

Toxic Anterior Segment Syndrome

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TSICP Annual Conference
April 26, 2019



Toxic Anterior Segment Syndrome (TASS): Definition

- ◆ Rare complication of ophthalmic anterior segment surgery (ie. Mainly cataract surgery, but also reported after corneal transplants and posterior segment surgeries)
- ◆ Sterile postoperative inflammation of the anterior segment (everything in front of the lens)
- ◆ Onset is usually acute (within 12-24 hours) but can also be delayed (after several months)

Toxic Anterior Segment Syndrome (TASS): Presentation

- ◆ Clinical presentation:
 - ◆ Patient presents next day or within 2 postoperative days
 - ◆ Decrease in vision, may or may not have pain, light sensitivity
- ◆ Clinical findings:
 - ◆ Severe anterior chamber reaction, possibly hypopyon
 - ◆ Diffuse corneal edema (usually limbus to limbus)
 - ◆ Photophobia
 - ◆ Increased IOP
 - ◆ Dilated or irregular pupil



TASS: Etiology

- ◆ May be multifactorial
 - ◆ Bacterial endotoxins or particulate contamination of balanced salt solutions
 - ◆ Intraocular irrigating solutions with abnormal pH, osmolarity or ionic composition
 - ◆ Denatured Ophthalmic Viscosurgical Devices (OVD)
 - ◆ Intraocular medications (antibiotics in the irrigating solutions or intracameral antibiotics)

TASS: Etiology

- ◆ May be multifactorial (continued)
 - ◆ Topical ointments
 - ◆ Inadequate sterilization of surgical instruments and tubing
 - ◆ Inadequate flushing of instruments between cases resulting in build-up of OVD
 - ◆ Metallic precipitate

TASS: General Pathology

- ◆ Severe inflammatory reactions in response to the contamination, toxins, imbalanced solutions, medications or preservative in the medications.
- ◆ This is a sterile anterior segment reaction
- ◆ There is no bacterial or fungal infection, although one potential cause of the inflammatory reaction is secondary to bacterial endotoxins

TASS: Diagnosis

- ◆ Acute onset within 12-48 hours of surgery
- ◆ Lack of bacterial or fungal growth from cultures of intraocular taps
- ◆ Good response to topical ophthalmic steroid drops

TASS: Differential Diagnosis

- ◆ Infectious endophthalmitis
 - ◆ Virulent organism: presents acutely
 - ◆ Most cases present 2-7 days after surgery
 - ◆ Intraocular diagnostic aqueous/vitreous taps are positive
- ◆ Retained lens material
 - ◆ Once inflammation is controlled with steroid, you can find the retained lens particle
- ◆ Uveitis
 - ◆ Patient usually has a history
 - ◆ Inflammation recurs after taper of steroid

TASS: Management

- ◆ Topical steroid treatment
- ◆ Rare, more severe cases: systemic steroid treatment
- ◆ Close followup
- ◆ Referral to a retina specialist to rule out infectious cause (vitreous tap)
- ◆ Rare cases: may need cornea transplant, glaucoma surgery or both

TASS: Complications

- ◆ Severe inflammation
- ◆ Pain
- ◆ Vision loss
- ◆ Iris atrophy either dilated or irregular pupil
- ◆ Cornea endothelial damage with corneal edema

TASS: Prognosis

- ◆ Most cases are successfully treated with topical steroids
- ◆ Few go on to need a corneal transplant or glaucoma surgery
- ◆ Depends on making the correct diagnosis early and getting steroids going

TASS: Prevention

- ◆ Use of proper balance salt solution with the correct pH, osmolarity, and ionic composition
- ◆ Good filtration of the BSS at the manufacturing site to eliminate particulate contamination and endotoxins
- ◆ Avoid any kind of preservatives in intraocular solutions, intracameral medications or irrigating solutions

TASS: Prevention (cont)

- ◆ Use of fresh ophthalmic viscosurgical devices (OVD)
- ◆ Adequate sterilization of instruments and tubing according to the manufacturers protocol
- ◆ Standard and clear operative and instrument processing procedures (SOP) need to be implemented
- ◆ The staff and surgeons should be well aware of the SOPs

TASS: topical drops

- ◆ Most topical ophthalmic drops contain preservatives or stabilizing agents, which are fine for the surface of the eye
- ◆ They are toxic to the corneal endothelium if they gain access to the inside of the eye (i.e. benzalkonium chloride BAK)
- ◆ Lidocaine uses methylparaben as a preservative; this should be used preservative-free in the eye
- ◆ Inadvertent seeping of ophthalmic ointment into the anterior chamber has also been implicated in causing TASS

