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ORIGINAL PAPER

Adverse events related to laser fibers and laser machines during ureteroscopy and stone lithotripsy: Insights from an updated 10-year analysis of the US MAUDE database

Patrick Juliebø-Jones [1, 2, 7], Mathias Sørstrand Æsøy [1], Christian Beisland [1, 2], Vincent De Coninck [3, 7], Etienne Xavier Keller [4, 7], Lazaros Tzelves [5, 7], Peder Gjengstø [1], Christian Arvei Moen [1], Bhaskar K. Somani [6], Øyvind Ulvik [1, 2]

[1] Department of Urology, Haukeland University Hospital, Bergen, Norway;
[2] Department of Clinical Medicine, University of Bergen, Bergen, Norway;
[3] Department of Urology, AZ Klina, Brasschaat, Belgium;
[4] Department of Urology, University Hospital Zurich, University of Zurich, Zurich, Switzerland;
[5] Second Department of Urology, National and Kapodistrian University of Athens, Sismanogleio General Hospital, Athens, Greece;
[6] Department of Urology, University Hospital Southampton, UK;
[7] EAU YAU Urolithiasis group.

Summary *Introduction: Ureteroscopy has become increasingly chosen as a treatment of choice for patients with kidney stone disease and laser as the energy source for stone lithotripsy is a key part of this. Our aim was to analyse a national database to evaluate the burden of adverse events related to laser fibers and laser machines.*

Methods: Search was performed of the Manufacturer User and Facility Device Experience (MAUDE) database in the United States for all events related to holmium laser fibers and holmium laser machines during ureteroscopy between 2012-2021. Information collected included the following: problem, timing, prolonged anaesthesia, early termination of procedure, injury and retained parts.

Results: 699 holmium laser fiber events were reported and these had been manufactured by 13 different companies. The commonest problems were breakage outside the patient while in use (26.3%) and breakage of the laser fiber tip (21.2%). Manufacturers concluded root cause to be device failure in 8.9%. 29% of issues occurred before the laser had been activated. 5.2% of cases had to be cancelled as a result of an event. Significantly more injuries were sustained intra-operatively by operating staff compared to patients (6% vs. 0.2%, p < 0.001). All these injuries were superficial burns to the skin with the hand being the most affected body part (88.1%). Zero ocular injuries were reported. Only eight events were related to laser machines and all involved sudden hardware failure but no patient injury.

Conclusions: Laser fibers are fragile. Most adverse events are due to operator error. Direct patient injury from laser fiber is scarce but operating staff should be aware of the risk of sustaining minor burns. Laser machines rarely incur problems and, in this study, did not result in any safety issues beyond need to abort the procedure due to lack of spare equipment.

KEY WORDS: *Ureteroscopy; Urolithiasis; Laser; Injury.*

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INTRODUCTION

Ureteroscopy is increasingly chosen as a treatment of choice for patients with *kidney stone disease* (KSD) (1). Multiple national registries have recorded that it is the surgical intervention for KSD, which has seen the greatest uptake in recent years (2, 3). A key reason for this shift in practice pattern has been the advancements related to the energy source employed for intracorporal endoscopic stone lithotripsy and more specifically, the advent of laser (*Light Amplification by Stimulated Emission of Radiation*) to urological practice (4-6). The *Manufacturer User and Facility Device Experience* (MAUDE) database is a registry in the United States that catalogues failures including damages related to surgical devices (7). This database, which is essentially a library of adverse events can therefore be examined to gain understanding in surgical fields (8). To date, and in contrast to other areas of urology, little has been explored in the area of lasers used in URS and stone lithotripsy (9). Our aim was to analyse this database and evaluate the events recorded with the principal purpose of evaluating its safety, insights and lessons learned from it relevant to laser machines and fibers.

