

# The Q-Net™ Monthly

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## What's News

Welcome to Q-Net's 13<sup>th</sup> year of publication.

Three articles written by this newsletter's editor-in-chief (LFM) will appear later this winter and spring in: ● **SGNA's Gastroenterology Nursing**, ● **APIC's American Journal of Infection Control**, and ● **SHEA's Infection Control and Hospital Epidemiology**. Push enteroscopy and the reprocessing of both flexible and rigid laryngoscopes are discussed in these three articles.

## Editor-in-Chief

All of the articles published in this newsletter are written by: **Lawrence F. Muscarella, Ph.D.**, Chief, Infection Control at **Custom Ultrasonics, Inc.** Ivyland, PA.

## What is 'Q-Net'?

**Q-Net** is a technology-assessment, Internet-based network of questions and answers. Its newsletter is *The Q-Net™ Monthly*.

The mail goal of **Q-Net** is to encourage the infection control, endoscopy, and OR communities to not only ask good questions but to also demand well referenced responses.

**Q-Net** addresses the needs of both the health care provider whose goal is to provide the best care possible and the patient who deserves affordable quality health care.

## Risk factors for Toxic Anterior Segment Syndrome (TASS)

❖ Adverse complications including serious eye damage associated with the **cleaning and sterilization of ophthalmic instruments** are discussed.

❖ A response to a final report issued last September (2006) by the **ad hoc TASS Task Force** under the aegis of the **American Society of Cataract and Refractive Surgery (ASCRS)** is provided.

❖ Focus is placed on two risk factors for TASS that are not discussed in this Task Force's final report: **flash sterilization** and the **AbTox Plazlyte™ Sterilization System**.

**Introduction:** Several reports of outbreaks of TASS, or *toxic anterior segment syndrome*, have been recently published.<sup>1-14</sup> The February 2007 issue of the magazine *Eyeworld* provides two articles that focus on the causes of TASS.<sup>9,10</sup> One of these articles expresses the concerns of this newsletter's editor-in-chief (LFM) about "flash" sterilization and other overlooked risk factors for TASS.<sup>9</sup>

The etiology of TASS has taken on new significance as the number of reported outbreaks of TASS has unexpectedly and inexplicably surged over the past two years. A hospital in Montreal, Canada, reported 14 cases of TASS in one day last year (March 2006).<sup>5</sup> And, one of the busiest cataract surgery cen-

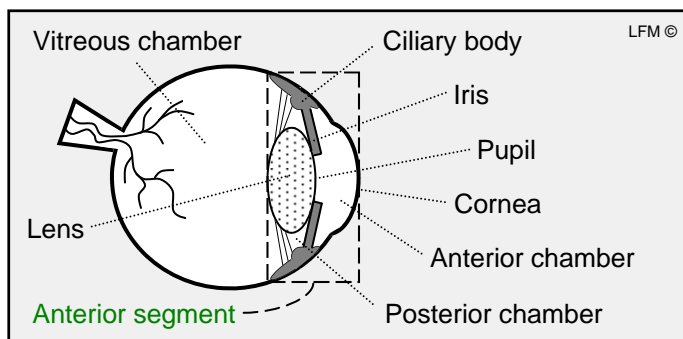
ters in Toronto, Canada, closed last November (2006) amid concerns of a potential TASS outbreak.<sup>2</sup> Several clusters of TASS have also been recently reported in Florida, the Midwest, and California.<sup>12</sup> In all, more than 100 eye centers across North America reported cases of TASS during the first half of last year.<sup>2,3,6</sup>

TASS is a rare and specific inflammatory response of the anterior segment of the eye to contact with toxic, non-infectious substances during ophthalmic surgery, usually cataract surgery (Figure 1, p. 2). TASS may sometimes also be referred to as "sterile inflammation" or "sterile endophthalmitis,"<sup>10,13</sup> with the onset of inflammation being sudden and usually within 12 to 24 hours after surgery.<sup>14</sup> This important characteristic distinguishes TASS from infectious endophthalmitis, which is a different postoperative complication of the eye's anterior segment and which, in addition to being caused by an infectious agent, is associated with symptoms that usually appear 3 to 7 days, or longer, after surgery.<sup>6,12,14</sup> Other distinguishing char-

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**Figure 1:** *The human eye.* TASS causes the anterior segment (enclosed in the dashed box) to become inflamed. The lens, cornea, iris, and ciliary body are structures of the anterior segment, within which are the anterior chamber (located in front of the iris, between the lens and the cornea) and the posterior chamber (located between the lens and the iris).

acteristics of TASS include improvement with steroidal treatment, the absence of inflammatory cells in the eye's vitreous cavity (Figure 1), and negative Gram-stain and culture results indicating that the inflammation is sterile and not due to an infection.<sup>1,6,13,14</sup> The baseline incidence of TASS is estimated to range between 0.1% to 2%.<sup>4</sup>

