

INTRODUCTION

Post-operative endophthalmitis and cluster infections are a great concern for every ophthalmologist. In recent times, the episodes of cluster infections have been painful and have urged us to revisit the scientific facts behind it.

In continuation to our commitment towards infection control in OT setup's, we had organized a **Livewire webcast** on 'Perspectives on infection control in ocular surgery' on 18th July 2015.

The speakers of the webcast included an international faculty, **Dr. Francis Mah** along with Indian faculty like **Dr. Savitri Sharma, Dr. Prashant Garg** and **Dr. Uday Gajiwala. Dr. Ravi Kumar Reddy** from MediVision Eye Care Centre, Hyderabad moderated the entire event.

The webcast was live at **27 centres** across India. It was a grand success with a participation of more than **900 doctors** from across India.

Following are key highlights of the scientific sessions of the webcast which may help you in your clinical practice.





Dr. Francis S. Mah, MD Director, Cornea & External Disease Co-Director, Refractive Surgery Scripps Clinic La Jolla, CA (USA) Dr. Uday Gajiwala, MS Superitendent, Tigics Eye Hospital Run by Divyajyoti Trust Surat, India



TIMING	TOPICS				
8:30 pm – 8:35 pm	Welcome & Introduction				
8:35 pm – 9:15 pm	International perspective on infection control guidelines in ocular surgery Dr. Francis Mah				
9:15 pm – 9:45 pm	Indian perspective on infection control guidelines in ocular surgery Dr. Savitri Sharma Dr. Prashant Garg				
9:45 pm – 10:00 pm	Cluster infections Dr. Uday Gajiwala				
10:00 pm – 10:15 pm	Panel Discussion & Closing Remarks				

SCIENTIFIC PROGRAMME

INTERNATIONAL PERSPECTIVE ON INFECTION CONTROL IN OCULAR SURGERY

Endophthalmitis post-cataract surgery is a serious concern for every ophthalmologist. Endophthalmitis rates post-cataract surgery may range from 0.07% to 0.12%. Although some recent studies indicate an increase in the rate of post-cataract surgery end ophthalmitis.

Risk factors

- Ruptured posterior capsule 4.5-14 x increase
- Externalized vitreous wick
- Wound dehiscence
- Breakdown of sterile technique
- Blepharitis, conjunctivitis, lacrimal pathology
- Complex or complicated cataract surgery

- Immuno compromised host Diabetes Mellitus; elderly; etc.
- Higher incidence in patients with temporal clear corneal cataract wound vs. scleral tunnel incisions

Prophylaxis of endophthalmitis

- Treat periocular conditions preoperatively
- Meticulous draping required
- Skin preparation: apply 5-10% povidone iodine scrub
 - Studies show that there is a 75-80% reduction in endophthalmitis rates with Povidone iodine use





Conjunctival preparation:

- Apply 5% povidone iodine (atleast 3 min contact time) and
- Apply a topical antibiotic (4thgeneration fluoroquinolone)

Evidence on antibiotic use for prophylaxis:

- 5% povidone iodine or topical anti-infective produced similar and substantial decreases in bacteria cultured from conjunctiva
- Combined use may give better results (83% of conjunctiva sterilized)
- Combination of 3 days of fluoroquinolone + povidone iodine irrigation resulted in 95% reduction of culture positivity
- Sustained therapeutic intraocular concentration of antibiotic is needed which can be achieved by:
 - Topical administration
 - Systemic administration
 - Sub conjunctival administration
 - Intracameral administration

For high risk patients

- Systemic Fluoroguinolone
- Subconjunctival Antibiotic

• Post-Operative Topical Antibiotics:

 High Dose should be given (at least QID) for short term until epithelium is healed and tapering of the dose should be avoided.

Etiology of Post-operative inflammation

- Bacterial pathogens: Staphylococcus epidermidis, Propionibacterium acnes
- Retained lens material
- Surgical trauma
- IOL (especially rigid and closed-loop anterior chamber IOLs)
- Exposure to toxic substances intra-operatively
- IOL contamination with toxic packaging or sterilizing compounds
- Endogenous uveitis

WHAT IS TASS?

It is an acute, sterile and non-infectious post-operative anterior segment inflammation. It has a low but growing incidence (0.1-2%). It may occur in clusters and outbreaks.

TASS outbreak is an environmental and toxic control issue that requires thorough investigation and complete analysis of all medications and fluids used during surgery as well as all operating room and sterilization protocols need to be reviewed.

