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Evaluation of the Moses Laser for Prostate Enucleation

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1.0 Background

Benign prostatic hypertrophy (BPH) is common with almost 50% of men having pathologic changes in the prostate between 50 and 60 years old[1]. There are many options for the treatment of BPH, though a minimally invasive approach has been favorable over the past decade. Enucleation of a prostate with a laser has become a mainstay of BPH treatment and has shown to be safe and effective. Traditionally, a holmium laser is used for this (i.e. Holmium laser enucleation of the prostate or HoLEP), though recent new technologies have been developed to improve laser surgery. One example is the Moses laser fiber produced by Lumenis (Yokneam, Israel), which alters laser pulse wave characteristics to improve the efficiency of energy delivery to a target. The technology is hypothesized to lead to better improvements in operative time and hemostasis [2,3,4]. Though the technology has been proven to be safe in human use, it has not been formally evaluated for prostatic enucleation. We seek to compare HoLEP to Moses laser enucleation of the prostate (i.e. MoLEP) for the treatment of BPH.

1. Berry SJ, Coffey DS, Walsh PC, Ewing LL. The development of human benign prostatic hyperplasia with age. J urol 1084; 132(3):474-479.
2. Elhilali M., Badaan S., Ibrahim A., Andonian S. Use of Moses Pulse Modulation Technology to Improve Holmium Laser Lithotripsy Outcomes: A preclinical study. Journal of Endourology (June, 2017)
3. Mark Cynk, Holmium Laser Enucleation of the Prostate is More Efficient with More Laser Power, abstract #MP7- 01, Moderated Poster Session 7: BPH/LUTS, WCE 2016
4. Beaghler M, Leo M, Gass J, March J, Sandoval S, et al. (2017) Initial Experience with New High Powered 120 W Holmium for Vaporization of the Prostate. Urol Nephrol Open Access J 4(2): 00119. DOI: 10.15406/ unoaj.2017.04.00119

2.0 Rationale and Specific Aims

The aims of this study are to:

1. Evaluate Moses laser technology for prostatic enucleation compared to traditional holmium laser enucleation.
2. Determine changes in blood loss, operative times, and quality of life improvements between the two technologies.

3.0 Animal Studies and Previous Human Studies

There are no previously published articles examining animal studies related to Moses fiber enucleation of the prostate. Currently, laser enucleation of the prostate with standard holmium or thulium lasers is routinely performed for BPH. Though Moses technology operates similar to other lasers on the market and has been shown to be safe in humans, it has not been evaluated for surgical outcomes.

4.0 Inclusion/Exclusion Criteria

- Exclusion criteria
    1. Pediatric patients (<18 years old)
    2. Abnormal anatomy precluding enucleation
- Inclusion
    1. Patients with planned prostatic enucleation for BPH.

5.0 Enrollment/Randomization

We will identify patients scheduled to undergo laser enucleation of the prostate for BPH through our urology clinic. Power analysis to detect a 50% change in blood loss (i.e. a change in hemoglobin level) will lead to approximately 20 patients in each group. A random number generator will be used at the beginning of each case after the induction of anesthesia to randomize patients to MoLEP or HoLEP.

6.0 Study Procedures

Patients will be consented in our clinic after being scheduled for surgery. All patients will fill out voiding symptom scores (i.e. International Prostate Symptom Scores(IPSS)), erectile dysfunction symptom scores (i.e. Sexual Health Inventory for Men(SHIM)) and have a preoperative urine flow, postvoid volume and a prostate specific antigen (PSA) recorded. Intraoperatively, total surgery time, as well as enucleation and morcellation times, will be recorded. Furthermore, intraoperative blood loss and surgical complications will be evaluated. Postoperatively, all patients will be observed overnight in the hospital with a urethral catheter. Routine labs will be sent including a complete blood count and metabolic panel. Postoperative day one, all patients will undergo a voiding trial for catheter removal. Patients will be monitored for routine complications after HoLEP such as urinary retention, urosepsis, urinary leakage. Other variables to be recorded will be age, sex, size of prostate, BMI, anticoagulation status, and other comorbidities. Patients will follow up at 4 weeks for a postoperative check and evaluation of symptoms (i.e. IPSS, SHIM, flow rate, postvoid residual volume and PSA).

7.0 Risks

The risks include all those that come with undergoing prostatic enucleation. That includes: urinary tract infection (<5%), urinary leakage (<5%), bleeding(<2%).

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

Any adverse events or anticipated problems will be reported to the IRB by the PI within 5 business days of the discovery.

9.0 Study Withdrawal/Discontinuation

Subjects would be withdrawn from the study if their anatomy complicates the assigned prostate surgery or intraoperatively, access is unobtainable in a retrograde fashion. Subjects may withdraw from the study at any time.

10.0 Privacy/Confidentiality Issues

Any information obtained will remain confidential and patient records will be de-identified. All information will be stored in password encrypted files. The results of the project may be made public and information published in profession journals, but no identifying information will be published.

11.0 Follow-up and Record Retention

It is anticipated the data collection will take 12 months to complete, and another 12 months to analyze the data. All identifiers will be destroyed 4 years after the study initiation, or 2 years after data collection is complete, whichever is sooner.