

Preventing Corneal Burns during Phacoemulsification

ABSTRACT

The Pennsylvania Patient Safety Authority has received 20 reports of corneal burns during cataract surgery (December 2004 through July 2009). Corneal burns occur immediately following any compromise to irrigation or aspiration while ultrasound power is being applied to remove a cataractous lens. Surgical staff must be alert to any condition that could reduce delivery of saline, which cools the probe used to extract the lens. This article identifies several conditions known to reduce saline delivery and provides guidance for avoiding these conditions. (Pa Patient Saf Advis 2010 Mar;7[1]:23-5.)

Extraction of lenses for cataract surgery is one of the most frequent outpatient surgical procedures; more than three million cases are performed annually in the United States.¹ Phacoemulsification is the commonly used method for cataract extraction. Phacoemulsification systems (also known as phacoemulsifiers, cataract extraction units, or simply, phaco units) apply high-frequency oscillations to remove a cataractous lens from the patient's eye. A cataract is a foggy area in the normally transparent lens that reduces light transmission to the retina and causes cloudiness of vision. The lens is then replaced with an artificial lens.

The entire procedure, including implantation of an intraocular lens, can be performed through one (coaxial) incision or two (bimanual) small incisions under conscious sedation. A vitrectomy is performed to remove extraneous vitreous material if the posterior capsule is accidentally ruptured during the phacoemulsification procedure.

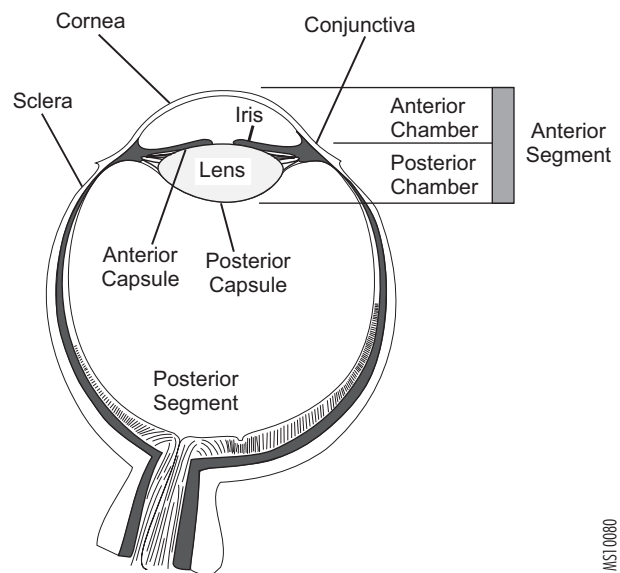
Saline is used to irrigate and aspirate surgical debris and to prevent the oscillating tip of the system's probe from overheating. In coaxial procedures, a single probe contains both irrigation and aspiration ports. In bimanual procedures, the probe contains only the aspiration port, and irrigation occurs through a separate probe inserted through a second incision. In both types of procedures, the surgeon inserts the probe(s) after removing the anterior lens capsule (see Figure) and depresses a footswitch to activate probe tip oscillation simultaneously with saline irrigation and aspiration. The cataract is not broken up by sound waves but rather by the probe tip moving against the cataract. The cataractous lens is emulsified using shaving or scooping motions with the probe tip, and lens fragments are then aspirated from the eye.

Controlling the Phacoemulsification Unit

Maintaining control of the phacoemulsification unit in the eye requires the surgeon to achieve balance between irrigation and the two aspiration parameters: flow and vacuum. During surgery, aspiration flow draws the lens and lens fragments toward the probe tip. The vacuum then holds the lens or fragments at the tip, while the lens material is broken apart. When small enough, the fragments are then aspirated through the probe tip at a rate determined by the aspiration flow. The flow parameter describes the rate at which fluid and lens fragments travel toward and through the probe tip. The vacuum parameter describes the suction force that holds material at the probe tip.

Phacoemulsification units allow surgeons to control the aspiration parameters using either a fixed or variable mode of operation. In fixed modes, the unit provides aspiration at set levels (as specified on the control panel) when the surgeon depresses the foot pedal. In variable modes, the depth to which the surgeon depresses the foot pedal controls one of the aspiration parameters. Operating the unit in a fixed mode is relatively straightforward; however, achieving the desired clinical performance also requires an understanding of the unit's variable modes of operation. The number and type of aspiration controls, as well as the use of the variable modes of operation, depend on the type of pumping mechanism the unit uses to generate flow and vacuum.

