

**Multi-Center Randomized Clinical Trial Evaluating the  
Efficiency and Safety of Holmium Laser with Moses  
Technology versus SuperPulsed Laser System with Thulium  
Fiber Laser on Renal Stones**

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## **Project Summary**

This is a prospective randomized controlled trial designed to assess the efficacy and safety of Lumenis® Pulse™ P120H holmium laser system with the Moses technology (holmium laser with pulse modulation) versus the Soltive™ SuperPulsed Laser System with the thulium fiber laser (thulium fiber laser), in dusting of renal stones during ureteroscopy with laser lithotripsy. We will apply a multi-center approach, which will allow us to test it in a wider array of settings with a wide range of population groups.

## **Study Sites**

University of Wisconsin, Department of Urology  
Ohio State University, Department of Urology  
University of California-Los Angeles, Department of Urology  
Mount Sinai, Department of Urology  
Cleveland Clinic, Glickman Urological Institute

## **Background and Significance**

The incidence of urinary tract stone disease is increasing. According to the National Health and Nutrition Examination Survey, as of 2012, 10.6% of men and 7.1% of women in the United States are affected by renal stone disease.<sup>i</sup> This has led to an increased demand on Urologists for efficient and safe surgical treatment of stone disease. Over the past two decades, ureteroscopy with laser lithotripsy has become the treatment of choice for most ureteral and renal stones globally.<sup>ii</sup> The holmium laser is considered the gold standard for laser lithotripsy.<sup>iii</sup> Holmium laser with pulse modulation and the thulium fiber laser are new technologies meant to improve the efficiency of laser lithotripsy. Both are FDA approved treatment modalities for stone disease. Two in vitro studies have compared holmium laser with pulse modulation versus thulium fiber laser and shown that thulium has higher ablative volumes than the holmium laser with pulse modulation.<sup>iv,v</sup>

We previously conducted a randomized clinical trial to compare the holmium laser with pulse modulation and thulium fiber laser. Our results suggested no significant difference between the holmium laser with pulse modulation and thulium fiber laser on the procedure time and stone free rate.<sup>vi</sup> However, the post-operative image was a kidney, ureter, and bladder (KUB) x-ray and CT is considered the gold standard of evaluating kidney stone fragments. Thus, the stone free rate between holmium laser with pulse modulation and thulium fiber laser may not be as accurate as if CT were used. It was also a single center study. A multicenter trial will allow us to include a larger number of participants, different geographic

locations, the possibility of inclusion of a wider range of population groups, and the ability to compare results among centers, all of which increase the generalizability of the study.

In this study, we are going to conduct a prospective, randomized clinical trial to determine whether there is a difference in stone free rate, procedural time, intraoperative parameters between the holmium laser with pulse modulation and the thulium fiber laser. This is significant as this may lead to shorter overall operative times, which may result in decreased operative costs and complications, as well as improved stone free rates.<sup>vii,viii</sup> Currently, at University of Wisconsin, we are using both the holmium laser with pulse modulation and the thulium fiber laser during ureteroscopies.

At our institution, we perform approximately 200 outpatient ureteroscopies with laser lithotripsy annually. Typically, we have evaluated surgical outcomes as part of routine quality improvement initiatives or as IRB-approved retrospective reviews. However, in this scenario, a randomized trial requiring IRB approval, we have the ability to conduct a higher-level study protocol and rigorously compare the time required for acceptable stone fragmentation using the two different lasers. A randomized trial, unlike a retrospective review of our surgical procedures, will reduce bias sufficiently to allow us to be sure of our results.

## **Study Objectives**

The primary objective of this study is to compare the stone free rate as determined by ultra-low dose limited renal CT at 2 months post operatively between the holmium laser with pulse modulation and the thulium fiber laser. Our hypothesis is that the thulium fiber laser will have a superior stone free rate compared to the holmium laser with pulse modulation. The setting for both lasers will be adjusted as needed by the surgeon during the case.