MATERIALS AND METHODS

Search was performed of the MAUDE database for all events related to holmium laser fibers and laser machines between January 1st 2012 to December 31st 2021 (10). Search terms used were "*laser*", "*laser fiber*", "*holmium laser*", "*ureteroscopy*" and "*laser machine*". This yielded 5450 events. Event reports combine the information given by health professional as well as a manufacturer summary and verdict on root cause. Each report was individually reviewed, and the following information was collected: problem related to the event, timing, prolonged anaesthesia, early termination of procedure, patient injury, surgeon

injury, retained parts and manufacturers´ final verdict on root cause. Reports were excluded if there was insufficient information (n = 37) and/or where the wording lacked clarity (n = 9). This also applied to any duplicates (n = 59). All information in this particular database is unrestricted and freely available to the public worldwide and completely anonymised. As such, ethical approval was not deemed necessary. Data was collected and analysed using SPSS Statistics v.26 (*IBM, Armonk, NY*). Where deemed appropriate, categorical variables were compared using Chi-square test with p-values < 0.05 considered to be statistically significant.

Results

Laser fibers

Over the study period, 699 were events reported related to laser fibers manufactured by 13 different companies (Table 1).

The commonest problems were inadvertent breakage outside the patient while in use (26.3%), breakage of the laser fiber tip inside the patient´s body (21.2%) and laser fiber that suddenly stopped working (16.7%). When laser fibers were reported to suddenly stop working, the cause was found to be micro cracks. If overheating of the laser fiber was reported (3.9%), the underlying cause was also found to be micro cracks. Manufacturers reported the laser fiber problem to have been caused by manufacturing fault, in 8.9% of the events. In that latter group, two skin burns to staff were recorded but no patient injuries. None of the procedures had been terminated but two had incurred prolonged anaesthesia.

While most issues arose while the laser had been activated and in use, 29% occurred before this happened. The most frequently reported reasons for the latter were either the laser being broken in the packaging (16.6%) or inadvertently broken by the assistant during preparation or assembly. While more than 9 in 10 of these events did not affect the procedure being successfully completed, it remained the case that 5.2% had to be cancelled and 14.7% required prolonged anaesthesia. The latter was typically due to the additional time required for basket retrieval of the detached laser fiber tip, which is not always straightforward. Overall, 5% of patients had a fiber fragment retained in the urinary system at the end of the case. Onward treatment plan for this issue appeared to come down to surgeon preference. While 60% of these retained fragments led to the patients being re-listed for elective URS and active retrieval, the remainder were left to pass spontaneously. In 10% of the latter group, a supplementary report had been filed to provide an update that the patient had been re-admitted with pain and required emergency URS and retrieval of the residual fragment. Details were not available to provide a further update on whether surgery to remove residual fragments was successful.

In 4.7% of the events, the ureteroscope was damaged. Cases were terminated early to insufficient spare equipment being readily available at the time of surgery rather than safety concerns except for one case. That particular event involved the surgical drapes catching fire while the laser fiber was resting against them while in use and was found to be broken. Limited details beyond this were available but it was confirmed that it was successfully extinguished, and no injury was sustained to the patient or staff. Significantly more injuries were sustained intra-operatively by operating staff compared to patients (6% *vs.* 0.2%, p < 0.001) (Table 2).

The distribution of injuries to surgeon and assistant/nurse was 45.2% and 54.8%, respectively. All these injuries were superficial burns to the skin with the hand being the most affected body part (88.1%). No ocular injuries were reported. Only two intra-operative injuries were recorded in patients. These consisted of a superficial skin burn to their leg and a case of thermal injury to the ureteric mucosa resulting in stenting.

Table 1.
Summary of events.

Characteristic	Frequency
Number of laser fibers	699
Problem	
Broken outside patient while in use	184 (26.3%)
Broken laser fiber tip	148 (21.2%)
Stopped working	117 (16.7%)
Broken in packaging	112 (16%)
Broken in preparation or assembly	67 (9.6%)
Overheating	27 (3.9%)
Broken on entry to scope	21 (3%)
Broken within body of scope	16 (2.3%)
Not registering	3 (0.4%)
Broken after reported stuck in machine	3 (0.4%)
Misfiring	1 (0.1%)
Visible location of laser fiber breakage while in use	
Distal section	169 (45.4%)
Middle section (i.e., within scope)	16 (4.3%)
Proximal section (i.e., outside patient)	187 (50.3%)
Damage to ureteroscope	
Yes	33 (4.7%)
Timing of problem	
Before laser used	203 (29%)
During laser use	488 (69.8%)
After completion laser usage	8 (1.2%)
Successful completion of procedure	
Yes	662 (94.8%)
Prolonged anaesthesia	
Yes	103 (14.7%)
Lost laser fiber tip left in patient at end of the case	
Yes	35 (5%)
Management:	
Conservative	14 (40%)
Re-listed for planned URS and removal	21 (60%)

Laser machines

There were few events related specifically to the holmium laser machine itself. In total, there were eight reported, and all involved a sudden shut down of the machine. These occurred after laser activation had been commenced. These all related in prolonged anaesthesia. While no patient or operating staff injuries were record-

Table 2.
Intra-operative injuries.