Etiology of TASS

Intraocular Irrigating Solutions (like BSS)

- Abnormalities of pH or ionic composition
- Osmolarity
- Particulate contamination
- Endotoxin contamination of BSS

Intracameral anaesthetics

- Preservatives in anaesthetics
- Higher concentration greater than 2% lidocaine may cause potential endothelial damage

Ocular medications

- Incorrect concentration, pH or osmolality
- Vehicle with incorrect pH or osmolality
- Preservatives in medications solution
- Intraocular medications
 - Antibiotics in irrigating solutions
 - Intracameral antibiotics

Intraocular lenses

- Polishing compounds
- Cleaning and sterilizing compounds

Ophthalmic Viscosurgical Device (OVD)

- Remnant OVD in anterior chamber
- Denatured residual OVD in reusable cannulas or hand pieces





Instrument contamination

- Detergent residues (ultrasonic, enzymatic cleaners, soaps)
- Bacterial LPS or other endotoxin residues
- Metal ion residues (copper and iron)
- Denatured OVDs
- Impurities in autoclave steam moisture

Clinical findings of TASS include:

- Diffuse corneal edema "limbus to limbus"
- Widespread endothelial damage
- Marked anterior segment inflammation
- Fibrin
- Hypopyon
- Descemet's membrane folds and corneal thickening secondary to edema
- Inflammatory keratic precipitates with inferior hypopyon
- Possible iris damage
- Dilated or irregular pupils
- Trabecular meshwork damage
- Possible secondary glaucoma

Infectious Endophthalmitis	TASS		
Occurs in 4-7 days	Occurs within 24 hrs		
Involves posterior segment primarily	Usually limited to anterior segment		
Corneal edema usually not severe	Highlighted by diffuse sever corneal edema		
Prominent vitreous inflammation	Lack of vitreous inflammation		
Responds to systemic or intravitreal antibiotics	Improves/resolves with topical/oral steroids		
Can be gram stain and culture positive	Always gram stain and culture negative		

Treatment of TASS

- Depends on type/amount of substance, duration of exposure and timing of treatment
- Prevention is the goal
- Intense topical corticosteroids (i.e., prednisolone acetate 1% qid 1-2 hours)
- Treatment of glaucoma (i.e., aqueous suppressants)
- Treatment of cystoid macular edema
- Close follow-up especially first several hours per day

INDIAN PERSPECTIVE ON INFECTION CONTROL IN OCULAR SURGERY

Postoperative endophthalmitis continues to remain as a serious concern for every ophthalmologist. Incidence of endophthalmitis is variable and may depend on geographic location, asepsis protocols, surgical technique and antibiotic prophylaxis.

Current incidence of post-operative infection after intraocular surgery < 0.1%.

Endophthalmitis may be cluster or sporadic. Cluster infects are usually reported in a small case series while sporadic ones are reported in a large case series. Causes of cluster infections are usually iatrogenic while patient and surgical factors mainly contribute to sporadic infections.

Risk factors for endophthalmitis:

• Preoperative factors include blepharitis, conjunctivitis, canaliculitis, dacryocystitis, contact lens wear





and systemic diseases like diabetes, immunosuppressant etc. Hence, good preoperative evaluation is essential.

- Intraoperative factors include exposed lid margin, breach in asepsis, contaminated surgical solutions and instruments and reusing solutions and instruments. All these causes may lead to cluster infections.
- Other intraoperative factors include clear corneal incisions, prolonged surgery, type of IOL used, etc.

Other factors which may contribute to surgical infection-

- OT design
- Efficiency
- Equipments and Method of sterilization
- Human elements (work ethics)

Operation theatre (OT) preparation and OT etiquettes

1. OT layout & Design

- Should be on upper floors, not facing the busy roads, cut off from human traffic
- Walls, floors and doors- should be non-porous, hard with minimalistic joints, color of the walls should be cool mild tones (gray, blue, beige), should have built in electrical fittings with no hanging wires and should have reduced ledges and gaps
- Temperature: 18-25°C
- Humidity: 50-55%
- Should have noise control
- Ventilation control methods include filters of pore size 0.3-5µm can be fitted to the AC; should have
 20 volume exchanges/hour with 4 units of fresh air, positive pressure compared to corridor should be
 10%. Ordinary air conditioners are not useful for this purpose
- **Disadvantages of using Formalin:** it is a potential carcinogen and hence not recommended, it gives a false sense of security at the expense of regular disinfection and cleaning.

