Recent advances in low temperature sterilization - Moving ahead from Cidex™/ETO to OPA/Ozone: An update

Sir,

Low temperature sterilization (LTS) has invaded the operation theatre (OT) because many components of advanced minimally invasive surgical (MIS) instruments, including robotic surgery equipment, have zero tolerance for high temperature steam sterilizers. Modern low-temperature sterilization processes[1-7] include ethylene oxide (ETO), hydrogen peroxide plasma, low-temperature steam and formaldehyde (LTSF), gamma radiation, electron beam technology and liquid chemical sterilizing (LCS), with the latest addition being ozone (O_3).

Cidex™ (2.4% glutaraldehyde, Advanced Sterilization Products; Cilag GmbH International), a five decade old, widely prevalent and effective LTS technique has several drawbacks including inadequate disinfection if used within 2 hours of activation. Immersion in Cidex[1] for 20 mins at 20ºC provides high level disinfection. Sporicidal activity/sterilization requires 10 hours contact time which is seldom possible in busy OTs. The same instruments are reused after immersion for merely 20 minutes in the mistaken belief that they are sterile or that antibiotics will take care of any remaining spores. Asthma, nausea, dermatitis, headache, eye irritation can occur in OT personnel, it is incompatible with "Green OT" concept, and it is incompatible with robotic instruments.

Advantages of ETO gas sterilisation include no damage to instruments from excessive heat, moisture or radiation. However it requires prolonged aeration times besides being mutagenic, carcinogenic, irritant to the eye, skin and airway, and can cause neurological, liver and kidney damage.[1,2] Gas plasma sterilization is safe, quick and requires no aeration. Vaccum, injection, diffusion, plasma and vent are the five steps followed by the Sterrad™ gas plasma system that are completed within 30 minutes.[1,2] A hand held plasma jet capable of inactivating all surface bacteria in 20 sec (airflow rate 5 l/min; distance 2 cm) is now available.[3] Both gamma and electron beam radiation are used commercially and have no harmful emissions. Gas-permeable packaging is not needed and Gamma rays can penetrate to all parts of the product. On the flipside, radiation degrades some plastic gels, teflon, rubber, polypropylene and products with batteries or electronic components. O_3 sterilization comprises two identical half cycles of vacuum, followed by humidification and O_3 injection, followed by the ventilation phase, and is completed within 10 minutes.[4,5] O_3 can process ophthalmic lenses, cables and cords, power batteries and Doppler probes. Ortho-phthalaldehyde (OPA) Cidex™ is 6500 times more toxic to aquatic life than glutaraldehyde requiring neutralization with glycine before drain disposal.

We have compared several LTS techniques[1-7] based on efficacy, penetration, organic matter resistance, duration of action, material compatibility and incompatibility, toxicity and cost [Table 1] for a quick update.

Reprocessing of instruments entails six steps: cleaning, inspection, packaging, sterilization, sterile storage

Table 1: Comparative analysis of low temperature sterilization methods

Sterilant	Efficacy	Penetration and Organic material resistance	Action time	Material compatibility	Cannot process	Toxicity	Cost
Ethylene oxide[1,2] (Eto)	All microbes and Spores	Excellent Penetrates even long lumens	12-24 Hours	Metal Plastic rubber	Flexible Scopes	Carcinogenic flammable Harms Environment	High $7.35 Per cycle
Gas plasma/ vaporized hydrogen peroxide[2,3]	All microbes and Spores	Cannot penetrate long lumens	30 Mins for gas plasma 55 Mins for vapour H_2O_2	Metal plastic Flexible scopes cameras Videolaryngoscopes	Liquids Powder Paper Cellulose	Non toxic by-products: water vapour and oxygen	Processor $65,000 - $130,000 (₹5-10 lac–local 10 Dollar per cycle
Ozone (O_3)[4,5]	All microbes and Spores Even prions	2Mm lumen with <25 cm length; 3Mm lumen with <47 cm length	20000-30000 ppm 80% humidity 3-5 min; 15000 Ppm 90% humidity 7-10 mins	Stainless steel Plastic; pvc Nylon teflon Silicone Plexiglass Pyrexglass Aluminium	Rubber Latex Textile Copper Brass Zinc Nickel Flexible scopes Ampoules	Non toxic byproducts: water and oxygen Osha:<0.3 O_3ppm over 15 min safe; 0.003Ppm O_3 detected by nose	Low 10 Cents/cycle; Smaller inventory required
Low-temp steam and formaldehyde[6] (2%) (LTSF)	All microbes and Spores	Excellent at 60-78°C	Pre-vacuum pre-pulses of steam formaldehyde sterilization washing pulses air pulses.	Endocopes Rigid laryngo scope blades	Vacuum and humidity sensitive equipment	Toxic Irritant to eyes and nose ?Carcinogenic 0.5Ppm=max safe limit	$255/Cycle
Nitrogen di oxide[7] (Eniware)	All microbes and Spores	Excellent	20-40 Mins	Stainless steel; glass Pvc; aluminium Silicon	Nylon Paper Polyester Thermopla elastomer	Supplied as liquid; turns to vapour at room temp	$500 For processor ($7/cycle)
Per acetic acid[1] (35%)	All microbes and Spores	Does not require activation	25 Mins	Endoscopes Broncho scopes	Lead, brass, copper, zinc	Environmental friendly by-products (acetic acid, O_2, H_2O)	Processor $18,200 Peracetic acid cups ($7/cup)
Ortho-phthalaldehyde (OPA)	All microbes and Spores	Does not require activation	5 Hours	Metals Plastic Elastomers	Stains skin and rubber grey	Avoid processing cystoscopes for bladder cancer patient	Low $25/Gallon
Cidex[1,2] (2.4% Glutaraldehyde)	Some mycobacteria are resistant	Requires activation	10 Hrs	Stainless steel aluminium brass copper elastomer plastic		Irritant(eyes and nasal passage) Contact dermatitis	Low ₹930/ 5-Litre $10/Gallon $1.5/Test strip

and quality assurance (bioindicator strains: spores of Geobacillus stearothermophillus).

According to a survey, 54% of Indian anaesthesiologists reuse standard rigid laryngoscope blades without disinfecting them, and only 1% used gas plasma sterilized blades.[8] 40% of handles deemed patient-ready tested positive for occult blood and 86% of them harboured *S. aureus*, Acinetobacter and other pathogens.[9] High level disinfection/sterilization is hence recommended for laryngoscope blades (gas plasma sterilization) and handles followed by wrapping in sterile towel for short term storage.[10] ETO/HP gas plasma is recommended for McGrath™ (Medtronic; Minneapolis; MN) videolaryngoscope instead of wipe-based cleaning. Manufacturers recommend HLD for soiled video batons and reusable blade and sterilization for Glide Rite™ rigid stylets.

The C-MAC™ D blade reprocessing is compatible with low temperature (upto 60°) disinfection and sterilization (Sterrad™, Sterris, ETO).

Low temperature sterilization techniques are constantly being improved and updated with introduction of new technology to cater for MIS instruments, videolaryngoscopes and the green OT concept. Need of the hour is replacement of Cidex™ and ETO with more effective, quicker, safer and environment-friendly sterilization options like OPA and ozone.

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There are no conflicts of interest.

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