	Frequency
Operating staff injury	
Yes	42 (6%)
Staff member:	
Surgeon	19 (45.2%)
Nurse/assistant	23 (54.8%)
Injury type:	
Superficial skin burn	42 (100%)
Anatomical location of burn:	
Hand	37 (88.1%)
Elbow	2 (4.8%)
Shoulder	2 (4.8%)
Abdomen	1 (2.4%)
Patient Injury	
Yes	2 (0.2%)
Injury type:	
Superficial skin burn	1 (0.1%)
Ureteric thermal injury (stented)	1 (0.1%)

ed as a result, six out of eight of these cases had to be cancelled as no spare laser machine was available.
Manufacturer claimed responsibility for this issue in only two cases. Reasons given by the manufacturer as to why responsibility could not be accepted in the other cases included previous repair having been performed by an external company and failure to service the machine in a timely manner.

Discussion

This study has found that the safety profile related to use of laser fibers is favourable. Risk of intra-operative injury to a patient related to a laser fiber problem seems to be a rare event. The risk for injury to operating staff is higher in comparison, but still relatively low. Likelihood of manufacturing failure is low, and most problems are the result of user error including mishandling of the fiber. While more than one in ten cases incurred prolonged anaesthesia, over 90% of cases were completed successfully despite the event. Lack of spare equipment being readily available leads to cancellation of cases mid procedure. Our study revealed limited results for laser machines, which would suggest that in comparison, that such hardware problems are rare and while they do not result in patient injury, having spare laser unit would prevent aborting the operation.
These findings from the MAUDE database confirm the fragility of laser fibers. Surgeons and operating staff alike should invest time in learning how to use and handle them safely and appropriately (11). Key points include being gentle when feeding the fiber into the scope as well as securing the fiber with a damp swab rather than with a glove or instrument (Table 3) (12).
Awareness of risk factors for fiber fracture can help minimise the risk of occurrence. These include increased angle of deflection, shorter pulse duration, higher core diameter and higher pulse energy (11). The soft, polytetrafluoroethylene lining of the flexible ureteroscope is extremely sensitive to damage such as by uncontrolled energy loss occurring during fiber fracture or the silicate tip itself. Relevant to this, is observing the safety distance concept of the laser tip in relation to the ureteroscope tip to prevent iatrogenic damage from the laser´s cavitation bubble or direct laser energy impact. It is worth noting a relatively low rate of damages to the ureteroscope in our analysis (4.7%), compared to a fourfold higher rate of breakage of the laser fiber tip (21.2%).
This observation suggests that the laser fiber tip may have broken relatively far away from the instrument in most cases, an event known to happen when working with a transparent fiber tip. Interestingly, a theme from the reports of the MAUDE database was that if the glass tip had not been clipped beforehand, identification and retrieval was more difficult. This is precisely the reason why some authors have suggested to cut the fiber tip though the coloured plastic jacket, discarding the transparent fiber tip and its risk of breakage and retainment (11). Note the laser pilot beam can be activated prior to use to help identify coating damage. Management of broken laser fiber tip appears to vary and indeed there is no precedent in terms of evidence to really guide how this should be. While this study has not compared single use and re-usable fibers, when using the latter, these should be carefully inspected and checked for cracks or damages, which can cause subsequent energy leakage (13). In this regard, single-use fibers may lower the risk of unintended laser energy leakages compared to re-usable fibers and would be readily available in case of fiber failure.
Our findings serve as a reminder that damage can occur outside the operating theatre such as during packaging and sterilisation process. While this remains an area where there is limited research to guide clinical practice, the authors recommend implementation of safety training courses locally for dedicated personnel training as well as hospital protocols for safe use of laser. A previous survey of endourologists revealed that institutional laser safety training was only present among 63% of the respondents´ hospitals and likewise, a formal committee was only found in 34% (14).
The potential for ocular injuries attracts a lot of attention and had led to continued debate regarding the absolute

Table 3.
Summary of prevention strategies for laser machine and fiber failure.