TASS: stabilizing agents

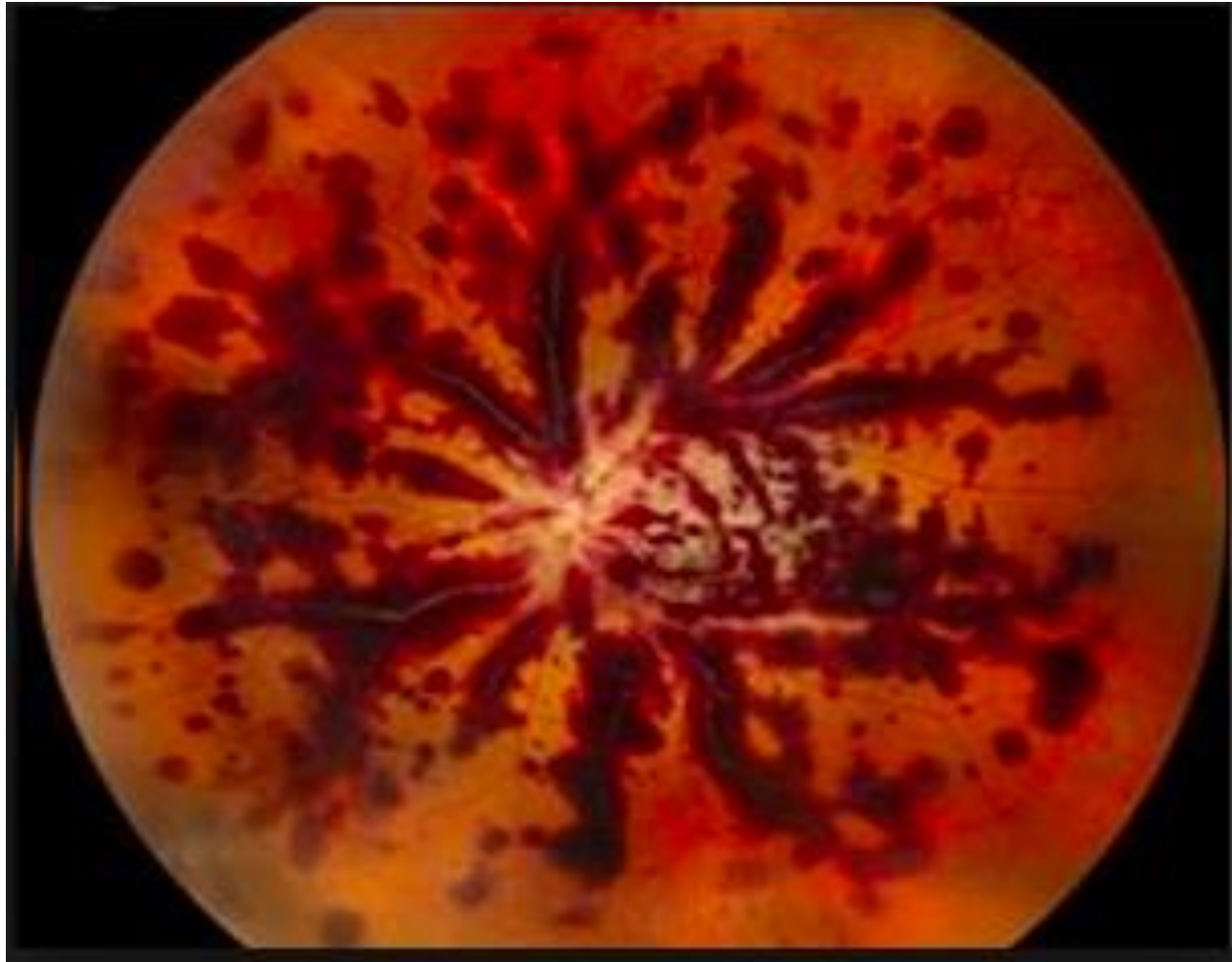
- ◆ Agents used to stabilize intraocular medications may also lead to TASS
- ◆ Technically not preservatives, but have been found to be toxic to the corneal endothelium and other cells of the anterior segment of the eye
- ◆ Most common stabilizing agents: bisulphites or metabisulphites; often used to stabilize epinephrine that is then added to BSS during surgery to help maintain dilation of the pupil

TASS: intraocular anesthetics

- ◆ As already discussed, only use 1% MPF (methylparaben-free) lidocaine
- ◆ Lidocaine at a level of 2% or higher has caused significant corneal thickening and opacification postoperatively

TASS: intraocular antibiotics

- ◆ Antibiotics placed in irrigating solutions have largely fallen out of favor. Gentamycin was found to be toxic to the retina, and Vancomycin has most recently been linked to HORV (hemorrhagic occlusive retinal vasculitis) in rare patients
- ◆ There has been a growing trend to place antibiotics in the anterior chamber at the end of cases to prevent infectious endophthalmitis and to ease the burden of postoperative drops for the patient.
- ◆ We depend on our source of these intracameral antibiotic solutions to insure that quality control and sterility practices are impeccable