Secondary outcomes will include intra-operative parameters and post-operative parameters. Our goal is to completely dust the renal stones. This is defined as fragmenting the stones until as close to the size of the laser fiber as possible (a 200 micron fiber will be used with both groups), to visually estimate the size of the resultant fragments.<sup>ix</sup>

We will use block randomization with a block size of 5. Patients will be randomized into groups by a ratio of 1:1. We do not plan to stratify by stone size for randomization because our previous results showed no difference when results were stratified by stone size.

## **Research Design and Methods**

This study will be a randomized clinical trial comparing ureteroscopy with laser lithotripsy with the Lumenis® Pulse™ P120H holmium laser system with the Moses technology

(holmium laser with pulse modulation) versus the Soltive™ SuperPulsed Laser System with the thulium fiber laser technology (thulium fiber laser). The primary objective is to compare the stone free rate as determined by CT scan at two months (6-10 weeks) post operatively. A single urologist will evaluate all CT scans for residual stones and will be blinded to which laser was used during ureteroscopy.

The following information will be collected for research purposes as secondary outcomes: (1) stone treatment time (time from the start of lasing to the end of lasing; minutes); (2) total operative time (minutes); (3) lasing time (minutes, time the laser was in use, not including pedal pauses); (4) total energy used (kilojoules, kJ); (5) laser efficiency (mm per minute); (6) number of times the laser pedals are pressed (left, right, and total pedal presses); (7) laser fiber size; (8) stone analysis; (9) complications, and (10) patients' quality of life. The results from the pre- and post-operative quality of life survey (WISQOL short form) will be obtained from the patient's medical record. A total of 3 clinic visits (i.e., the pre-operative visit and the stone surgery, one post-operative visit after 2 months of the surgery) will be needed for this study. All these visits are standard of care. Stone parameters (i.e. size, location, Hounsfield units, presence of hydronephrosis, stone volume, and composition), demographic information, co-morbidities, and post-operative parameters will be collected from the medical record in HealthLink.

The Thulium laser company is not involved in this research.

### **Number of Participants**

Approximately 310 patients will be enrolled (see Data Analysis for sample size justification). The goal is to enroll 62 patients per site with a minimum of 20 patients at a single site to be included in the study. At UW, the enrollment of this study is 130 patients. This is to account for the shorter duration of the study and slower enrollment at other participating sites and ensure that the enrollment goal of 310 is reached regardless of study duration or enrollment numbers at other participating sites. All urologists at UW have agreed to use the laser device dictated by randomization.

### **Inclusion Criteria**

1. Patients at least 18 years of age, and less than 89 years old.
2. Patients with renal stones who require endoscopic laser treatment in the outpatient operating room. Patients may have an ureteropelvic junction (UPJ) stone if the treatment of the stone is completed in the kidney.
3. Patients' stone size in a single renal unit of  $\geq 5$  mm and  $\leq 20$  mm. Stone size is defined as the largest diameter of a single stone on pre-operative CT as assessed by the

urologist. Patients with multiple stones will be included as long as their largest stone size falls within the above parameters.

### **Exclusion Criteria**

1. Patients under 18 years of age and over 89 years old.
2. Pregnant patients
3. Patients with transplant kidneys or other anatomic variations: horseshoe kidney, pelvic kidney, ptotic kidney, urinary diversion or ureteral stricture
4. Patients with irreversible coagulopathy
5. Patients with known ureteral stricture disease
6. Patient who do not have a pre-operative CT
7. Non-English speaking patients and patients in other vulnerable groups such as lacking of decision-making capability, prisoner, or adult unable to consent
8. Uric acid composition > 50% on pre operative stone analysis. Patients will be excluded post operatively if stone analysis from the time of surgery is >50% uric acid.
9. Prior ureteroscopy within 6 weeks of current surgery
10. Urothelial tumor(s), direct extraction of the stone(s) without needing laser lithotripsy, and failure to reach the stone in the upper urinary tract with the ureteroscope
11. Patients with only ureteral stones (UPJ stones may be included as long as treated in the kidney)
12. Patients with renal tubular acidosis or medullary sponge kidney

