Clinical Article Summary

Comparative Analyses and Ablation Efficiency of Thulium Fiber Laser by Stone Composition

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Paper

Purpose: There are limited data on ablation effects of thulium fiber laser (TFL) settings with varying stone composition. Similarly, little is known surrounding the photothermal effects of TFL lithotripsy regarding the chemical and structural changes after visible char formation. We aim to understand the TFL's ablative efficiency across various stone types and laser settings, while simultaneously investigating the photothermal effects of TFL lithotripsy.

Materials and methods: Human specimens of calcium oxalate monohydrate, calcium oxalate dihydrate, uric acid, struvite, cystine, carbonate apatite, and brushite stones were ablated using 13 prespecified settings with the Coloplast TFL Drive. Pre- and post-ablation mass, ablation time, and total energy were recorded. Qualitative ablative observations were recorded at 1-minute intervals with photographs and gross description. Samples were analyzed with Fourier transform infrared spectroscopy pre- and post-ablation and electron microscopy post-ablation to assess the photothermal effects of TFL.

Results: Across all settings and stone types, 0.05 J x 1000 Hz was the best numerically efficient ablation setting. When selected for more clinically relevant laser settings (ie, 10-20 W), 0.2 J x 100 Hz, short pulse was the most numerically efficient setting for calcium oxalate dihydrate, cystine, and struvite stones. Calcium oxalate monohydrate ablated with the best numerical efficiency at 0.4 J x 40 Hz, short pulse. Uric acid and carbonate apatite stones ablated with the best numerical efficiency at 0.3 J x 60 Hz, short pulse. Brushite stones ablated with the best numerical efficiency at 0.5 J x 30 Hz, short pulse. Pulse duration impacted ablation effectiveness greatly with 6/8 (75%) of inadequate ablations occurring in medium or long pulse settings. The average percent of mass lost during ablation was 57%; cystine stones averaged the highest percent mass lost at 71%. Charring was observed in 36/91 (40%) specimens. Charring was most often seen in uric acid, cystine, and brushite stones across all laser settings. Electron microscopy of char demonstrated a porous melting effect different to that of brittle fracture. Fourier-transform infrared spectroscopy of brushite char demonstrated a chemical composition change to amorphous calcium phosphate.

Conclusions: We describe the optimal ablation settings based on stone composition, which may guide urologists towards more stone-specific care when using thulium laser for treating renal stones (lower energy settings would be safer for ureteral stones). For patients with unknown stone composition, lasers can be preset to target common stone types or adjusted based on visual cues. We recommend using short pulse for all TFL lithotripsy of calculi and altering the settings based on visual cues and efficiency to minimize the charring, an effect which can make the stone refractory to further dusting and fragmentation.

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Coloplast Key Takeaways

- This was a bench study which may not extrapolate to clinical conditions.
- Authors recommend using short pulse for all TFL lithotripsy. It was more efficient for ablation according to their study.
- For patients with unknown stone composition, lasers can be preset to target common stone types or adjusted based on visual cues use.
- Optimal settings are stone type dependent.
- Alter settings based on visual cues and efficiency.
- Short pulse is recommended to minimize charring.

Coloplast TFL Drive Brief Statement

Indications

The Coloplast TFL Drive laser device and its accessories are intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue with or without an endoscope, in the following indications: Urology, Lithotripsy, Gastroenterological Surgery and Gynecological Surgery. Refer to the Coloplast TFL Drive User Manual for specific indications within these surgical specialties.

Contraindications

The use of the laser is contraindicated:

- In patients whose general medical condition contraindicates surgical intervention.
- When appropriate anesthesia is contraindicated by patient history or inability to receive anesthesia.
- Where tissue (especially tumors) is calcified.
- For hemostasis of vessels with diameters over approximately two millimeters.
- Where laser therapy is not considered the treatment of choice.
- In patients who have recently undergone radiotherapy. Such patients may be at greater risk of tissue perforation or erosion.
- In patients unable to receive endoscopic treatment.
- In patient suffering from bleeding disorders and coagulopathy.
- Diagnosed with acute or chronic prostatitis, prostate cancer, or severe urethral stricture.
- Diagnosed at the time of treatment with acute or chronic urinary tract infection.

Other considerations requiring Physician's clinical judgement:

- Patients with compromised renal function or upper urinary tract obstructive diseases.
- Patients who still wish to have children.
- Patients with an ASA classification of physical status 5.
- Patients with a prostate gland > 120g.

