

TOXIC ANTERIOR SEGMENT SYNDROME(TASS) IN THE AMBULATORY SURGERY SETTING

STRATEGIES TO IDENTIFY AND CORRECT THIS TROUBLING PROBLEM.

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WHO I AM

- Part of large, multi-specialty group in Metro East and Southern Illinois
- 13 offices, 8 satellites, 5 surgery centers
- 13 Surgeons and 9 full time Optometrists
- High volume cataract surgeons over 10,000 in 2011
- Early adopters of Premium IOLs with high conversions
- #1 LenSx Cataract practice in the country through 8/2012



WHO I AM

- I'm a paid speaker and consultant for Alcon and Allergan
- I'm involved in clinical research with Alcon and Avedra
- I've been a paid speaker for B&L in the past



WHO I AM NOT



WHO I AM NOT

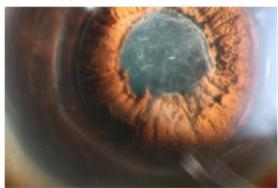
- An infectious disease specialists
- A uveitis expert
- A philosopher
- A political pundit

Basically I'm a high volume surgeon who works with other high volume surgeons in our numerous surgery centers. Our practice has had experience dealing with TASS and I'll relate how we dealt with it.



WHAT IS TASS?

- "An acute,
- sterile,
- anterior segment inflammation,
- following uneventful cataract or anterior segment surgery"



WHAT IS TASS?

- A long recognized, but poorly understood problem
- First accurately described and named in 1992 by Monson, et al
 - Monson MC, Mamalis N, Olson RJ. Toxic anterior segment inflammation following cataract surgery. *J Cataract Refract Surg*. Mar 1992;18(2):184-9.



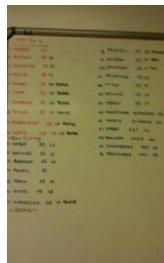
TASS = ACUTE INFLAMMATION

- If treated in time, can resolve with excellent results
 - Over 90% of cases eventually return to pre-operative predicted best acuity potential
- Usually responds well to steroids
 - Non-infectious so antibiotics have no benefit
- Delay in treatment can cause permanent damage
 - Mainly persistent corneal edema requiring transplant
- Delay in diagnosis can lead to "Outbreaks" in high volume centers



WHY SO IMPORTANT?

- 5 million cataract surgeries done each year
 - More and more each year
- High volume centers can do 40+ cataract procedures a day
- A TASS inciting event can affect dozens or more of patients before it's corrected
- Leads to morbidity for patients
- Leads to tarnished reputation for an ASC and its surgeons



DEALING WITH TASS

- 1. FAST AND ACCURATE DIAGNOSIS AFTER SURGERY
- 2. PLAY DETECTIVE IN THE ASC TO IDENTIFY PROBLEM(S)
- 3. ACT RAPIDLY TO FIX SUSPECTED PROBLEMS



MAKING A FAST DIAGNOSIS



FAST/ACCURATE DIAGNOSIS

- Critical to differentiate it from INFECTIOUS endophthalmitis
- For clinicians: Treatments and outcomes are vastly different
- For ASC's: Causative events are much different, with different solutions



DIFFERENTIATING FEATURES

TASS:

- Rapid onset, 12 to 24 hours after sx
- Eye is “quieter”
- “Fibrin” in A/C
- Less pain
- Culture negative
- Rapidly responds to steroids



INFECTION:

- Delayed onset, 4-7 days after
- Eye is “angry red”
- Purulent hypopyon in A/C
- Extreme pain
- Culture positive
- Slowly responds to intravitreal antibiotics



TASS DIAGNOSIS CONFIRMED

- Alert ASC right away
- Alert other surgeons who operated during the suspected time
- Monitor other patients who had surgery around that time very closely
 - More detailed exam
 - Possibly bring them back at day 2, 3, etc.

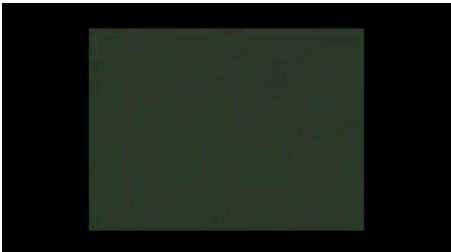


TASS DIAGNOSIS CONFIRMED

- Now what is your role in the ASC?
 1. Make sure ALL surgeons at the facility are aware, so they can be on the lookout for more cases
 2. Investigate possible cause(s) of TASS: PLAY DETECTIVE
 3. Change one variable at a time, wait for results
 4. Seek help: most surgical companies have a TASS squad that will come in if needed