Figure. The Anatomy of the Eye



Callouts indicate the areas of interest during phacoemulsification. Reprinted with permission from ECRI Institute, Plymouth Meeting, Pennsylvania.

Peristaltic pump. Systems with peristaltic pumps have two aspiration controls: aspiration flow and vacuum limit. The aspiration flow control determines the pump's operating speed; the faster the pump operates, the greater the resulting flow rate. The vacuum limit is simply a safety setting that stops the pump when the vacuum reaches a set limit. Peristaltic systems can have linear flow and/or linear vacuum (vacuum limit) modes. The availability of these modes for each machine function (e.g., phacoemulsification, irrigation/aspiration, vitrectomy) depends on the device manufacturer and model. In the linear flow mode, the flow rate is controlled by the foot pedal, and the vacuum limit is constant. This mode allows the surgeon to adjust the speed with which fluid and objects move toward the tip. In the vacuum limit mode (sometimes called the variable vacuum mode), the pump speed remains constant, but the vacuum level at which the pump shuts off varies depending on the depth to which the foot pedal is depressed (i.e., as the pedal is depressed, the vacuum limit increases before the pump shuts off).

Venturi or diaphragm pump. On systems using either a venturi or diaphragm pump, the only aspiration control is vacuum. This vacuum setting is the actual negative pressure applied to the collection container and aspiration tubing. For a given vacuum setting, the flow rate is determined by the dimensions of the tubing, fluid viscosity, and the degree of occlusion (i.e., typically, the flow rate will be proportional to the applied vacuum). These systems have a fixed or variable vacuum mode. In the variable mode, the applied vacuum is controlled by the foot pedal. With this type of pumping mechanism, adjusting the vacuum affects the flow rate.

It is important to understand that the vacuum setting on a peristaltic system does not control the same aspiration characteristic as the vacuum setting on a venturi or diaphragm system.

The Problem: Overheating of the Probe Tip

In the 20 events reported to the Pennsylvania Patient Safety Authority (December 2004 through July 2009) and in the more than 1,400 reports to the U.S. Food and Drug Administration's Manufacturer and User Device Experience (MAUDE) database (May 1992 through June 2009), thermal injuries at the location where the probe entered the eye were most likely caused by overheating of the probe tip. During extended use of the probe, the rapid oscillatory motion of the probe tip and the friction generated are known to cause excessive heating. Tests with porcine eyes and egg albumin have shown that overheating of the tip can occur very rapidly (within one to three seconds) and can cause injury even if present for only a short time.² However, the same tests demonstrated that excessive heating does not occur when both irrigation and aspiration flow are present.

Insufficient irrigation or aspiration can have many causes. For example, irrigation can be blocked or

inhibited if the irrigation fluid bottle is empty, if the bottle is positioned too low for adequate flow, or if the irrigation tubing or sleeve is crimped or compressed. Similarly, aspiration flow can be inhibited or stopped if the probe tip becomes occluded (e.g., by lens fragments), if the vacuum limit is set too low, if the aspiration tubing becomes crimped, or if the cassette/tubing set is not correctly installed. Burns caused by a lack of sufficient irrigation and aspiration flow—both of which help cool the probe tip—can be avoided if proper surgical technique and procedures are observed. Factors that contribute to problems with the use of these devices are discussed below.

Causes of the Problem

Lack of Familiarity with the Equipment Used

Because maintaining control of a phacoemulsification unit requires achieving a delicate balance between irrigation and aspiration flow and vacuum, the use of unfamiliar equipment can lead to undesirable results. Surgeons often learn a procedure on one machine, memorizing that system's settings; however, if they try to use those settings on another supplier's system—particularly one that employs a different aspiration system—the likelihood of problems will increase.

For example, some systems use a peristaltic pump that automatically adjusts the pump's speed in relation to the achieved vacuum and the set vacuum limit. As the actual vacuum exceeds the manufacturer's set limit, the system automatically slows the pump to reduce the vacuum rise time after the tissue is captured. This feature has been implemented to avoid undesirable vacuum overshoot. To achieve the flow rate characteristics they are accustomed to, surgeons can set the vacuum limit higher than on previous systems. This is because the flow rate on this unit would be significantly lower than expected at the vacuum limit settings that they have used on other systems.