Problem	Prevention
Machine failure	Laser machine testing prior to procedure
	Spare machine (if available)
	Regular servicing and testing of machine
Laser fiber failure	Careful removal from packagiung to acoid breakage
	Careful insertion of fiber into the scope
	Secure fiber on outside with wet swab
	Cutting the distal tip of the fiber after use (for resuable fiber)
	Laser fibers should not be wrapped too tight. If a lesion is detected, cut the fiber proximal to this lesion
	Activate laser pilot beam prior to use to help identify coating damage

need for protective eyewear (14). Operating staff injuries were mostly limited to skin burns, with no eye injury at all. This data adds to the evidence supporting the possibility of omitting wearing protective glasses for laser interventions in urology, except for Greenlight laser where the risk of injury to the retina remains a safety hazard. Similarly, a previous review has found that no injuries of this kind related to Ho:YAG have ever been reported in the literature over the past 20 years (15). *Villa et al.* found the critical laser fiber tip to eye distance for injury to be 5 cm when using Ho:YAG (16).

Limitations

There are drawbacks to acknowledge in this study. Firstly, the total number of cases performed over this study period is not known and therefore the incidence of these events cannot be calculated. Given manufacturers were providing evaluations on their own equipment, inherent bias can be present. There was only one case of thermal injury to the ureter reported, which is acknowledged to not be representative of its true burden. Similarly, late complications such as ureteral stricture, which can occur because of thermal injury have not been captured in this data set and this is also a limitation.

The data in MAUDE is added prospectively, however, the intention for its use is not primarily for academic research purposes. Research groups wishing to study this data are reliant on trusting the quality of information provided. In this regard, we were strict to exclude events where information was limited or deemed of insufficient quality. The database also does not register certain parameters such as hospital setting (e.g., community *versus* academic), surgeon experience nor any information regarding patient characteristics such as comorbidities, stone burden or anticoagulation status (17). Also, specific details on prolonged anaesthesia such as precise timings were not available. However, there are valuable insights that arise from reviewing this database, which is relatively unique in nature and the largest of its kind globally. Our study sheds light on events that while they may have been heard of or reported in individual case reports, such data lies outside the standard parameters that are recorded in clinical studies. Moreover, nearly all studies that evaluate the intricacies of laser properties are exclusively performed in the pre-clinical setting.

A strength of databases such as MAUDE is that they are well suited for reporting events that are often related to user error as the information can be shared anonymously. It is such that authors rarely strive to publish results, which could potentially place their own reputation and their hospital´s in an unfavourable light, which may in turn lead to underreporting go these events.

Conclusions

Laser fibers are fragile, and the vast majority of adverse events related to them are not caused by a manufacturing fault, but rather operator and handling errors. Damage to a patient specifically from the physical laser fiber is very seldom but operating staff should be aware of the risk of sustaining minor burns when handling the laser fiber while in use. Laser machines rarely incur problems intraoperatively and in this study did not result in any safety issues beyond the need to abort the procedure due to lack of spare equipment.

References

1. Herout R, Baunacke M, Groeben C, et al. Contemporary treatment trends for upper urinary tract stones in a total population analysis in Germany from 2006 to 2019: will shock wave lithotripsy become extinct? World J Urol. 2022; 40:185-91.

2. Jour I, Lam A, Turney B. Urological stone disease: a 5-year update of stone management using Hospital Episode Statistics. BJU Int. 2022; 130:364-9.

3. Geraghty RM, Jones P, Somani BK. Worldwide Trends of Urinary Stone Disease Treatment Over the Last Two Decades: A Systematic Review. J Endourol. 2017; 31:547-56.

4. Staehler G, Hofstetter A, Gorisch W, et al. Endoscopy in experimental urology using an argon-laser beam. Endoscopy. 1976; 8:1-4.