### **Recruitment methods**

Patients who are to be scheduled for laser lithotripsy treatment of renal stones as outpatients will be approached for study participation. During patients' pre-operative clinic visit, study team members with valid access to patient medical records will perform eligibility screening (by reviewing patients' medical record that is relevant for inclusion/exclusion criteria) before recruitment. If patients meet the inclusion criteria, they will be initially approached by a study team member who also works in the urology clinic (i.e., the surgeon informs the patient that there's a research study they may be eligible for, and asked if they want to learn more about it).

No other recruitment materials will be used in this study. Holmium laser with pulse modulation or thulium fiber laser to treat stones is our routine care. Patients have been informed about the laser lithotripsy treatment before they schedule their surgery. We will only

recruit patients from the outpatient OR, so this will not include patients who come in emergently through the Emergency Department.

No compensation will be provided to participants.

### **Consent Process**

A study team member who is affiliated with the patient's clinical care (e.g., the surgeon) will initially approach the patients who are scheduled for laser lithotripsy treatment of urinary stones (i.e., informed that they may be eligible for a research study and asked if they want to learn more about it).

If the patient is interested in the study, a member of the research team will approach him/her for enrollment. The consent process will be conducted face to face by a member of the study team. Participants will be provided a written consent form in person. No waiting time is expected between informing the prospective participant and obtaining the consent.

Consent will take place in a private exam room during patients' pre-operative clinic visit. If patients are interested and there is not enough time to consent the patient in urology clinic, study information will be sent home with the patient and the patient will then be consented before their surgery in a private exam room (pre-operative room). The pre-operative room provides 1-1 1/2 hours of time. This should be ample time to conduct the consent process before surgery anesthesia.

All information about the study will be provided, and ample time will be made available for the participants to consider participation in the study and have any questions answered.

The study team will follow all applicable sections of HRP 090: Informed Consent Process for Research when conducting informed consent. To document signed consent, the study team will follow all applicable sections of HRP 091: Written Documentation of Consent.

### **Patient Randomization**

Patients will be randomized (ratio 1:1) to be treated with either the holmium laser with pulse modulation or the thulium fiber laser. Each site will randomize their own patients. Block randomization in block sizes of 5 will be used to assign patients to each laser treatment group. If unable to use the specified laser for any reason, the patient will be considered a withdrawal.

This is a multicenter study. Research procedures will take place at the Ohio State University, Wexner Medical Center, Department of Urology; Cleveland Clinic, Glickman Urological & Kidney Institute; UCLA Urology; and Mount Sinai Health System, Milton and Carroll Petrie Department of Urology. No community advisory board involved. Each site will apply IRB approval.

## **Study Procedures**

1. The study team members review patients' medical record during patients' pre-operative clinic visit to see whether patients meet inclusion/exclusion criteria.
2. If patients meet the inclusion criteria, a study team member who is affiliated with the patient's clinical care (e.g., the surgeon) will initially approach the patients who are scheduled for laser lithotripsy treatment of renal stones. (i.e., informed that they may be eligible for a research study and asked if they want to learn more about it).
3. If the patient is interested in the study, a member of the research team will approach him/her for enrollment.
4. Patients will be asked to fill out a WISQOL short form at their pre-operative visit. This is standard of care for all stone patients in our clinic.
5. They will then be randomized to either the holmium laser with pulse modulation or the thulium fiber laser group.
6. Patients will undergo stone surgeries with the laser that they are randomized to. A 200 micron fiber will be used with both machines to measure the stone(s). The patient's stone(s) will be treated with the goal of dusting the entire stone burden. One stone fragment will be collected for stone analysis if the patient does not already have a stone analysis on file (this is also standard of care). The faculty surgeons will perform all surgeries. We are unable to blind the surgeon to the laser used as the laser fibers and laser machines appear and sound different.
7. Laser time as well as other information (see Study Design for the detailed information) is collected.
8. At 6-10 weeks after surgery, patients will have a follow-up appointment where they have a ultra-low dose limited renal CT scan and fill out a WISQOL short form. Both of these procedures are standard of care. Postoperative complications will be collected.
9. Post-operative CT scans will be assessed by a single urologist for residual fragments. The urologist will be blinded to which laser was used for ureteroscopy. Parenchymal stones will be noted in the operative report and will not be considered residual stones.