Several complications are associated with TASS and may include vision loss, high intraocular pressure and glaucoma, and corneal edema extending from limbus-to-limbus.<sup>6,13,14</sup> TASS may also be associated with potentially irreversible toxic damage to intraocular tissues, iris atrophy, and permanent dilation of the eye's pupil.<sup>1,6,13,14</sup> While a few patients have experienced severe eye damage, the injury and inflammation associated with most of the recent cases of TASS have been moderate and without persistent corneal edema.<sup>3,6,12</sup> The majority of these cases has responded quickly to frequent doses of topical steroids.<sup>12</sup> Treatment with antibiotics is not indicated, because TASS is not a bacterial infection.

In general, the etiology of TASS has proved elusive, and the specific causes of most of these recent clusters of TASS have not been identified.<sup>2,3,6,10</sup> Several factors, either alone or in combination, are likely responsible for these recent TASS outbreaks. One investigation identified endotoxin contamination of a balanced salt solution (BSS) used during cataract surgery as the cause of an outbreak of TASS.<sup>3,6</sup> Another investigation linked postoperative sterile endophthalmitis to the use of a specific type of intraocular lens.<sup>15</sup> A third investigation found endotoxins in distilled water used during the preparation of a medication to be the cause of an outbreak of endophthalmitis.<sup>7</sup> In addition, TASS has been linked to surgical trauma, ocular ointments or medications, and the equipment used during phacoemulsification.<sup>1,4,6,14</sup>

While each of these are important risk factors for TASS, the methods and materials used to clean and sterilize ophthalmic instruments used during cataract surgery are suspected to

have been the cause of most of the recent outbreaks of TASS.<sup>2,3,6,10</sup> For example, one investigation concluded that improper maintenance of an autoclave steam generator, resulting in contamination of ophthalmic instruments with endotoxins during steam sterilization, was likely responsible for an outbreak of TASS.<sup>4</sup> A second investigation linked the use of a liquid chemical sterilant to an outbreak of TASS.<sup>11</sup> Other reports suggest that the recent outbreaks of TASS were caused by bacterial and endotoxin contamination of ultrasound water baths used to clean ophthalmic instruments, or to residues of enzymatic detergents that remain on ophthalmic instruments following cleaning.<sup>1,3,6,10</sup> (The temperatures reached by steam sterilizers (*i.e.*, < 140° C) are insufficiently high to deactivate endotoxins and detergent enzymes.<sup>1,3,14</sup>)

#### Discussion: A. The AbTox Plazlyte™ Sterilization System:

The American Society of Cataract and Refractive Surgery (ASCRS) established an *ad hoc* TASS Task Force whose goal was to identify the specific cause(s) of these recent outbreaks of TASS.<sup>3</sup> This Task Force's final report, which was published this past September (2006), suggests that the methods and materials used to clean and sterilize ophthalmic instruments warrant further investigation and are the possible, if not likely, causes of many of these recent TASS outbreaks.<sup>3</sup> *Although its contribution is impressive, this final report did not include a requisite historical discussion of reports of serious eye injuries caused by a low-temperature system that used plasma gas to sterilize ophthalmic instruments.*<sup>4,16-18</sup>

This low-temperature plasma gas system was marketed as the AbTox Plazlyte™ Sterilization System (Mundelein, Ill.), and it used a vaporized mixture of peracetic acid, acetic acid, and hydrogen peroxide at a low temperature to sterilize ophthalmic instruments and other types of surgical instruments (*see the April 1998 issue of this newsletter for a discussion of the AbTox system*). The AbTox system was responsible for serious eye injuries, resulting in its recall and removal from the U.S. market in March 1998.<sup>16-18</sup>

Some ophthalmic instruments may feature small lumens and hinges that contain nickel- and chrome-plated brass.<sup>16-18</sup> According to the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), the AbTox system's sterilization cycle caused salts of copper and zinc to form by oxidation on the surfaces of ophthalmic instruments (and other types of instruments) that contained brass (as well as copper or zinc, or which had been soldered).<sup>16-18</sup> These salts are toxic to human corneal endothelial cells, and some of the serious eye injuries caused by the AbTox system included TASS with localized corneal endothelial damage, which is also known as toxic endothelial cell destruction syndrome (TECD).<sup>14,16-18</sup> Whereas the gastrointestinal and respiratory tracts have not been reported to be irritated or injured by contact with endotoxins and these types of salts, the eye's tissues, particularly corneal endothelial cells, are very sensitive to and can become inflamed by small amounts

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of substances including endotoxins, copper, and zinc.<sup>18</sup>