PLAY DETECTIVE. LOOK AT CLUES.
SOLVE THE RIDDLE



CASE 11/11: TASS AT IES

- Received urgent call from Nancy Mueth, RN, Director of our Swansea ASC on a Friday
- 3 out of 7 cataracts done from a surgeon on Thursday morning had "endophthalmitis"
- Afternoon surgeon had not yet seen his patients, unsure if there was more
- Fortunately Thursday was a low volume day, but the upcoming week had hundreds of cases scheduled



INITIAL REACTION

- We needed to make diagnosis: Were these cases infectious or inflammatory (TASS)?
- Questioned the retinal specialist Tom Fleming, who saw the patients
 - Rapid onset (24 hours)
 - Not real painful, just blurry vision
 - No hyper purulence, relatively quiet eyes other than inflammation in A/C
- Determination was that it was TASS, not infectious
- Detective work began



FIRST EXAMINE THE USUAL SUSPECTS



THE USUAL SUSPECTS

- **BSS solution**
 - Largest ever outbreak in 2005
 - From endotoxin contaminated BSS made by Cytosol
- **Use of enzymatic cleaners**
 - 2006 in Maine hospital
 - Outbreak was investigated by CDC
- **Use of highly concentrated detergents**
 - 2006 outbreak in the West
- **Inadequately flushed reusable cannulas**
 - 2007 in Florida, reported at ARVO
- **Contaminated water in ultrasonic water baths that the instruments are reprocessed in**
 - Suspected in 2001 outbreak in Utah



FRIDAY AFTERNOON

- Met to discuss the situation
- Discussed the "usual suspects" for TASS outbreaks
 - BSS solution: began pulling lot numbers for comparison
 - Cleaners/detergents: hadn't been changed in years
 - Cannulas: Some surgeons used reusable, some disposable. We changed all to disposable right away
- Identify variables that may have led to outbreak:
 - 1. Recently changed phaco machines (3 months prior)
 - New and different type of tubing as well
 - 2. Recently changed IOL from silicone to acrylic (4 months prior)
 - 3. Added LenSx laser assisted surgery (4 weeks prior)
 - 4. Added new staff member, responsible for washing instruments (2 weeks prior)



FIRST CHANGE TRIED

- On Monday, we had an experienced staff member wash instruments, new one just watched
- Also, mandated disposable only cannulas
- Had 7 cataracts in the AM by one surgeon, 12 in PM by me
- Wait and watch
- In the meantime, one more case of TASS by yet another surgeon the week prior was identified



TUESDAY

- 2 out of 7 of AM surgeon's cases develop TASS
- None of mine
- We still did not allow new staff member to wash
- 10 more cases being done on Tuesday



WEDNESDAY

- 1 of 10 cases from Tuesday have documented TASS, 1 more from the 7 Monday AM cases now diagnosed as well
- Have 35 cataracts scheduled split between 2 surgeons
- We now have 2 whole days of not using the new staff member to wash and yet have still had documented cases of TASS
- Need to reexamine our variables



WEDNESDAY

- Recently changed from a spray OR cleaner to cleaning wipes (about a month prior)
 - Right away went back to the old wipes
- All cases of TASS had pre-op numbing drops and dilation drops from same lot number
 - Changed to different lot number for both
- Looked at phaco handpieces: No correlation
- Looked at visco-elastic lot numbers: No correlation
- Looked at BSS lot numbers: No correlation
- Had Alcon bring in expert to watch us wash instruments
 - Approved of all techniques during this high volume day



THURSDAY

- Devastating: 7 cases from AM surgeon with TASS
- Total cases with TASS over the 1 week period was 19
- Obviously the changes we made weren't working:
 - Had changed staff to more experienced
 - Had forced all surgeons to use disposable cannulas
 - Had changed all pre-op drops to different lot number
 - Had gone back to the cleaning wipes instead of the spray



EVERYTHING WE TRIED FAILED



SUMMARY SO FAR

- 19 cases of confirmed TASS in one week
- 6 out of 7 surgeons had confirmed cases (I was only one that actually didn't)
- We'd examined all variables
- We'd had experts watch our techniques
- Frustration was setting in for staff and surgeons
- Next step:
 - I learned more about cleaning instruments than I ever had
 - Researched more about TASS
 - Other than the 2005 BSS case, detergents and cleaners are far and away the most common



COMPARE NOTES

- We have several other ASC's, all use the same equipment
- NO OTHER CASES ANYWHERE but in Swansea
- I wanted to match up everything
- I contacted nurse managers Michelle Looney at our Edwardsville ASC and Nikki Will from our Maryville ASC
- I was specifically interested in cleaning methods:
 - Brand and concentration of detergents used
 - Manual or autoflushing