## **Comparison of usual care and study procedures**

Compared with our routine care, the only interventions imposed on subjects as a result of this study are (1) randomization to laser lithotripsy with either holmium laser with pulse modulation or thulium fiber laser, (2) the use of patient & surgery information collected in describing our results.

All the other activities are part of our routine clinical practice. During surgery, patients' stones will be treated in accordance with our routine clinical practice of dusting the entire stone.

Surgeons will use a 200 micron fiber for both the holmium laser with pulse modulation and the thulium fiber laser per standard of care, but they will have the discretion to switch to a different fiber (ex. 150 micron thulium fiber) if they feel it is necessary during the case. If the surgeon changes the fiber during the surgery, the data will be analyzed separately.

A stone fragment will be collected for stone analysis if the patient does not have one on file. This is our standard of care suggested by AUA guidelines.<sup>xi</sup>

Post-operative imaging is standard of care and CT abdomen/pelvis without contrast is one of the recommended imaging modalities by AUA guidelines.<sup>x</sup> At our institution, we use ultra-low dose limited renal CT as our standard of care.<sup>xii</sup> This is a robust tool of stone surveillance, with low radiation (similar to abdominal X-ray, and 92% lower than a standard CT), and low cost (less than the charge of a renal ultrasound at our institution). All patients enrolled will undergo routine post-operative follow up including clinic appointments and imaging evaluation (ultra-low dose limited renal CT).

WISQOL short form will be administered during the pre-operative appointment and at the post-operative appointment, which is standard practice in our clinic.

### **Withdrawal of participants**

Patients can withdraw anytime. Once they decide to withdraw, they will continue their standard clinical care with us. We will continue to collect patients' information from patients' medical records for their routine medical care. Patient information gathered while the patient was active in the study will remain in the study record, but no information will be added to the record following their withdrawal.

In rare cases, the study team may withdraw a patient from the study. Such cases include the surgeon being unable to find the stone in the kidney, discovery of an unknown ureteral structure prior to the surgery, stones are basket not lased, or the surgeon being otherwise unable to treat the renal stone. If those happen, patients will be taken out from this study.

### **Study Intervention**

Holmium laser with pulse modulation and thulium fiber lasers will be used for this study. All settings of the holmium laser and thulium fiber lasers are routinely used in ureteroscopies. Both are FDA approved lasers for the treatment of urinary calculi through an endoscope. The holmium laser with pulse modulation emits two separate laser pulses with a short time interval between them. The first pulse divides the water between the laser fiber tip and the stone and the second pulse hits the stone unobstructed.<sup>xiii</sup> The goal is to increase stone ablative volume and decrease retropulsion of the stone. The thulium fiber laser has a different wavelength than the holmium laser with pulse modulation and thus has slightly different energy properties. It



has also been shown to increase ablative volume and decrease retropulsion without any safety concerns.<sup>xiv</sup> The two lasers have similar specifications; the two fibers are the same size and will interact with the instruments (ureteroscopes) similarly.

Evaluation of the devices on study fall under FDA IDE exemption. Neither the holmium laser nor the thulium fiber laser were regulated as drugs before enactment of the Medical Device Amendments. Both are approved by the FDA for use in renal stone treatment as they are being used in this study.

### **Study Timelines**

For each patient, the study duration is from consent to the two-month post-operative clinic visit. Patients will be on study for approximately 8-10 weeks.

