

Canadian Urological Association Best Practice Report: Holmium: YAG laser eye safety

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SUMMARY AND RECOMMENDATION

1. After over 20 years of extensive use, no eye injuries have ever been reported with the Ho:YAG laser
2. Based on recent experimental data, it is evident 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. Current evidence does not support mandatory safety eyewear for all OR personnel
4. For operating surgeons who may already be wearing prescription glasses, laser goggles over glasses leads to significant visual impairment and could affect the surgeon's ability to identify important visual cues.
5. Standard prescription eyeglasses are as protective as laser safety goggles,
6. Those who do not wear prescription glasses and may be in close proximity to the laser fibre (within 5 cm) may wish to consider protective eyewear

Objectives

Since the introduction of the Holmium:yttrium-aluminum-garnet (Ho:YAG) laser over 2 decades ago, it has become an indispensable tool in the urologist's armamentarium. More specifically, in the subspecialty of endourology, the Ho:YAG laser has revolutionized the approach to kidney, ureteral and bladder stones, endoluminal tumours, strictures and benign prostatic hyperplasia (BPH)[1]. Since its widespread adoption, and as with other laser wavelengths there have been concerns regarding its safety. In particular, the potential risks of eye injury to patients and operating room personnel have led laser manufacturers and governing bodies (including the Canadian Standards Association (CSA)) to require/mandate that all intraoperative personnel wear laser safety goggles. Despite this recommendation, the actual risk of eye damage associated with the Ho:YAG laser during endourological procedures has not been clearly defined. The objectives of this best practice report are to review the current literature regarding the risks of eye injuries and to provide practical and evidence-based recommendations on eye safety with the use of the Ho:YAG laser. This best practice report was developed in conjunction with members of the Canadian Endourology Group.

Background

The Ho:YAG laser is a pulsed laser with a wave length of 2100 nm, with a total energy emission that can vary between 0.2- 6 joules and a frequency of 6- 50 Hz. The depth of penetration is limited to 0.4 mm, and with a wavelength in the mid-infrared spectrum it is avidly absorbed by water. Since human tissue is composed mainly of water, the majority of the Ho:YAG laser energy is absorbed superficially and allows for precise superficial cutting or tissue ablation, with minimal collateral tissue injury.

The first reported use of the Ho:YAG laser was in 1992 in a canine model and was followed by the first human application in 1994 for the treatment of a superficial bladder tumor[2, 3]. Without question this laser has evolved to become an essential tool in the contemporary management of numerous urological conditions including urinary stone disease, urethral and ureteral strictures, urothelial tumors and benign prostatic hyperplasia (BPH). While data is difficult to obtain, most hospitals in Canada with a urological service are likely to have a Ho:YAG laser that is used multiple times a week for various indications.

As with most laser devices used for medical indications and according to the American National Standards Institute (ANSI) standards, the Ho:YAG laser is considered a class 4 laser, meaning it may cause immediate injury to eye and skin through direct or reflected exposure to the beam[4].

When considering the risks associated with laser usage and the need for personal protection, several definitions are important to understand. The Maximum Permissible Exposure (MPE) is the maximum level of laser radiation to which a person may be exposed without hazardous effects or biological changes in the eye or skin[5]. The MPE is determined by the specific wavelength of laser, the energy involved, and the duration of the exposure. MPE is

usually set as 10% of the power or energy density that has a 50% probability of causing damage under worst-case conditions[5].

The Nominal Hazard Zone (NHZ) relates to the space within which the level of direct, reflected or scattered laser radiation exceeds the MPE[5]. Exposure levels beyond the boundary of the NHZ are below the applicable MPE, and therefore no safety measures are needed. The Nominal Ocular Hazard Distance (NOHD), is the distance along the axis of the unobstructed beam from the laser to the human eye beyond which radiant exposure is not expected to exceed the appropriate MPE[4]. Avoiding direct eye exposure to a laser's beam closer than the NOHD through the wearing of eye protection is recommended as the beam's power density (irradiance) from the source to the NOHD exceeds the MPE limit. Once beyond the NOHD however, the beam is considered completely eye safe since the irradiance falls below the MPE limit. It is important to note, that eye exposure even within the NOHD will not automatically cause an eye injury or is even likely to cause an injury. The NOHD is a "nominal" hazard distance, not an actual hazard distance. Given the characteristics of the Ho:YAG laser wavelength in that it can be partially absorbed through water, injuries to the cornea and the lens are possible, but not to the retina[6].