Refer to the Coloplast TFL Drive User Manual for specific contraindications when undergoing URS, PCNL, Gynecology, Gastroenterology and Lithotripsy surgical procedures.

Warnings

The Coloplast Drive Laser System is a surgical device that should be used only by physicians or surgeons who have been thoroughly trained in laser surgery. Surgeons using Coloplast TFL Drive Laser System must understand the laser's unique properties prior to using the device.

As with conventional endoscopic surgery, the possibility of complications and adverse events (such as chills, fever, edema, hemorrhage, inflammation, tissue necrosis or infection) may occur following treatment. In extreme cases, death may occur due to procedural complications or concurrent illness.

The manufacturer has no clinical information or experience concerning the use of the Laser System on pregnant women or nursing mothers. As with conventional non-laser surgical procedures, there is no guarantee that treatment with the Laser System will entirely eliminate the disease. Repeated treatment or alternative therapies may subsequently be required. The laser may not be effective for coagulation in massive haemorrhage situations. The surgeon must be prepared to control haemorrhages with alternative non-laser techniques, such as ligature or cautery.

Potential Complications

Complications and risks are the same of the conventional laser surgery. Refer to the Coloplast TFL Drive User Manual for specific potential complications when undergoing endoscopic urology procedures (URS, PCNL, Gynecology, Gastroenterology and Lithotripsy).

Acute pain may occur immediately following laser therapy and may persist for as long as 48 hours. Immediately following laser therapy, the patient may experience fever and leucocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment. Laser ablated tissue may become necrotic or infected after treatment. In case of concerns about any possible infection, appropriate treatment should be carried out.

The following complications could be serious and could result in death:

- Patients may experience bleeding at the site of laser therapy. Haematocrit analysis after treatment is recommended to identify this potential complication.

- Sepsis can result from performing any surgical procedure. In case of concerns about any possible sepsis, appropriate evaluations should be made.
- Perforation may occur as a result of laser treatment. In order to diagnose perforations, patients must be carefully followed post-operatively with appropriate tests.

Additional complications include aspiration, allergic reaction to medication, hypertension, arrhythmia, distension due to gases, pneumothorax, ulceration, edema, chills, healing delay and embolism, which may be thermally or non-thermally induced. There may be urine leakage following the laser procedure. The use of flexible endoscopes carries a risk of stricture formation. Although rare, loss of a kidney may occur as a result of the procedure or because of the stone itself.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company website at www.coloplast.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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TFL Single-use & Reusable Optical Fibers Brief Statement

Indications

Optical Fibers are indicated for use in general surgical applications such as: incision, excision, vaporization, ablation, hemostasis, coagulation of soft tissue and stone treatment in a contact semi-contact or non-contact mode. Applications are defined by the intended use of the surgical laser device, while optical fibers cannot be associated to any specific application. Laser techniques are most commonly applied in surgical fields such as Urology, Gastroenterology, Arthroscopy, Spine surgery, Gynecology, ENT, and General Surgery.

Indications are the ones that the laser claims, while fibers cannot be associated to any specific indication.

Contraindications

For warnings, cautions, contraindications, and clinical use of the fiber refer to the medical laser device User Manual. Optical Fibers are contraindicated for treatment of patients for whom endoscopic procedures are contraindicated. Medical opinion is critical to determine if a patient can withstand a laser treatment, considering also the contraindications related to the specific clinical applications.

Warnings & Precautions

This product shall be used by trained and qualified users only. Indications involving heart or central circulatory system, or the central nervous system are excluded from optical fibers intended use. Reusable Optical Fibers should not be used on patients with confirmed or suspected Transmissible Spongiform Encephalopathies (TSEs).

For Single-use Optical Fibers Only: Reuse, re-processing, or re-sterilization may compromise the structural integrity of the device and/or lead to a device failure or create risk of contamination. This may result in patient injury, illness or death, or in transmission of infectious disease from one patient to another.

Potential Complications

Refer to the laser system User Manual for specific instructions concerning warnings, cautions, contraindications, and clinical use of the laser. Complications that could occur during laser treatments include: • local and/or systemic infection • thermal damage • local hematoma • dissection and perforation • tissue adhesion • Pain.

Note: It is possible that the optical fiber tip breaks off during use.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company website at www.coloplast.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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