MOSES Lithotripsy Technology Applied to Stone Fragmentation during Ureteroscopy.

Principal Investigator: Marcelino Rivera, MD
IU Health Physicians Urology
1801 N Senate Blvd
Suite 220
Indianapolis, IN 46202

Co-Investigators:
Tim Large MD
Deepak Agarwal, MD

Table of Contents:

1.0 Background

MOSES technology was developed by Lumenis Ltd to maximize the lithotripsy potential of high powered lasers. Typically, a holmium laser unit is used to treat kidney a ureteral stones that are too large to remove en block. Laser lithotripsy allows for a large stone to be partitioned into smaller fragments that can be removed with an endoscopic basket device. Holmium technology has existed for more than 20 years, however, low total power (40 watt) and minimal modulations (Joules and Hertz) of the laser energy by the laser units limited the capacity to improve lithotripsy efficiency.

With the advent of high power (120 watt) lasers with 4 laser cores and developments in software to modulate the laser energy, many more options have emerged for laser lithotripsy of kidney and ureteral stones. At our institution, the laser units used for nephrolithotripsy are engineered and produced by Lumenis Ltd. These units are fitted with MOSES technology. Standard laser lithotripsy or MOSES laser lithotripsy can be performed using the same unit and during the same case by simple turning MOSES on or off on the laser touch screen (image 1). MOSES is propriety technology that is software based modulation of the laser energy delivered from the holmium::yag laser source. The software changes the pulsed laser to have two peaks of energy – one to displace the water in front of the stone and the second to deliver the laser energy to the stone. Holmium laser energy dissipates quickly in water, so the displacement of water in front of the stone means more energy is delivered to the stone. With more energy delivery, we would expect stone fragmentation to occur more rapidly.

When treating kidney or ureteral stones, there are two distinct surgical approaches. One technique is to use laser lithotripsy to break a stone into tiny pieces called *dusting*. Dusting technique attempts to turn a stone into a slurry of 2mm or less stone fragments that the patient can pass spontaneously. There are some urologist who promote the use of MOSES technology to improve the efficiency of the dusting technique and reduce operative time. Another approach to endoscopic stone surgery is to laser the stone into fragments to remove with a basket. There is far less laser energy used in this process, however, hard stones and larger stones can take time to fragment. We feel, based on the dusting ureteroscopy data, that MOSES technology could still improve fragmentation efficiency and reduce overall operative time.

2.0 Rationale and Specific Aims

To determine the effects of MOSES laser modulation technology can improve the safety and efficiency to laser fragmentation resulting in decreased total laser time, reduced potential for injury to the patient, and total OR time and utilization.

3.0 Inclusion/Exclusion Criteria

Inclusion criteria:

- >18 years of age
- Kidney or ureteral stone requiring laser lithotripsy fragmentation

Exclusion criteria:

- < 18 years of age

- Infectious, struvite stones.
- Atypical collecting system anatomy that prolongs the case (ureteral stricture, malrotated kidney, infundibular stenosis, ureteral duplication)

4.0 Enrollment/Randomization

Potential subjects will be identified during their pre-operative clinic visit. Physician-investigators will review medical chart and relevant pre-operative testing to make this determination. Potential subjects will then meet with a member of the study team to read the consent in detail and discuss the study in full.

After consent has been obtained, the study personnel obtaining consent will then obtain and assign the appropriate randomization for that subject. The patients will be randomized 1:1 to either standard laser lithotripsy or MOSES laser lithotripsy. Randomization will be performed using the redcap randomization application.

5.0 Study Procedures

This is a blinded study. Our research coordinator will present to the OR prior to the surgeon to meet with OR staff. At this time, the coordinator will inform the OR staff which group the patient has been randomly assigned. OR staff will be educated to set the laser as instructed by the surgeon but not share whether the MOSES laser lithotripsy is being used. Surgeons will not be aware of the group assignment. The surgeons are only able to adjust the laser energy settings between 0.4-1.0 joules and 4-15 hertz. To control for stone fragment size, surgeons will have to use an 13 french ureteral access sheath independent of ureteral diameter. The MOSES setting is turned on with a touch pad attached to the laser unit. Once the surgeon is ready to laser fragment the stone, they will request that the laser be activated and provide the laser energy settings. The laser technician/nurse will follow randomization and add or remove the MOSES option. The surgeons will not be informed if they are using standard laser or MOSES augmented laser technology. At the conclusion of laser fragmentation, stone basket extraction will occur and once all fragments are removed, the patient will have a ureteral stent placed, awoken, extubated and transferred to the post anesthesia recovery unit. Objective data about laser settings, utilization time and total energy will be obtained at the conclusion of the case. Additionally, the circulating team will record the total OR time. Other variables of interest include blood loss, blood transfusion requirements and complications (utilizing Clavien-Dindo classification) with an expected rate of approximately 1-2%. Subjective grading of stone movement during laser fragmentation as well as stone migration will be recorded.

In addition to the intraoperative variables mentioned above, we will obtain clinical information including stone size, location, and stone analysis will be recorded.

6.0 Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

All adverse events or unanticipated problems related to study participation will be reported in keeping with the IRB's guidelines regarding such events.

7.0 Study Withdrawal/Discontinuation

If a subject wishes to withdraw from the study, he may do so by verbal or written request to the research team. A subject may be withdrawn from the study by a physician-investigator if determined to be in the subject's best interest for medical reasons.

8.0 Statistical Considerations

Overall OR duration may differ up to 10 min with an average OR time for URS estimated at approximately 1 hour. A power analysis with 80% power and an alpha of 0.05 requires a total recruitment of 106 patients with 53 patients in each treatment arm. Due to a 10% chance of withdrawal rate, the study will enroll 116 subjects for 106 subjects to complete the study. Statistical analysis of the obtained data will include a student T-test for comparison of two continuous variables and chi-squared for categorical variables. If enough events occur to warrant a multivariate analysis, a Cox regression utilizing forward selection will be performed.

8.1 Endpoint Considerations

The primary endpoint of interest will reduction in total laser time and total OR time. Secondary endpoints will evaluate complication rates using the Clavien-Dindo score.

9.0 Privacy/Confidentiality Issues

All information obtained from the medical record will be kept secured in a password secured REDCap database and only accessed by study personnel. Manual entry will be performed and double entry verification will occur between research nurses and study personnel. Data will undergo regular backups during data entry. All data will be de-identified from the patient, and the key for the de-identification process will be maintained in a secure location. The presentation of the results of this study will maintain patient confidentiality.

10.0 Follow-up and Record Retention

Enrollment for this study is expected to be completed within 12 months of initiation. Identifiable data will be kept until data analysis is complete. A limited data set will be kept for a minimum of 7 years.