5. Kronenberg P, Cerrato C, Juliebo-Jones P, et al. Advances in lasers for the minimally invasive treatment of upper and lower urinary tract conditions: a systematic review. World J Urol. 2023; 41:3817-27.

6. Juliebø-Jones P, Keller EX, Haugland JN, et al. Advances in Ureteroscopy: New technologies and current innovations in the era of Tailored Endourological Stone Treatment (TEST). Journal of Clinical Urology. 0(0):20514158221115986.

7. Gurtcheff SE. Introduction to the MAUDE database. Clin Obstet Gynecol. 2008; 51:120-3.

8. Lee J, Kaplan-Marans E, Jivanji D, et al. Post-cystoscopy infections and device malfunctions in reprocessed flexible cystoscopes in a national database. Can J Urol. 2022; 29:11361-5.

9. Althunayan AM, Elkoushy MA, Elhilali MM, Andonian S. Adverse events resulting from lasers used in urology. J Endourol. 2014; 28:256-60.

10. Administration UFaD. MAUDE - Manufacturer and User Facility Device Experience 2023 [Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/textsearch.cfm.

11. Keller EX, Kronenberg P, Tailly T, et al. Laser accessories: surgical fibers, strippers, cleavers, and protective glasses. Curr Opin Urol. 2022; 32:330-338.

12. Talso M, Emiliani E, Haddad M, et al. Laser Fiber and Flexible Ureterorenoscopy: The Safety Distance Concept. J Endourol. 2016; 30:1269-74.

13. Juliebo-Jones P, Somani BK, Gjengsto P, et al. Holmium and Thulium Fiber Laser Safety in Endourological Practice: What Does the Clinician Need to Know? Curr Urol Rep. 2023; 24:409-15.

14. Paterson NR, Fitzpatrick R, Blew B, et al. Perceptions and Practice Patterns of Holmium Laser Goggles in Endourological Procedures: An Unnecessary Evil? J Endourol. 2019; 33:146-50.

15. Bhojani N, Andonian S, Watterson JD, et al. Canadian Urological Association best practice report: Holmium:YAG laser eye safety. Can Urol Assoc J. 2020; 14:380-2.

16. Villa L, Cloutier J, Comperat E, 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 Endourol. 2016; 30:332-7.

17. Gopal N, Long B, Phillips J, Eshghi M. Endovascular Stapler Complications During Minimally Invasive Nephrectomy: An Updated Review of the FDA MAUDE Database From 2009-2019. Urology. 2021; 153:181-4.

Correspondence
Patrick Juliebø-Jones, MD (Corresponding Author)
jonesurology@gmail.com
Resident
Department of Urology, Haukeland University Hospital, Bergen, Norway

Mathias Sørstrand Æsøy, MD
mathias.asoy@gmail.com
Peder Gjengstø, MD
peder.gjengsto@helse-bergen.no
Christian Arvei Moen, MD
christian.arvei.moen@gmail.com
Consultant urological surgeon
Department of Urology, Haukeland University Hospital, Bergen, Norway

Christian Beisland, MD
christian.beisland@helse-bergen.no
Consultant urological surgeon, Professor of Urology
Department of Urology, Haukeland University Hospital, Bergen, Norway

Vincent De Coninck, MD
vdconinck@gmail.com
Consultant Urologist
Department of Urology, AZ Klina, Brasschaat, Belgium

Etienne Xavier Keller, MD
etienne.xavier.keller@gmail.com
Consultant urological surgeon
Department of Urology, University Hospital Zurich, University of Zurich, Zurich, Switzerland

Lazaros Tzelves, MD
lazarostzelves@gmail.com
Consultant Urologist
Second Department of Urology, National and Kapodistrian University of Athens, Sismanogleio General Hospital, Athens, Greece

Bhaskar K. Somani, MD
bhaskarsomani@yahoo.com
Consultant urological surgeon, Professor of Urology
Dept of Urology, University Hospital Southampton, UK

Øyvind Ulvik, MD
doc.ulvik@online.no
Consultant urological surgeon, Associate Professor of Urology
Department of Urology, Haukeland University Hospital, Bergen, Norway

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