TEXT MESSAGES:

- Nov 17, 2011 12:52 pm from Michelle Looney:
 - "Not sure what u mean by brand of detergent. Just distilled water and flush with air"
- Nov 17, 2011 12:58 pm from Nikki Will:
 - "Only distilled water and then air through it." "No detergent"



DIRECTIONS FOR USE (DFU)

- Varies from machine to machine
- We've had now 5 generations of phaco machines at our center
- All, up to the current unit, allowed low concentration detergents to be used
- Our new machines (four months old) require distilled water only and flush with air.
- In their DFU it states, use of detergents has been associated with episodes of TASS



INFINITI® OZII® AND U/S HANDPIECE

DIRECTIONS FOR USE

Refer to the driving console Operator's Manual (and Addendums) for handpiece compatibility.

CAUTION: The Handpiece Directions-for-Use are not intended to substitute for the necessity of reading and understanding the driving console Operator's Manual. The Operator's Manual, which is provided with the console, includes in-depth material intended to familiarize the Operating Room Staff with the controls and functions of the console.

CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician.

WARNINGS:

DIRECTION FOR USE: The following cleaning and sterilization instructions provide a method for effectively cleaning and sterilizing the Infiniti® Ozii® Handpieces per EN ISO 17664. Due to the potential for Toxic Anterior Segment Syndrome (TASS), Alcon does not recommend the use of enzymatic cleaners and detergents. If however, local jurisdictions mandate their use relative to ophthalmic instruments, the materials of construction are safe for use, up to a pH of 11.3, when the enzymatic chemicals and detergents are completely inactivated immediately after cleaning/processing.

1. Thoroughly clean the handpiece before initial use and **IMMEDIATELY** after each subsequent use. Do not allow the handpiece to dry after use until thoroughly cleaned. Both a manual cleaning process and a cleaning process using an automated washer are presented.

2. **Cleaning Procedure:** Manual

Perform the following steps to manually clean the handpiece:

Step One: Remove the irrigation and aspiration tubing from the handpiece.

Step Two: Unplug the handpiece connector from the console and install the protective cap.

Step Three: Remove the infusion sleeve and tip from the handpiece and discard according to surgical facility guidelines.



CHANGES

- We switched to distilled water right away
- No further episodes of TASS, almost 5000 cases later
- Great learning opportunity for our practice
- Now have established guidelines for dealing with outbreaks or suspected outbreaks



STRATEGIES

- Communication is key



STRATEGIES

- Communication is key
 - Clinician must make diagnosis quickly (differentiate it from infectious)
- Then must alert the ASC ASAP
 - ASC must alert other surgeons who operate there
 - Get input from all surgeons about changes in technique, equipment, etc.
 - Alert surgeons of your suspected variables



SUSPECT THE USUAL SUSPECTS

- BSS, cleansers, detergents, cannulas, ultrasonic water
- Other than the nationwide outbreak in 2005 from BSS, the **VAST MAJORITY** relate to cleansers or detergents



GUILTY UNTIL PROVEN INNOCENT

- American Academy of Ophthalmology, American Society of Cataract and Refractive Surgeons, Center for Disease Control, Intermountain Ocular Research Center, and TASS Task Force all agree:
 - **It's an instrument processing problem until proven otherwise.**
 - Quality of cleaning
 - Brand or strength of detergents
 - Retained OVD in cannulas



DOCUMENT ANY CHANGES TO PROTOCOL

- Easily assessed and ruled in or out as possible causes
- ANY change: from brand of equipment to air filters in the heating unit
- Alerting ALL surgeons anytime there is a change
 - Maybe they've heard something through the grapevine...



STAY UP ON DIRECTIONS FOR USE

- What worked with older equipment, may not work with newer stuff
- Involve the surgical device company if not sure
- In-service with ALL staff when purchasing new equipment. Great time for DFU to be discussed



TEACH THE SURGEONS

- I've done over 10,000 eye surgeries
- NEVER ONCE (before this) did I ask how things got cleaned
- I now know intimately how instruments are cleaned at all the centers I go to
- HIGHLY recommend at least a brief overview of how your ASC cleans instruments to the surgeons



SHARE YOUR EXPERIENCES

- In the end, we're all in this together
- I had luxury of having multiple ASCs to communicate with
- It was that direct communication that solved our problem
- Don't be afraid to reach out to other friendly ASCs
- Contact your device manufacturers
- Contact the TASS Task Force



OUR EXPERIENCE

- TASS-free at all facilities since
- Much higher degree of understanding the processes involved
- TASS/infection protocol in place





Illinois Eye Surgeons

THANK YOU!

Any Questions?

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