The FDA issued a warning in April 1998 to alert the public of these reports of serious eye injuries caused by the AbTox system.<sup>16</sup> Of importance to the investigations of the etiology of these recent reports of TASS outbreaks, this warning by the FDA did not rule out the possibility that other low-temperature systems used to sterilize ophthalmic (and other types of surgical) instruments might also be associated with eye damage.<sup>16</sup> Reports suggest that low-temperature sterilization systems are currently used in the ophthalmic operating-room setting.<sup>19,20</sup> Moreover, a manufacturer's marketing brochure indicates the use of a low-temperature system for "sterilizing," among other types of surgical instruments, ophthalmic instruments.<sup>21</sup> The possibility, therefore, remains that some of the recent outbreaks of TASS might have been caused by the formation of toxic substances on the surfaces of ophthalmic instruments sterilized by a low-temperature system (or biocidal agent).

Any report that publishes a list of all of the potential risk factors for TASS would be incomplete unless all of the processes, chemical agents, and detergents used to clean and sterilize ophthalmic instruments associated with TASS and other types of serious eye damage are identified and included (although the analysis of the cause of a TASS outbreak can be complicated by a healthcare facility using more than one type of sterilization process or detergent to reprocess ophthalmic instruments). As part of a thorough investigation into the etiology of the recent spate of TASS outbreaks, it is essential to ask not only whether any data have been published to conclude without doubt that *every one* of the medical facilities in North America that reported a case of TASS used *only* traditional steam sterilizer to process ophthalmic instruments as implied by the Task Force's final report and by other recent discussions of the causes of TASS,<sup>1,3,4</sup> but also whether some of these medical facilities might have used, in lieu of or in addition to steam sterilization, a low-temperature sterilization system that uses, for example, peracetic acid, acetic acid, or hydrogen peroxide to process ophthalmic instruments.

*The reasons for the TASS Task Force's final report not to have discussed the previously identified association between the AbTox system and serious eye injuries including TASS are unclear.* This final report could have been more complete and could have hit its mark with greater authority and veracity had it discussed the AbTox system and addressed whether any currently available low-temperature sterilization systems (or detergents) that use an oxidizing agent in a liquid, vapor, plasma, or gas state to sterilize ophthalmic instruments might be, like the recalled AbTox system, a risk factor for TASS.<sup>14,16-18,22</sup> The failure by the Task Force's final report, or any other report that researches the etiology of TASS, to discuss materials' incompatibility and the potential for toxic substances to form on the surfaces of ophthalmic instruments during low-temperature sterilization precludes a thorough understanding of all of the potential risk factors for TASS and other serious eye injuries.

**B. Flash sterilization:** A complete understanding of all of the potential risk factors for TASS also requires a discussion of "flash," or short-cycle, sterilization. Briefly, flash sterilization is a convenient, rapid, thermally-based sterilization process that has become overused, if not misused, in many fields of medicine including ophthalmology.<sup>1,5,10,8,23,24</sup> Although its intended purpose is very limited and to quickly sterilize an instrument that was, for example, dropped in the operating room,<sup>1</sup> "flashing" has become a more routine method used as a replacement for traditional steam sterilization. Whereas a traditional steam sterilization cycle typically exposes pre-cleaned, wrapped instruments to pressurized steam at 121° C for 30 minutes, followed by instrument drying, a flash sterilization cycle typically exposes unwrapped instruments, which may not have been thoroughly or properly cleaned, to pressurized steam at a higher temperature of 134° C for as few as 3 or 4 minutes, with no time for drying, leaving the instruments wet (and unwrapped) at their time of use.

#### TASS TALK

- ◆ **What's TASS?** An inflammatory response of the eye's anterior segment to sterile (noninfectious) toxins.
- ◆ **What's the focus?** The cleaning and sterilization of ophthalmic instruments as an important risk factor for TASS.
- ◆ **What's the conclusion?** The TASS Task Force's final report<sup>3</sup> did not discuss that **flash sterilization** and the use of **low-temperature sterilization systems** (or biocidal agents) are important risk factors for TASS.

Flash sterilization has transformed from a process used to sterilize instruments only when absolutely necessary, or only in emergency situations as instructed by *The Joint Commission on Accreditation of Healthcare Organizations (JCAHO)* and others,<sup>1,23,25,26</sup> to an all too often practice for quickly sterilizing instruments for immediate use.<sup>26</sup> Flash sterilization is bactericidal, but its process requires close monitoring and is associated with an inherently narrower margin of safety compared to traditional steam sterilization. Flashed instruments are typically unwrapped and wet when they are transported to and used in the sterile field, even though wet instruments significantly increase the risk of nosocomial infection.<sup>27</sup> Indeed, flash sterilization of implants is contraindicated.