TASS: OVD's

- ◆ Can be a potential source of TASS if too much OVD is left in the anterior segment at the conclusion of surgery
- ◆ Especially a problem in prolonged surgeries (complex cataract cases)
- ◆ Residual OVD in the lumen of reusable cannulas or handpieces may also cause inflammation
- ◆ Residual OVD in lumens may also harbor materials such as detergent or enzymes used during the cleaning and processing of the instruments

Ophthalmic Viscosurgical Devices Market



TASS: enzymes and detergents

- ◆ Enzymes and detergents used in the cleaning of ophthalmic instruments were an important factor in the etiology of some TASS cases
- ◆ Residues of these cleaning materials are potentially toxic when they accumulate on the inside surfaces of reusable cannulas or handpieces

TASS: ultrasound baths

- ◆ The use of US baths in the cleaning of ophthalmic instruments is another potential source of TASS
- ◆ Baths may become contaminated by gram-negative bacteria producing heat-stable endotoxins, which are extremely difficult to remove from instruments
- ◆ While the bacteria themselves are killed by the heat used in autoclaving, the endotoxins on the cell surface can remain active
- ◆ Surgery centers should reconsider the use of US baths for cleaning ophthalmic instruments; thorough flushing of ophthalmic handpieces and cannulated instruments at the conclusion of each case should eliminate any residual material, such as cortex or OVD

TASS: water impurities

- ◆ Problems with the water in the devices used for cleaning and sterilizing instruments
- ◆ Residual heavy metal condensates as well as sulphate condensates and impurities may be found in the water supply to the steam sterilizers of autoclave systems
- ◆ These may build-up and gain access to the ophthalmic instruments being sterilized
- ◆ Need proper maintenance of the steam sterilizer to prevent this

A scenic landscape photograph of a mountain valley. In the foreground, a vibrant turquoise lake is nestled among dense evergreen forests. The middle ground shows a wide valley with a winding river and more forested slopes. In the background, majestic mountains with patches of snow rise against a blue sky with scattered white clouds. The overall scene is bright and clear, suggesting a sunny day.

**If I have seen further than others,
it is by standing upon the
shoulders of giants.**

Isaac Newton

TASS: History and case reports

- ◆ 2005 TASS outbreak in US
 - ◆ Surgeons began to notice clusters of patients with acute postoperative inflammation that was initially thought to be infectious
 - ◆ Aqueous cultures remained negative, patients responded well to topical steroids
 - ◆ Cooperative investigation by the CDC and the University of Utah analyzed 112 cases from this outbreak

TASS: 2005 outbreak

- ◆ Vast majority were exposed to a particular brand of BSS during cataract surgery
- ◆ The BSS lots were found to have levels of endotoxin exceeding the allowable limit of 0.5 endotoxin units per milliliter (EU/mL)
- ◆ The withdrawal of the brand of BSS from market (Cytosol Laboratories) stopped this particular outbreak

TASS: Maine 2006 incident

- ◆ In October 2006, an ophthalmologist noticed that 8 out of 10 patients from the same surgery day had an unusual degree of inflammation and decreased visual acuity. The surgeon had been practicing for 20 years and only operated once a week out of the same facility
- ◆ All patients responded favorably to topical steroids and had negative anterior chamber culture results.

TASS: Maine 2006

- ◆ Initial steps the center took:
 - ◆ Epinephrine in irrigation bottles was changed to a preservative-free solution
 - ◆ The solution for the US bath was changed twice a day rather than once a day
 - ◆ They got rid of all lot numbers of medications that were used for these surgeries and started fresh
 - ◆ Staffing was adjusted in the surgeon's OR to include only those people that had worked with eye cases for many years
 - ◆ The autoclave passed a new inspection
 - ◆ The topical iodine antiseptic was switched to single-use containers
 - ◆ A new tip for the phaco handpiece was to be used for each patient

TASS: Maine 2006

- ◆ The ophthalmologist informed the four surgery patients for the next surgical date that TASS had occurred but that these steps were taken to prevent further occurrences
- ◆ All four patients had TASS after surgery again
- ◆ Cataract surgeries were suspended at this center and further modifications were made

TASS: Maine 2006

- ◆ Further testing/modifications:
 - ◆ New (rather than reprocessed) cannulas were to be used for each procedure
 - ◆ A new lot of BSS was obtained
 - ◆ Equipment removed from the US bath was rinsed with sterile, distilled water rather than tap water
 - ◆ Use of an enzymatic cleaner in the US bath was discontinued
 - ◆ A rapid test for the presence of endotoxin in the solutions from the US bath was performed and was positive

