


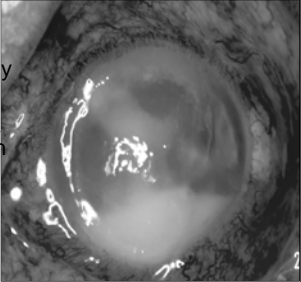
MEETING THE SAFETY CHALLENGES IN OPHTHALMIC SURGERY: INSTRUMENTATION

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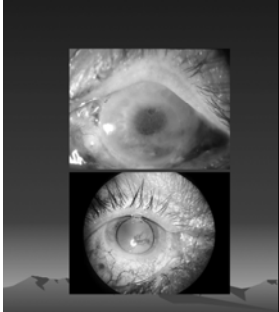
Analysis of Toxic Anterior Segment Inflammation

Rule out infectious etiology
Later onset (4-7 days postop)
Anterior segment reaction
Corneal changes
Due to an infectious etiology (contamination)



TASS DIAGNOSIS

- { POD1 Marked inflammation
- { Limbal to limbal corneal edema
- { Usually good vision and little pain



Clinical Course

TASS Syndrome

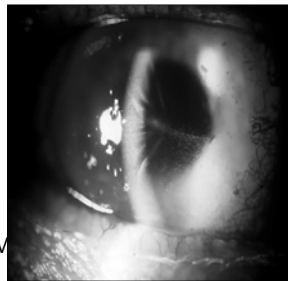
- Rapid clearing of inflammation - mild cases
- More prolonged clearing (3-6 weeks) - moderate cases



Clinical Course

TASS syndrome

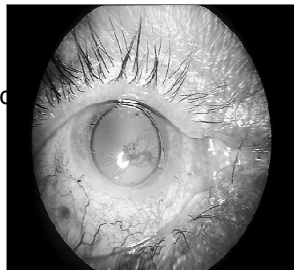
- Severe cases - permanent damage
 - Corneal edema
 - Chronic inflammation/CM E



Clinical Course

TASS Syndrome

- Permanent fixed dilated pupil
- Glaucoma resistant to treatment



Etiology of TASS Syndrome

Ophthalmic Viscosurgical Devices (OVDs)

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

Etiology of TASS Syndrome

Sterilization of Instruments and Tubing

- | Detergent and enzyme residues
- | Endotoxin contamination of sterilizers, water/ ultrasound baths
- | The friday AM TASS Mystery!

Etiology of TASS Syndrome

Sterilization of Instruments and Tubing

- | Impurities in autoclave steam moisture

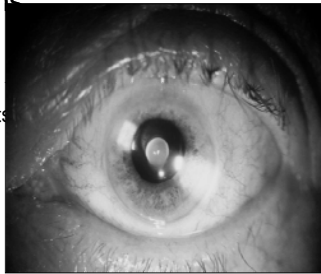
TASS

- | The possibilities beggar the imagination!
- | Consistently get several outbreaks each week.
- | Usually related to cutting corners, costs and turnover time.
- | Big offenders: heat stable endotoxin, autoclaved OVDs re-injected and faulty products.

Etiology of TASS Syndrome

Topical Medications

- | Topical ointments into
- the anterior chamber



Etiology of TASS Syndrome

Endotoxin contamination of BSS

- | Outbreak of TASS secondary to endotoxin contamination of BSS, Fall-2005
- | Cytosol manufactured BSS including Endosol

Epidemic TASS Outbreak

- Late Feb. 2006 to 2007
- Widespread North Amer. distribution
- No single etiological factor identified to date
- Multiple potential causes being investigated

Toxic Anterior Segment Syndrome (TASS) Outbreak Instrument Reprocessing Questionnaire

- Short time available between cases to reprocess and properly clean instruments
- Use of reusable cannulated instruments, tips, and hand pieces with possible inadequate flushing
- Build up of residual cortex, OVD, and other materials

Toxic Anterior Segment Syndrome (TASS) Outbreak Instrument Reprocessing Questionnaire

- Possible contamination within steam sterilizers
- Endotoxin

**Toxic Anterior Segment Syndrome (TASS) Outbreak
Instrument Reprocessing Questionnaire**

- Use of enzymes or detergents to clean instruments with possible residues left on ophthalmic instruments
- Ultrasound water baths with possible endotoxin contamination

**Toxic Anterior Segment Syndrome (TASS) Outbreak
Product Questionnaire**

- Intracameral anesthetic use
 - Must be preservative free
 - Proper concentration necessary
- No single type of IOL implicated in the outbreak
- Possible issues involving cleaning of reusable inserters

**Toxic Anterior Segment Syndrome (TASS) Outbreak
Final Task Force Report**

- No conclusive data to suggest responsibility of a single product
- No single cause or point source related to this outbreak
- Multiple potential etiologic factors

TASS Task Force On-going Endeavors

- Education
- Video symposium now available
- Establishment of instrument cleaning, sterilization, and processing guidelines and protocols

How do I respond to possible TASS?