Flash sterilization is also likely to introduce two standards of care. Although its methodology has some limitations, one study found a statistically significant higher incidence of nosocomial infection associated with flash sterilization.<sup>1</sup> Furthermore, whereas traditional steam sterilization of instruments is typically performed by experienced reprocessing staff members in a dedicated processing department, flash sterilization is instead performed near (or in) the operating room by operating room staff members whose primary focus

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is patient care, not instrument sterilization.<sup>1</sup> Moreover, wet, unwrapped flashed instruments may be used more frequently during one time of the day (e.g., morning) compared to the use of wrapped, dry instruments during other hours of the day. Flashing may also encourage the (unnecessary?) preoperative administration of prophylactic antibiotics.<sup>1</sup>

The rapid heating and cooling of surgical instruments during a flash sterilization cycle can also cause chipping, flaking, and other types of instrument damage.<sup>28</sup> Some manufacturers of surgical instruments contraindicate flash sterilization.<sup>29</sup> Whether flash sterilization could be damaging ophthalmic instruments causing pieces of the instrument's surface to be introduced into the eye's anterior segment during cataract surgery increasing the risk for TASS is unclear. Whether for these and other reasons flash sterilization would require patient disclosure and informed consent is also unclear.

*Although increasing in use, commonly practiced in ophthalmology, and identified in some reports as a risk factor for TASS,<sup>1,5,6,8,10,23,24</sup> flash sterilization was not discussed in the Task Force's final report.* This is particularly surprising, because some reports single out flash sterilization as one of only a few likely causes of these recent TASS outbreaks.<sup>5,6</sup> Rather than provide a requisite discussion of flash sterilization, the Task Force's final report indirectly alludes to it by expressing concern about "the short time available between cases to reprocess and properly clean instruments. This may be an important factor in the etiology of TASS."<sup>3</sup> Without mentioning flash sterilization by name, the Task Force's final report is suggesting, albeit cryptically, that some of the medical facilities that reported cases of TASS may have been using flash sterilization (or a low-temperature sterilization process amenable to the short period of time medical facilities allot between cases) to sterilize ophthalmic instruments.

The Task Force sidesteps the topic of flash sterilization and does not mention it by name, implying instead that the rationale for flashing an instrument—namely, the short time between cases—rather than the process of flash sterilization itself, is a risk factor for TASS. In short, unless data are available to conclude that every medical facility that reported a case of TASS used only traditional steam sterilization, it is necessary to presume that flash sterilization (and/or a low-temperature sterilization system) was most likely used to sterilize ophthalmic instruments linked to recent cases of TASS.

(The Task Force's final report may have been reluctant to discuss flash sterilization as a risk factor for TASS, because of, among other considerations, JCAHO's objection to its routine use.<sup>23,25,26</sup> Cataract surgery can take as little as 5 or 10 minutes to perform, while proper cleaning and sterilization of ophthalmic instruments may require longer than 30 minutes. As a result, eye centers have two choices: to increase their costs and purchase additional expensive instrument sets to compensate for sterilization downtime; or, to reduce costs and use an alternative more rapid sterilization process like flash sterilization, the potential risks associated with flash sterilization notwithstanding.)

**Conclusion:** It is incumbent on any report that discusses the etiology of TASS and provides recommendations for its prevention to discuss both flash sterilization and the historical significance of the AbTox system vis-à-vis TASS, as well as to include the following two recommendations: **First**, to not use peracetic acid, acetic acid, hydrogen peroxide or another oxidizing agent as a liquid, vapor, plasma, or gas to sterilize (or to clean) ophthalmic instruments unless validated independent data confirming the safety and compatibility of these oxidizing agents for reprocessing ophthalmic instruments have been published and reviewed by the FDA. Toxic debris that forms on the surfaces of ophthalmic instruments as a result of oxidation (or corrosion or wear) during sterilization is an important risk factor for TASS and other serious eye injuries. (Steam sterilization is recommended for any surgical instrument not damaged by heat, pressure, and moisture.<sup>30</sup>) And, **second**, to contraindicate the use of flash sterilization to reduce costs and compensate for an inadequate number of instrument sets in inventory. *Flash sterilization is indicated only for emergency situations.*<sup>1,23,25,26</sup> Medical facilities are recommended to purchase additional ophthalmic instrument sets: to allow sufficient time for thorough cleaning and traditional steam sterilization in a central instrument processing department; to eliminate flash sterilization, which is a oft-overlooked risk factor for TASS; and to practice a consistent standard of care. Measures that support compliance with these recommendations warrant further discussion. ■ **The End LFM**

References for this article are available at:  
[www.myendosite.com/refs010207.pdf](http://www.myendosite.com/refs010207.pdf)

Thank you for your interest in this newsletter. *I have addressed each issue and topic to the best of my ability.* Respectfully, *Lawrence F. Muscarella, Ph.D.* Please direct all correspondence to:

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