Lack of Experience Performing the Procedure

Surgeons performing the phacoemulsification procedure gain proficiency with the technique over time. However, because phacoemulsification is such a delicate and complex procedure, thermal burns can—and occasionally do—occur even when the operating surgeon has a great deal of experience performing the procedure. Authority reports suggest that surgical staff may simply forget to perform a pre-use test or be distracted and fail to notice a nearly empty saline container. To prevent these kinds of errors, it is good practice to frequently monitor the drip chamber while the phaco unit is activated to ensure that saline is flowing.

When surgeons start using a new phacoemulsification technique (e.g., transitioning from coaxial to bimanual procedures) or a different phacoemulsification system model, they are again operating at a level of reduced proficiency. For example, phaco models have different warning signals (e.g., audio signal, vibrating foot pedal, automatic ultrasound mode change from continuous to pulse) that indicate a full occlusion,

and the surgeon must be able to recognize the signal to deactivate the ultrasound mode. Therefore, it is important to take the time to master both the surgical technique and the controls of the new unit when making such changes.

Use of Smaller Incisions and Smaller-Diameter Probe Tips

A trend in cataract surgery is to use smaller incisions and smaller diameter phacoemulsification tips. Surgeons should be aware that the smaller diameter will further restrict aspiration flow and be easier to occlude than standard tips.³

Risk Reduction Strategies for Avoiding Corneal Burns

None of the Authority reports of thermal injury suggested a failure of either the phacoemulsification unit or the probe used for the procedure. There is also no information indicating that corneal burns are more frequently associated with a particular phacoemulsification model. Any phacoemulsification system can cause thermal lesions.

Surgeons and nurses must, therefore, understand how the fluidic systems (i.e., irrigation and aspiration) operate on the phacoemulsification units they use. Specifically, surgeons need to understand how fluid flow and vacuum affect the clinical performance they are trying to achieve. For example, consider the following event reported to the Authority:

The handpiece was handed to [the physician] without the irrigation tubing being inspected by technician for verification that tubing was attached. The tubing was not secured to the handpiece, which resulted in a corneal burn of moderate severity that required suturing.

The report further noted that this event resulted from human error and that the facility should reeducate staff about the importance of equipment verification prior to handoff to surgeons for use.

The following strategies may reduce the risk of thermal injury during phacoemulsification. They are directed to surgeons and circulating nurses who perform phacoemulsification procedures; the last four strategies⁴ are surgeon-specific.

1. Distribute this article to ophthalmic surgeons at the facility and to circulating nurses who assist them. Ensure that they are experienced in the operation of the phacoemulsification unit to be used. In particular, surgeons need to be familiar

with the unit's aspiration characteristics and follow the manufacturer's recommendations, which might include different parameter settings than those used with other models.

2. Perform all pre-use irrigation and aspiration tests recommended by the manufacturer. Such checks can help prevent problems with tubing placement, cassette loading, and irrigation bottle height.
3. Use audible vacuum indicators and alarms to call attention to blockages of aspiration on machines with peristaltic pumps. (Machines with venturi or diaphragm pumps supply a constant vacuum level, regardless of occlusions.)
4. Monitor the saline drip chamber to verify that aspiration and irrigation are unrestricted during activation of the ultrasonic generator.
5. Verify that the incision is large enough throughout its entire depth to avoid pinching the irrigation and/or aspiration sleeve and to allow some fluid leakage.
6. Avoid using excessive ultrasound power. Apply power only while shaving the lens, not while the tip is imbedded in the lens or while moving the tip away from the lens. Reducing the amount of phacoemulsification power where possible will also help limit heat generation.
7. Avoid over-torquing the wound. Excessive probe manipulations can narrow the incision and increase friction.
8. Avoid coring the lens with the probe tip, or, if such a technique is used, ultrasound should not be activated while the tip is embedded in the lens.

Notes

1. Centers for Disease Control and Prevention. U.S. outpatient surgeries on the rise [online]. 2009 Jan 28 [cited 2009 Aug 26]. Available from Internet: <http://www.cdc.gov/media/pressrel/2009/r090128.htm>.
2. ECRI Institute. Scleral and corneal burns during phacoemulsification [hazard report]. *Health Devices* 1996 Nov;25(11):426-31.
3. Devgan U. Surgical techniques in phacoemulsification. *Curr Opin Ophthalmol* 2007 Feb;18(1):19-22.
4. ECRI Institute. Scleral and corneal burns during phacoemulsification [hazard report]. *Health Devices* 1996 Nov;25(11):41.

PENNSYLVANIA PATIENT SAFETY ADVISORY

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