

Impact of Low temperature Sterilisation on ophthalmologic lenses, using STERRAD® NX™ and 100NX™ technology.

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Context and Objectives :

In our Sterilization Unit, low temperature sterilization is used to sterilize devices that cannot be steam sterilized, especially ophthalmologic lenses, **without clear guidelines for low temperature** from the devices's manufacturers.

Because **retinal surgery (nearly 3000 a year in our hospital)** is considered to be **at risk of transmission of Non Conventional Transmissible Agents (ATNC)**, process for a lense in XV-XX hospital is (after pre disinfection):

- treatment during 15 minutes with prionicid agent (ALKA100®) in an ALKAZYME® bath
- double manual washing
- standard cycle STERRAD® 100NX™ sterilization.

⇒ Middle number of viability for Miniquads e.g. is 46 cycles in our practice.

The aim of this study is to understand the impact of respectively, prionicid agent, and sterilization with the STERRAD® technology (and if there was differences between NX™ and 100 NX™)

Methodology :

Prospective study comparing 3 arms

GROUP 1(G1) : ADVANCED STERRAD® NX™ Cycle

GROUP 2(G2) : STANDARD STERRAD® 100NX™ Cycle

GROUP 3 (G3) : 15 MINUTES MANUAL DISINFECTION WITH ALKA 100®

standard sterilization load with :

3 Three Mirrors standards lenses (V3M) + **2** Three Mirrors laser lenses (V3ML) + **3** Miniquad (MQ)

(for every cycle, they all were placed first, in a soaking bath of an enzymatic disinfectant solution during 15 minutes)

The devices were identified as: GnA to GnC for V3M, GnD and GnE for V3ML, GnF to GnH for MQ

[n is the arm number in the study]

Criteria :

After every cycle, lenses were not used for surgery but observed in microscopy to evaluate viability and notify event. Event was defined as : **bubble(s) on optics, bubble(s) on collaret, scratch(s), opacification, crack(s), other (with description)**

Nearly all 20 cycles a referent surgeon in vitreous retinal surgery confirmed if lenses could be usable in clinical practice

Results :

Clinical viability (Cycle when lenses were declared unusable)	GROUP 1 STERRAD NX	GROUP 2 STERRAD 100NX	GROUP 3 ALKA 100
Cycle 42	V3ML G1D (opacification, collaret crack)		
Cycle 57	V3ML G1E (scratches opacification, bubbles on optic)		
Cycle 70		V3M G2A (scratches)	
Cycle 86	V3M G1A G1B and G1C (scratches -cracks) MQ G1G and G1H (bubbles on collaret and opacification)		
Cycle 87		V3M G2B and G2C (scratch, white concretion in patient side) MQ G2G (bubbles on collaret) and G2H (opacification)	
Cycle 99		V3ML G2E (cracks)	
Cycle 100	MQ G1F (Bubbles on collaret)	V3ML G2D, MQ G2F (bubbles on collaret but usable)	All lenses were usable after 100 cycles but MQ G3E to G3H had bubbles on collaret without impact on optical quality.
End of study	All lenses unusable	One miniquad usable	All lenses usable

Discussion :

In all 3 arms, we have registered the lenses transformation after every cycle, excepting for the V3M and V3ML in the ALKA 100 arm (no event). Results show that **ALKA 100 seems to be safe for lenses and sterilization may have different impact** probably explained by the manufacturing process of the lenses. **However we didn't observe significant differences between 100NX and NX, except for the V3ML, without a clear explanation.**

The limit of the trial is size of samples, explained by cost and time : 2 seniors Pharmacists in alternance for every cycle, to avoid manipulator bias. But it allowed us to **objectify our process without bias of current using in surgeon rooms.** It would be interesting now to test combination of ALKA 100 and STERRAD 100NX according to our daily practice.

We decided to give all the lenses used in this study to ASP for an expertise in their laboratories, in order to have complementary explanations of mechanism of progressive destruction of the lenses, to complete events observed.

Conclusion :

Manufacturers develop single use lenses, and this study shows that low temperature sterilization with Sterrad NX technology may be a cost effectiveness solution in ophthalmology in our hospital : e.g. 100 single use MQ cost nearly 3400€ and a reusable MQ used during 100 cycles cost less than 3000 €. This study could help device's manufacturers to establish guidelines.

Further studies shall be considered to validate these findings.