- Be very suspicious!
- Save EVERYTHING!!
- Go over every step of the procedure and assume nothing!
- Close the place if TASS persists.

Postoperative Endophthalmitis / Inflammation
Investigative Protocol

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Preoperative Data

A. Patient Information:
Name: _____
Age: _____
Sex: _____
Race: _____

B. Ocular Hx:
Concurrent Ocular Disease (circle appropriate)
 Blepharitis
 Acne/Rosacea
 Poor Lid Hygiene
 Hordeolum
 Chalazion
 Other _____
Dry Eyes, chronic ocular surface diseases: _____
Prior Ocular Surgeries (and associated complications): _____

C. PMH: Systemic diseases (circle appropriate)
 Diabetes
 HTN
 Collagen/fibrosular diseases
 Malignancies
 Medications
 List: _____
 Allergies
 List: _____
 NKDA
 List: _____

TASS Investigation Results

- { Can find a cause about 60% of the time (the higher the incidence the greater the odds of success)
- { Can have huge public health impact!
- { To ignore is to invite “nolo contendere” litigation.

Recent TASS Examples

- { Methylene Blue instead of Trypan Blue
- { IC antibiotic mixed with BSS+ additive and not BSS+
- { BSS with heat stable endotoxin
- { IOLs with polishing paste residua on the lens
- { Sterile water used instead of BSS

CMS Compliance Audits

- { Contractors using recovery funds.
- { In 12 states every ambulatory surgery center is to be audited.
- { Eventually all states should have this happen.
- { Looking for compliance breakdown; protocol violations or lack thereof.

Compliance audit findings

- { Too few instrument sets
- { Too little time cleaning & flushing instruments
- { Autoclave violations
- { Poor protocol compliance or no protocols
- { Outdated meds

Other Considerations?

- { Single Use Instruments (mandated in France and being considered in all of Europe).
- { Safety shields on all sharps.

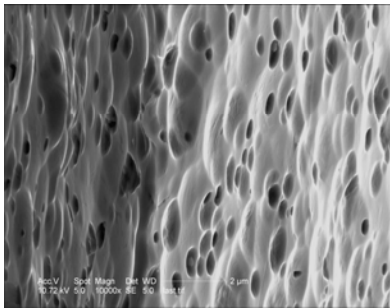
Safer Medical Instrumentation

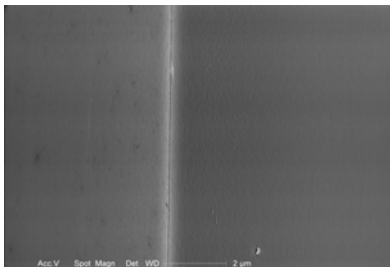


Why Not?

- Too costly (average set single use \$30-35)!
- Diamond blade is my only choice and cannot be disposable!

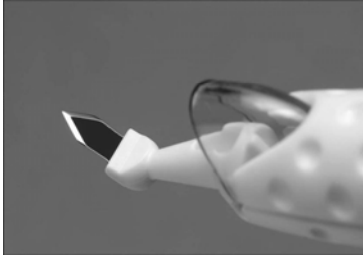
Metal Edge at 10,000 x





Atomic Edge at 10,000 x

Atomic Edge Blade



A TRUE Cost Comparison!

- { Considering time to follow all protocols?
- { All repair and resharpening costs?
- { Time and cost recovery for TASS/endophthalmitis and sharps injuries?
- { A prion case in your OR?
- { Complications from a damaged instrument?

Consider all costs!

- Time to reprocess each tray
- All labor in reprocessing
- Number trays reprocessed
- Utility costs for autoclave
- Number of autoclave cycles
- Cost of sterility slip

Other Costs

- Autoclave depreciation
- O & M on equipment
- Cost of damaged instruments
- Cost of sharps injuries in reprocessing
- Burn-out in stress of hectic turn-around

Full Protocol Costs

- Considering all costs, \$3-5 per used instrument per case.
- Single use set can be had for \$30 for routine cases.
- So is the US being penny smart and pound foolish?

Conclusions

TASS Syndrome

- A rare but potentially devastating postop problem
- Awareness of the etiology, analysis, and treatment of this syndrome is essential
- Scrupulous attention to detail (protocols).
- Considering all issues might single use instruments and safety blades