### **Risks and Potential Benefits**

Treatment with the holmium laser with pulse modulation and thulium fiber laser can be associated with the common risks of hematuria, stent pain, passing fragments, UTI, dysuria. The rare risks include perforation of the urinary tract, bleeding, and stricture of the ureters. However, the surgeon who will perform the surgery will not exceed safe levels. All procedures are performed by surgeons who are board-certified. If significant injury or inefficient fragmentation of the stone occurs, the surgeon will have the discretion to transition to a different laser for patient safety reasons. All patients enrolled will undergo routine post-operative follow up including clinic appointments and imaging evaluation. Any complications will be recorded, reported, and treated appropriately.

There is a risk that patient information could become known to someone not involved in this study. Data safety and security considerations to minimize this risk are detailed in Data Management and Confidentiality below.

There is no direct benefit to patients as a result of participating in this study. Potentially, more efficient laser and laser settings may be identified which may result in faster procedural time and lower complication rates.

### **Safety Monitoring Plan**

All procedures performed by surgeons who are board-certified. If significant injury or inefficient fragmentation of the stone occurs, the surgeon will have the discretion to transition to a different laser for patient safety reasons (The data will be analyzed as an intention-to-treat analysis). All patients enrolled will undergo routine post-operative follow up including clinic appointments and imaging evaluation. Any complications will be recorded, reported, and treated appropriately.

Regular inquiries of study flow, pertaining to patient recruitment, randomization, and adverse events will be scheduled to occur the first week after study initiation, and subsequently

every two weeks. The lead researcher of each site will be responsible for the inquiries. Any adverse events will be monitored as per standard protocol in clinical use. A comparison of adverse events between groups (e.g., to determine whether those assigned to the thulium fiber laser group are experiencing more frequent or serious adverse effects) will be included. No significant adverse events are anticipated for the lasers, as they are routinely used in urology practice. Any adverse events or unanticipated problems will be reported to the PI and IRB and treated accordingly. In addition, members of the study team will be performing these procedures and will monitor the patient during treatment for any signs of complications.

### **Date Management and Confidentiality**

Both department server and REDCap will be used for data storage. All UW electronic data will be stored on a HIPAA compliant department server which is maintained on password and firewall-protected computers in locked offices of the Department of Urology, located in a security-protected building. Data to be analyzed after extraction. All paper records (such as WISQOL) will be saved in a locked office/cabinets of IRB approved study staff. Only key personnel listed on this study will have access to this information. All data analysis files will be devoid of direct patient identifiers, and the key linking identifiers to the study data will be stored separately from the study data. Direct identifiers will be destroyed at study closure or at the time of publication. De-identified data will be stored for potential future studies that have proper approval. REDCap is only used for other sites to transfer their data to UW and store the data from other sites.

We will use university-based OneDrive to temporarily save the enrollment log. At UW, the study team member will use their Net ID to access the enrollment log. The enrollment log is completely deidentified. Only participant ID (such as 101, 102) and the laser each participant is randomized to are saved in the enrollment log. Once we complete data collection, we will permanently delete it from the cloud.

In order to protect patient privacy, all IRB-approved study personnel will be up to date on all required institutional HIPAA, human subjects research, and good clinical practice trainings. Medical records will only be accessed by study team personnel with authorized access, and patients will provide consent for the study team to access their medical records. All research procedures will be performed in private rooms where others cannot see or hear the procedures being performed, and the study will not collect any information that could pose a risk to patients. Patients will be encouraged to ask any questions about the research that are necessary to assure their safety and comfort. No patient will be coerced or forced to consent to participate in the study or in any study activities they do not want to do. There will be no negative consequences if a patient declines to participate in the study, and their typical healthcare will remain unchanged from the standard of care.

## Sharing of results

No research information will be shared with patients.

We will only publish aggregate results. No individual results will be shared.