2. OT environment and etiquettes

- Clean room Environment in OR is essential
- Proper disinfection of instruments & equipment should be done
- Choice of disinfectant to be used- one which is widely available, phenolic solutions, correct strength to be used, Bacillocid (universal)- formaldehyde, Gluteraldehyde; hydrogen peroxide (universal) which is eco-friendly
- Environmental decontamination frequency:

Area/Item	Before 1 st patient	After each patient	Once a day	Once a week	Once a month	When contaminated
Floor	+	+				+
Trash		+				
Closed Cabinet				+ or	+	
Open shelves			+			
Walls				+		+
OT table top	+	+				+
OT entire table			+			+
Instruments stand	+	+				
Supply table	+		+			+
Stools/ Chairs	+		+			+

- Particulate biological matter that accumulates and circulates in the OR \approx no. & movement of people, hence restrict the number of people in the OR
- Proper gloving and scrubbing are essential parts of OT etiquette





- OR etiquette includes personal hygiene, trimmed nails, no nail polish, jewellery
- No item should be thrown on the floor
- Equipment's should be well covered and free of dust
- There should be no leaks in sinks or water supply
- Aquaguard water should be used for scrubbing

Instrument preparation

- Cleaning-RO purified water is preferred, cleaning should be done in running water.
 - Method-Soak in Intru Plus- wash in 1% Aceptik- clean in running water- two changes of distilled water- dry- pack- sterilize
 - For hollow bore instruments- Distilled water irrigation should be done immediately after surgery, flush with air gun and sterilize

• Points to remember for Sterilization

- Understand the autoclave function well, proper packing, and loading to be done not be tightly packed
- Package should include Date, Name of package, load no. and signature on chemical indicator; expiry of sterile package: Autoclaved linen pack-48 hours;
- Reject instrument if it is poorly cleaned or has debris, deposits
- Reject fluid with particles
- 121°C for 15 minutes- on low speed
- 134°C for 3 minutes- on high speed
- Indicators for efficacy of sterilization: Biological, cycle, TST strip or chemical indicators
- **Storage and transport of sterile products** store in closed cabinets if possible, should have limited access and a visible indicator on it, facilitate stock rotation, should be away from soiled material
- Re-sterilization of linen packed autoclaved material should be after 48 hours
- Re-sterilization of plastic packed gas sterilized material should be after 1 month

Points to remember for effective endophthalmitis prophylaxis

- Good preoperative work-up is essential
- Strict discipline in the OT
- Povidone iodine 2.5% to be used before surgery
- Proper skin preparation and draping
- Special care in high risk patients
- Use of intracameral antibiotics

Toxic Anterior Segment Syndrome (TASS)

It is an acute postoperative sterile inflammatory reaction of the anterior segment secondary to toxic substance. It can occur after any anterior segment surgery.

Clinical Features

- TASS usually presents in 12-48 hours
- Presents as diffuse limbus-limbus corneal edema with anterior segment inflammation
- Usually painless
- Causes/Risk factors
- Surgical factors like OVD, irrigating solutions, intracameral antibiotics, ophthalmic ointments, etc.
- Sterilisation factors like inadequate cleaning of instruments reuse of disposable cannulas, use of tap water, reuse of phaco tubing, etc.





- Surgeon factors like instrument tip and glove touch, use of toxic concentrations of intracameral antibiotics, addition of antibiotics to irrigating solutions, use of instruments with oxidised metal deposits, etc.
- Recommendations to prevent TASS
- Flush phaco hand piece, I/A cannulas, and other reusable cannulas
- Use manual flushing
- Use preservative free intracameral drugs
- Properly maintain ultrasonic baths
- Avoid reuse of phaco machines
- Separately process intraocular instruments from extra ocular instruments

Documentation and Outbreak Policy

It is essential to monitor if protocols are being followed in the OT. Do not take anything for granted. Human elements are more unreliable than machines! Systemic surveillance and documentation is the backbone.

Microbiological Surveillance

- Not recommended routinely, should be done before initiation of the OT, after renovation of the OT and when there is an outbreak of postoperative infection. It helps for legal purposes. There are no guidelines on how often it should be done.
- Samples to be collected for surveillance should be from operation table surface, microscope handles, instrument trolley, AC ducts, autoclave and water for scrub- aquaguard water
- Microbiological Testing of the OT air by settle plate method- This can be done before starting new OT, after major OT repairs. Method- Expose plates for 30 minutes on OR table, close, seal with meditape and send. (Blood agar- 37°C/48 hrs, or Sabourauds dextrose agar plates- 27°C/4 days)- Bacterial colonies should be < 10 and fungal colonies should be zero