Methodology

A panel of content experts who are members of the Canadian Endourology Group, was convened to develop the scope and content of this best practice report based on the guidance of the CUA Guidelines Committee. A systematic literature review was conducted in search of published reports of eye damage associated with clinical use of the Ho:YAG laser. The search was performed of the English-speaking literature using the Pubmed, Medline and Cochrane Library databases and search items included: eye, cornea, endoscopy, urology, holmium and laser. References obtained from this process were then reviewed and the articles examined for relevance and inclusion. Following the systemic literature review, an international twitter poll was conducted as well as direct contact with 7 Canadian academic and 23 US academic institutions. Additionally, the various urological association websites were examined to determine if any guidelines were available regarding Ho:YAG laser eye safety. Finally, consultation was undertaken with a physicist in order to determine if our findings /recommendations were consistent with the laser's known properties. Herein we present the results of the systematic review and survey findings and provide recommendations based on the current evidence and contemporary practice.

Results

A total of 4 studies (1 review article, 3 original manuscripts) were identified and included[7-10]. A study by Althunayan et al reviewed The Manufacturer and User Facility Device Experience (MAUDE) and the Rockwell Laser Industries Laser Accident Database from 1992-2012[9]. Both databases are voluntary but mandatory reporting systems of adverse events (AE). The MAUDE database, developed by the United States Food and Drug Administration, includes all medical

devices used in patients whereas the Rockwell Laser Industries database is restricted to experimental AEs. Upon review of both databases, AEs were identified associated with various laser wavelengths including 209, 140, 45 and 39 AEs attributed to the neodymium-doped yttrium aluminum garnet (Nd:YAG), Ho:YAG, potassium titanyl phosphate (KTP) and the Indigo 830 nm diode lasers respectively. The majority of the AEs (86%) attributed to the Ho:YAG laser were due to generator/fiber failures. Regarding 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. Although eye injuries were reported with the Nd:YAG, KTP and the Indigo 830 nm diode lasers, no eye injuries associated with the Ho:YAG laser have ever been reported during the 20 year history of the 2 databases.

A study by Villa et al, examined laser eye safety in an *ex vivo* porcine model[8]. This study assessed the Ho:YAG laser at various and 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. The effect of the Ho:YAG laser on eye damage was evaluated by directing the fiber towards the center of the pigs' eyes at different laser settings including: 0.5J at 20 Hz; 1J at 10Hz; 2J at 10 Hz. These laser settings were then applied at 6 different distances (laser tip to eye surface): 0cm, 3cm, 5cm, 8cm, 10cm and 20cm. The experiment was performed 3 times: once with laser safety goggles, once with standard eyeglasses and once with no eye protection. It was determined that without eye protection, no eye damage occurred at any setting 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.

To gauge current practice, a survey of the Endourological Society membership was conducted by Paterson et al[10]. This study was based on a 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 but that only 40% of respondents routinely wore laser safety goggles. Notably it was found that 70% of respondents who used the laser safety goggles reported that the goggles impaired their vision while operating. 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.

An international twitter poll was conducted and included 322 respondents from around the world. Among participants, only 19% routinely wore laser safety goggles. Similarly, a survey of 7 Canadian academic and 23 US academic institutions demonstrated that only 3/30 surgeons wore laser safety goggles, and only 3/30 sites enforced usage. The majority of 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. Similarly, the EAU guidelines on lasers and technologies published in 2014 states that “all intra-operative personnel should wear proper eye protection to avoid corneal or retinal damage.” Additionally, in the EAU guidelines, it is mentioned that this is particularly important for the Nd:YAG laser but also recommended for the Ho:YAG laser[11]. Finally, CSA, also 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[6].

Summary and recommendations

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. Furthermore, 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 5cm of the cornea). The majority of participants in international polls do not use laser eyewear protection. The mandate to have all operating room personnel wear laser safety eyewear is not based on contemporary evidence. Moreover, particularly for operating surgeons who may already be wearing prescription glasses, placing laser goggles over their own glasses leads to significant visual impairment and could affect the surgeon’s ability to identify important visual cues. It has been determined that standard prescription eyeglasses are as protective as laser safety goggles, with this wavelength. 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.

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