In this study, UW data will not be shared with other institutions. We will only receive data collected from other sites. Data will be transferred via REDCap Ortho/Rehabilitation and Urology. UW-Madison has created a REDCap project that accounts for all collected data variables (see Appendix), which all sites will be able to access in order to input their data but will not have the access to download the data. Thus, other sites won't see each other's data, and only UW can see of all sites. Data stored in REDCap will be coded, and the keys linking the codes to patient identifiers will be maintained separately by each study site, such that the REDCap project contains no directly identifying information. Study data saved on REDCap will be deleted once the study is completed.

When patients consent to participate in the study, they also consent to have their data banked. Patients who do not consent to having their data banked are asked not to participate in the study. Data will be stored indefinitely in a secure, password-protected department REDCap server and accessible only by IRB-approved study personnel. Stored data will have identifiers removed, with no code maintaining the link between the patient and their identifiers. Because the data will be anonymized, patients will not be able to request withdrawal of their data from the bank, as there will be no way for the study team to link the patient to their data. Researchers who want to access this data bank for future urology research must obtain approval from the department, and the research must be approved by the IRB.

## Economic burden to participants

This study does not place a financial burden on patients. The study interventions are part of our routine clinical practice to treat stones. Treatment and costs will be the same as if they are not involved in this study. The cost of the two laser treatments is equivalent.

## Resources Available

Will the research be conducted outside School of Medicine and Public Health or UW Hospitals and Clinics (e.g. the researcher does not have an SMPH research feasibility attestation for this study)?	<input type="checkbox"/> YES (complete 25.1) <input checked="" type="checkbox"/> NO (remove text below, but retain this section)
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## Data Analysis

The data collected will be analyzed as an intention-to-treat analysis. Statistical analyses will include T-test and, if appropriate, Chi-square tests (e.g., for categorical data), and two-way MANOVA. Patient demographics and stone characteristics will be summarized as appropriate as continuous variables (mean and standard deviation) or categorical variables (frequency, percentage). To compare the two groups, continuous variables such as laser time, total OR time, WISQOL etc., will be analyzed using T test and MANOVA. Categorical variables such as stone free rate will be analyzed using chi-square. We will also stratify the results by the laser settings and the study sites using MANOVA or collected as a co-variate using MANCOVA. The Thulium laser company will not be involved in data analysis for this study.

In our last study, the stone-free rate is measured by post-operative image (CT, KUB, or US). The stone free rate of renal stones are 64% vs. 52% (thulium vs. Moses). However, only 8.6% of patients had post-operative CT. Thus, the stone-free difference between Moses and thulium may not be accurately measured. A recent randomized trial by Ulvik et al<sup>[i]</sup> that showed thulium laser had improved stone-free rate (CT in 3 months) of renal stones treatment (66% vs. 33%,  $p = 0.005$ ). However, they used an older low-powered 30W holmium laser. Considering the difference between the low-power holmium laser and Moses 2.0 (high power and frequency), we estimate the stone-free difference between Moses and thulium as 20%, to achieve 80% of power, 186 patients (93 per arm) are need to detect a significant difference ( $p < 0.05$ ). We also decide to increase the sample size by 40% (155 patients per arm, 310 in total). This will allow for the possibility that the randomization scheme is intra-operatively abandoned for some reason (see patient withdrawal section), that the planned procedure was unable to be completed for some reason, as determined by the surgeon in charge of the case, lost follow up, and/or that the patient – after his/her procedure – wishes to withdraw from the study and exclude his/her information from our analysis.

## Appendix

List of data to be collected across sites and stored in REDCap project

1. Stone-free rate on 2-month post-operative CT
2. Stone treatment time (time from the start of lasing to the end of lasing; minutes)
3. Total operative time (minutes);
4. Lasing time (minutes, time the laser was in use, not including pedal pauses)
5. Total energy used (kilojoules, kJ);
6. Laser efficiency (mm per minute)
7. Number of times the laser pedals are pressed (left, right, and total pedal presses);
8. Laser fiber
9. Stone composition analysis;
10. Complications

11. Quality of life survey (WISQOL short form) both pre-operatively and post-operatively.

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