• In case of Endophthalmitis outbreak-Checklist to know what went wrong

- Check the draping and cleaning method in use
- Check autoclave records, scrubbing and gloving techniques, quality of scrub water, trace all items used for surgery, check their sterility
- Ascertain all items used for surgery with the help of documentation
- Check techniques of assisting in surgery- no touch technique, no break in sterility, no mistakes when handing sterile items
- Check AC, HEPA filter, cleaning protocols of the OR
- If more than one case-look for presence of any common factor
- To do all of this most important requirement is Traceability & Documentation

Documentation

- Record in CSSD should include Date, Load no., In time, out time, items, signature and TST
- Surgery Record in OR should include Date, Sequence of surgery, Name of patient, MR no., Age, Sex, Diagnosis, Type of surgery, Doctor, Nurse, Items used for Surgery: Type of sterilization, Sterilization date, Load no.
- Laboratory record should include Date of sample received, Processing done, Report sent
- Patient record should include Name of patient, MR no., Age, Sex, Diagnosis, Date of Surgery, Sequence of surgery, Type of surgery, Doctor, Nurse, Items used for Surgery, Batch no./expiry date of items used, sterilization records of items used for surgery, Operating notes, complications, time taken for surgery, intracameral antibiotic, postoperative findings, patient compliance to drugs, hygiene load no.

No outbreak/infection can be investigated effectively without documentation. No documentation is complete without traceability





CLUSTER INFECTIONS

Current issues with cataract surgical systems in India

- Large number of eye surgeons in non-surgical position
- High concentration of eye surgeons in urban areas
- Higher prevalence in geo-physically difficult areas and socially underprivileged groups
- Increase in population of aged due to rise in life-expectancy
- Sustainability of the programme difficult in the absence of cost recovery mechanisms

NPCB data on cluster infections

- NGO-22.5%
- Government-10.2%
- Mixed-25.58%
- Being investigated- 10%

After evaluation, following factors have been said to be associated with cluster infection outbreak

- Improper layout of the theatre
- Availability of Staff vs. Volume
- Scrubbing –gowning –gloving technique (needs major improvement)
- No. of instruments sets available
- Chemical sterilisation in use
- 80-100 surgeries done by one surgeon in a day
- OT being run for long hours
- Same day surgery on the day of examination
- Expired IOL being implanted
- Common trolley in use
- No change of gloves after one session
- Same set of instruments used for several surgeries
- Plastic bottle injection RL and pre-filled viscoelastic in use
- Method of autoclaving not known
- No monitoring of activities
- Very weak pre-operative protocol or non-existence of protocol

Root cause of the problem

- Lack of uniform guidelines for the country
- Available guidelines do not reach the end user
- Philanthropic minded people unaware of the protocols and guidelines
- Medical education lacking in training doctors in infection control measures
- Cost constraints
- Enforcement of law-poor in the country
- Lack of commitment for a change
- Disagreement on the methods/protocol used

Cluster infection cases can be reduced by following proper guidelines and maintaining necessary discipline inside the OT

Need of the hour is to come up with a revised infection control guideline under the national programme, spread information across the country, enforce implementation of the guidelines through various efforts including supervisory inputs, make all the people involved in medical care more quality conscious and add infection control as a separate subject in the medical curriculum.

Some international guidelines on infection control

- 1. Joint Commission International Accredited Standards For Hospitals
- 2. Best Practices in Infection Control An International handbook
- 3. ESCRS guidelines on prevention, investigation & management of post-operative endophthalmitis
- 4. Ophthalmic operation theatre practice A manual for developing countries. Published from ICEH, London
- 5. Hand hygiene CDC guidelines





Some national guidelines on infection control

- 1. Hospital Infection Control Manual published yearly from CMC, Vellore
- 2. Consensus guidelines for the prevention of infections in the operating rooms by Hospital Infection Society, India
- 3. The Operating Theatre Journal
- 4. Guidelines for Pre-operative, operative and post-operative precautions for eye surgery by NPCB
- 5. General precautions to safeguard against Post-operative infections following ophthalmic surgery by
- 6. Sterilisation and aseptic practices in an ophthalmic operation theatre by Aravind eye hospitals
- 7. A manual for eye operation theatre by SEWA rural, Jagadia
- 8. Guidelines for Quality Cataract Management in secondary level eye care centres by Sight savers international
- 9. AIOS guidelines to prevent intraocular infection
- 10. Vision 2020: e-resource Sterilisation Protocol

With the advent of advance cataract surgical techniques like refractive surgeries, knowledge of infection rate in one's own hospital would help us to follow rigorous Infection Control practices.

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Cipla Data on File
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