TASS: multifactorial

- ◆ Most important factor is often the issue of cleaning and sterilization of instruments
- ◆ Reusable, small-bore instruments such as cannulas or handpieces may be a potential source of TASS due to small internal diameters of these instruments
- ◆ It is of utmost importance to thoroughly FLUSH reusable cannulas and handpieces at the end of EACH case
- ◆ Difficult to control staff, who are faced with shorter turnover times
- ◆ Surgeons and surgical centers are encouraged to reconsider the use of ultrasound baths for the cleaning of ophthalmic instruments

TASS: ASCRS, AAO and OOSS recommendation

- ◆ “Based on the documented risk of TASS associated with enzyme detergent use, without proven benefit for endophthalmitis prevention, enzymatic detergent should not be required for routine decontamination of ophthalmic intraocular instruments.”

TASS: use of certain topical antibiotics preoperatively

- ◆ There was a recent cluster of TASS cases from a single surgeon who used Besivance (besifloxacin) immediately preoperatively in his cataract patients
- ◆ It was determined that the Durasite vehicle in this drop may cause TASS
- ◆ The use of medications with the Durasite vehicle (Besivance, Durazol or Azasite) should not be used immediately preoperatively in the surgical setting

TASS Registry

- ◆ <https://ascrs.org/tass-registry>
- ◆ TASS Task Force, in association with the ASCRS, is working with the FDA to help analyze potential sources of TASS
- ◆ The webpage will present guidelines the taskforce has created regarding sterilization, as well as tools needed to determine potential risk factors for TASS



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OUTPATIENT OPHTHALMIC
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Guidelines for the Cleaning and Sterilization of Intraocular Surgical Instruments

Ophthalmic Instrument Cleaning and Sterilization (OICS) Task Force

Co-chairs: David F. Chang, MD, Nick Mamalis, MD

OICS Task Force Members:

American Society of Cataract and Refractive Surgery (ASCRS): Robert J. Glonn, MD, Richard S. Hoffman, MD, Francis S. Mah, MD, Neal H. Sherstain MD, Nancy K. McCann, Director of Government Relations, Joyce J. D'Andrea, COMT, Director of Allied Health Education

American Academy of Ophthalmology (AAO): Michael X. Repka, MD, MBA, Flora Lum, MD, Vice President, Quality and Science Division

Ophthalmic Outpatient Surgery Society (OOSS): Jeffrey Whitman, MD, Michael A. Romansky, JD, Washington Counsel, Nikki Hurley, RN, MBA, COE

TASS Registry

- ◆ Along with the Taskforce Guidelines,
- ◆ There is an Instrument Reprocessing and Product Questionnaire that can be submitted for your center
- ◆ There is a link to voluntarily report any TASS cases to the FDA

TASS Taskforce

- ◆ Recommended practices for cleaning and sterilizing intraocular surgical instruments:
 - ◆ Ensure adequate time for thorough cleaning and sterilization
 - ◆ Rigorous adherence to recommended procedures for cleaning and sterilization
 - ◆ Sufficient inventory of instruments to meet surgical volume and to provide adequate time between cases
 - ◆ Follow manufacturer's directions for use (DFU)

TASS Taskforce

- ◆ Do not allow OVD to dry on instruments; should be rinsed with sterile water immediately following their use
- ◆ Used instruments should be transported from the operating room in a closed container
- ◆ Try to use disposable instruments and/or tubing
- ◆ Do not reuse single use only devices
- ◆ Clean intraocular instruments separately from non-intraocular instruments

TASS Taskforce

- ◆ Avoid using enzymatic detergents for cleaning. If it is necessary, instruments should be thoroughly rinsed with copious volumes of sterile water to remove all detergent
- ◆ Ultrasonic cleaners should be emptied, cleaned, disinfected, rinsed and dried at least daily and preferably after every use
- ◆ Do not reuse manual cleaning tools unless designed for reuse
- ◆ If brushes are reused, they should be cleaned and treated with high-level disinfection or sterilization, preferably after each use

TASS Taskforce

- ◆ Rinsing should provide flow of water through or over instruments and agitation in a basin of water should not be used
- ◆ Following thorough rinsing, instruments with lumens should be dried with forced or filtered compressed air
- ◆ If reusable woven materials are used for draping or wrapping trays or instruments, they should be laundered thoroughly between each use to eliminate surgical compounds, debris and cleaning agents
- ◆ Cleanliness and integrity of instruments should be verified

TASS Taskforce

- ◆ Importance of administrative controls:
 - ◆ Policies and procedures regarding cleaning and sterilizing intraocular surgical instruments should be written and reviewed periodically
 - ◆ Personnel should be educated about TASS and its causes at hire and updated regularly thereafter
 - ◆ Conduct competency validations by direct observation of performance, using a competency checklist to ensure uniform evaluation of all personnel.

Thank you!

◆ Any questions?

