CUA Best Practice Report on Holmium:YAG Laser Eye Safety

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Objectives

- Review the current literature regarding risk of eye injuries when using the Holmium laser
- Provide practical and evidence-based recommendations

Background

- Ho:YAG laser
  - 2100 nm pulsed laser
  - Energy emission 0.2–6 joules and frequency 6–50 Hz
  - Depth of penetration 0.4 mm
- 1992: First reported case in a canine model
- 1994: First human application for bladder tumor removal
- Current use
- American National Standards Institute (ANSI)
  - Class 4 laser

Methodology

A panel of experts who are members of the CEG was convened to develop the scope and content of this BPR based on the guidance of the CUA Guidelines Committee.

1. Systematic literature review was conducted
   - English-speaking literature using the Pubmed, Medline, and Cochrane Library databases
   - Search items included
     - Eye, cornea, endoscopy, urology, holmium and laser
2. Following the systematic literature review, an international Twitter poll was conducted, as well as direct contact with 7 Canadian academic and 23 U.S. academic institutions.
3. Additionally, the various urological association websites were examined to determine if any guidelines were available regarding Ho:YAG laser eye safety

Results

- A total of 4 studies (1 review article, 3 original manuscripts) were identified and included:
    1. Doizi S, et al. The eye of the endourologist: what are the risks? A review of the literature. *World J Urol* 2019;37(12): 2639-47.
    2. Althunayan AM, et al. Adverse events resulting from lasers used in urology. *J Endourol* 2014;28(2):256-60
    3. Villa L, et al. Do we really need to wear proper eye protection when using Holmium:YAG laser during endourologic procedures? Results from an ex vivo animal model on pig eyes. *J Endrourol* 2016;30(3):332-7.
    4. Paterson NR, et al. Perceptions and practice patterns of Holmium laser goggles in endourological procedures: An unnecessary evil? *J Endourol* 2019;33(2):146-50

Althunayan et al

Methods:

- Reviewed The Manufacturer and User Facility Device Experience (MAUDE) and the Rockwell Laser Industries Laser Accident Database from 1992–2012
- The MAUDE database, developed by the U.S. FDA, includes all medical devices used in patients
- The Rockwell Laser Industries database is restricted to experimental Aes

Results:

- The majority of the AEs (86%) attributed to the Ho:YAG laser were due to generator/fiber failures
- Regarding all AEs related to the medical operator, there were only 11 reported with Ho:YAG laser
  - These injuries were minor skin burns that were related to firing of the laser with a broken laser fiber

AE: adverse events

Villa et al

- Examined laser eye safety in an ex vivo porcine model
- This study assessed the Ho:YAG laser at most commonly used urological laser settings and at different distances from the ex vivo pig eye.
- Additionally, and importantly this study examined the protection afforded by the use of laser safety goggles and standard eyeglasses in preventing eye damage
- 78 pig eyes were used for this study

- Different laser settings:
  - 0.5J at 20 Hz
  - 1J at 10Hz
  - 2J at 10 Hz.
- 6 different distances:
  - 0cm
  - 3cm
  - 5cm
  - 8cm
  - 10cm
  - 20cm
- The experiment was performed 3 times:
  - With laser safety goggles
  - With standard eyeglasses
  - With no eye protection.

Villa et al cont’d

- It was determined that without eye protection, no eye damage occurred when the tip of the laser fiber was at least 5 cm away from the cornea
- Additionally, no eye damage occurred at any distance in protected eyes
  - More specifically, the use of standard eyeglasses was as protective as laser safety goggles at all laser settings and at all distances

Paterson et al

- Survey of the Endourological Society membership
- Voluntary 24 question survey and included 264 (14%) urologists from the Endourological Society
- It was determined that 97% of the urologists who responded to the survey routinely used the Ho:YAG laser
- Only 40% of respondents routinely wore laser safety goggles
- 70% of respondents who used the laser safety goggles reported that the goggles impaired their vision
- Finally, it was found that 19% of respondents had witnessed some form of injury associated with the Ho:YAG laser, however, no eye injuries were witnessed by any individual at any institution with or without the use of safety goggles

International Twitter poll and survey

- International Twitter poll was conducted and included 322 respondents from around the world.
  - Only 19% routinely wore laser safety goggles.
- Survey of 7 Canadian academic and 23 U.S. academic institutions demonstrated that only 3/30 surgeons wore laser safety goggles, and only 3/30 sites enforced usage.
  - Most sites (90%) had institutional policies that recommended the use of laser safety goggles

Laser manufacturers/EAU guidelines and CSA recommendations

- Ho:YAG laser manufacturers recommend that all intraoperative personnel wear proper laser eye safety goggles
- EAU guidelines on lasers and technologies published in 2014 states that “all intraoperative personnel should wear proper eye protection to avoid corneal or retinal damage”
- The Canadian Standards Association (CSA) mandates that all interoperative personnel wear proper laser safety goggles; this recommendation comes from the Occupational Health and Safety Act under ANSI Z136 which is a series of laser standards
- It should be noted that most laser standards focus on the theoretical basis for safety and use a mathematical approach

Summary and recommendations

1. To date, after over 20 years of extensive use no injuries to the eye have ever been reported with the Ho:YAG laser, with only a minority of surgeons reporting routine use of laser safety goggles
2. Based on recent experimental data it is evident that there is no damage to the unprotected eye unless the laser is fired very close to the eye (within 5 cm of the cornea)
3. The mandate to have all operating room personnel wear laser safety eyewear is not based on contemporary evidence
4. Particularly for operating surgeons who may already be wearing prescription glasses, placing laser goggles over their own glasses leads to significant visual impairment that could result in patient complications
5. It has been determined that standard prescription eyeglasses are as protective as laser safety goggles
6. For those personnel who do not wear prescription glasses, and if likely to be in close proximity to the laser fibre (within 5 cm) they may wish to consider protective eyewear