its spring-assisted mechanism. After the incision has been made, the blade can be reshielded with a simple press of the finger so that the instrument can be handed off safely to an assistant.

The shield is currently available on metal blade instruments (BD Safety Knife with BD Xstar Blade). A new silicon product (BD Safety Knife with BD Atomic Edge) will be launched soon, and BD plans to make the safety shield available on other blade types in the future.

"Concerns about prion disease transmission have led many countries in Europe to introduce legislation requiring all instrumentation coming in contact with the eye be single-use, disposable devices. However, the United States seems to be far behind in this approach," Dr. Olson said.

"However, OSHA regulations state healthcare workers and institutions need to implement any safety technology available that can minimize occupational exposure to bloodborne pathogens in order to remain in compliance. Used properly, currently available disposable instruments with safety shields could render surgical blades completely safe, and so they appear to represent the benchmark against which other technology should be compared," said Dr. Olson.

"Annually there are up to 1 million accidental needlestick or sharp injuries among healthcare workers, and probably almost all ophthalmic surgeons will experience a blade injury at least once in their career. While we fortunately are working most often with disposable instrumentation, there are still risks associated with single-use instruments while many surgeons continue to favor their multiple-use diamond blades. Universal use of these disposable, protected instruments should be seriously considered because it is truly in the best interest of patients and surgeons," said Dr. Perry, who is also director of research pathology

laboratories, New York Eye and Ear Infirmary and medical director, Lions Eye Bank for Long Island and North Shore University Hospital.

The panel members also acknowledged that despite advances in metal blade technology, no metal blade can compare with a diamond knife with respect to sharpness. However, sharpness of the new silicon blade from BD is approximately 30 nm (diamond is up to 20-nm sharpness), which is a dramatic difference compared with the thicker 200-nm sharpness of steel blades.

"Objections among surgeons about switching to disposables should be eliminated with the availability of this new silicon blade. With its sharpness, I expect anyone would have a hard time telling the silicon blade apart from the diamond knife," Dr. Olson said.

While offering comparable performance relative to diamond blades, the silicon instrument has some advantages. First, it is always reliably sharp. In addition, studies performed by John Marshall, PhD, indicate that the wounds it creates may have greater tensile strength posthealing with improved incisional resistance to rupture.

"The medical device manufacturing community is stepping up to the plate in providing surgeons with safer, high-performance instrument alternatives. We need to pay attention to what is available for ensuring protection of us and our patients," Dr. Olson said.

## Economic considerations

The panel also underlined the fact that the cost of safety-engineered disposable instrumentation is not a deterrent to its implementation. One statistic to consider comes from the American Hospital Association that estimates one case of serious infection by bloodborne pathogens can add up to $1 million or more in expenditures for testing follow-up, lost time, and disability payments.

'We need to pay attention to what is available for ensuring protection of us and our patients.'

Randall J. Olson, MD

"These diseases carry a high cost in terms of their morbidity, but they may also be fatal and there is really no price that can be put on a human life," said Dr. Mah, who is also co-medical director, Charles T. Campbell Ophthalmic Microbiology Laboratory, University of Pittsburgh Medical Center.

At his institution, Dr. Mah participated in a committee looking at the risks of CJD and the associated costs of implementing safer instrumentation. The group determined that if use of reusable cataract surgery instruments was continued, it would be necessary to purchase four to six additional sets of instrumentation per room in order to maintain the current case turnaround rate and comply with CDC recommendations for 1-hour pressure or chemical prion decontamination regimens.

"However, we also need to consider that the adequacy of those measures for destroying prions remains uncertain and also factor in the costs for routine maintenance and repair of diamond knives. After taking the latter into account, depending on the center, there may be no cost difference between reusable and disposable blades, or there may even be a cost benefit for the disposable blades," Dr. Mah added. OT



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