

20 Diopter Condensing Lens with Disintegrating Paint; A Potential Problem?

Abstract

Purpose: To report a potential complication resulting from an inappropriate sterilization method of a 20 Diopter condensing lens intended for use during scleral buckling surgery.

Results: Repeated or prolonged sterilization with STERRAD, low temperature hydrogen peroxide gas plasma, can result in chipping of paint on medical equipment. The retention of particulate material in the eye exposes the patient to increased risk of sub-conjunctival granuloma or a misdiagnosis and may result in further surgery. The institutional policy has been revised to prevent recurrence of such event.

Conclusion: Disinfection or sterilization of surgical equipment should be performed according to the manufacturer's recommendations and surgical equipment should be inspected pre-operatively.

Keywords: Condensing lens for binocular indirect ophthalmoscopy; Particulate material; Decontamination; Indirect ophthalmoscope

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Introduction

Posterior segment surgery may involve scleral buckling and the need for retinal examination with indirect ophthalmoscopy using a 20 Diopter condensing lens. The condensing lenses can be decontaminated in several ways before surgery. "Decontamination" is a general term that encompasses a combination of cleaning, disinfection and/or sterilization processes to make re-usable items safe for both patients and staff for further use. Decontamination of surgical instruments and clinical devices is important to reduce the risk of complications such as infection, particulate material getting into eye, transmission of bacterial toxins and prion material (https://www.rcophth.ac.uk/wp-content/uploads/2014/12/2012_PROF_174_Ophthalmic-Instrument-Decontamination.pdf).

Disinfection aims to reduce the number of viable organisms and is usually achieved by the use of liquid chemicals or moist heat. Sterilization however refers to the elimination of all organisms including fungi, bacteria and viruses as well as spores. Present day manufacturers have guidelines for decontamination of examination lenses, however if guidelines are not adhered to, not only decontamination is ineffective but may result in damage to the lens itself.

We came across one such situation which can describe the effect of improper sterilization and its potential effects. During scleral buckling surgery, black flakes were found on the optical surface of a 20 Diopter condensing lens (Nikon, Japan) with a painted black rim that was intended to be used (Figure 1). The lens was over 5 years old and had been used multiple times previously. It was regularly sterilized using STERRAD, a low temperature hydrogen peroxide gas plasma sterilization system to effectively sterilize a variety of instruments including examination lenses (<http://www.aspjj.com/emea/products/sterrad-sterilization>, <http://www.aspjj.com/emea/products/sterrad-100s/features-and-benefits>).



Figure 1: Flaky 20D lens. Figure shows black paint flakes on optical surface of 20D lens.

Closer inspection revealed that the black flakes originated from the disintegrating paint on the rim of the lens. Wiping the rim of the lens with wet gauze resulted in more flakes coming free from the rim. The lens was deemed unfit for purpose, due to concerns of potentially introducing foreign material sub-conjunctively or into the orbit during scleral buckling surgery. Further enquiries revealed that the manufacturer of the present lens has discontinued their ophthalmic diagnostic lens production, indicating that the index lens was no longer commercially available. It has been reported by another manufacturer that with STERRAD use, some examination lens rings tend to discolour after multiple uses (<http://www.volk.com/pdf/CCG-001-Cleaning-and-Care-Guide.pdf>). Chipping of paint coatings has also been reported with STERRAD use over time with other types of unspecified medical equipment (<http://www.mddionline.com/article/compatibility->

medical-devices-and-materials-low-temperature-hydrogen-peroxide-gas-plasma).

Individual ophthalmic lens manufacturers have specific guidelines for cleaning, disinfection and sterilization of examination lenses. Examination lenses are disinfected by immersing the lens in sodium hypochlorite solution or glutaraldehyde for a specific time. To avoid lens surface damage, the surface should not be cleaned with alcohol, peroxide or acetone (http://www.volk.com/infoweb/?page_id=44). Present day manufacturers of examination lenses have come up with autoclavable and non-autoclavable examination lenses. Only autoclavable lenses can safely undergo steam sterilization without damage; for the non-autoclavable lenses ethylene dioxide or STERRAD gas plasma sterilization are recommended (<http://www.volk.com/pdf/CCG-001-Cleaning-and-Care-Guide.pdf>).

In addition to multiple sterilizations, damage to the lens surface and rim may also occur over time if the concentration of sodium hypochlorite or if the immersion time in the disinfectant is not in accordance with the manufacturer's recommendations. The use of a condensing lens with particulate material on its surface during surgery could result in iatrogenic deposition of matter in the orbital, sub-tenon, or sub-conjunctival tissues. Sub-conjunctival foreign bodies have been associated with granuloma formation [1,2] and confused with uveal prolapse [3]. Retained material or foreign object at the time of surgery is regarded as a "never event" and is a significant risk to patient's safety (<http://www.england.nhs.uk/wp-content/uploads/2015/03/never-events-list-15-16.pdf>).

The authors revised the local institutional policy regarding

sterilisation of reusable examination lenses for surgical use, which had become out-dated. The lack of up-to-date guidelines from the lens manufacturer may have contributed to the inappropriate sterilisation technique however; their successors Righton warn against use of plasma sterilization and recommend sterilizing the examination lens with ethylene oxide and allowing it to aerate at a temperature of 50°C to 60°C (http://righton-oph.com/jp/product/download/pdf/lens_e.pdf). Furthermore, at a cost of £8.30 per unit (exc VAT), the use of single-use examination lenses would obviate the need for sterilisation of examination lenses.

Conclusion

The authors are not aware of a similar previously reported case and suggest that raising awareness of this issue may help avoid potential harm. We highlight the importance of adhering to a regimen of cleaning, disinfection and sterilization according to the manufacturer's guidelines followed by visual inspection of examination lenses by the operating team. The use of a disposable condensing lens would be a simple alternative.

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