Endoscopic enucleation of the prostate with Thulium Fiber Laser (ThuFLEP). A retrospective single-center study

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Summary

Purpose: The aim of the present, retrospective study was to describe our initial experience and early outcomes of Thulium Fiber Laser enucleation of the prostate (ThuFLEP) with the use of the FiberDust™ (Quanta System, Samarate, Italy) in patients with benign prostate hyperplasia.

Methods: From June 2022 to April 2023, all patients who underwent endoscopic enucleation of the prostate at Urology Department of the University Hospital of Patras were included. A single surgeon utilizing the same standardized operative technique performed all the surgeries. The primary endpoints included the uneventful completion of the operation, the surgical time and any minor or major complication observed intra- or post-operatively.

Results: Twenty patients with benign prostate hyperplasia were treated with ThuFLEP. All the surgeries were completed successfully and uneventfully. The enucleation phase of the operation was completed in a mean time of 45 ± 9.1 min, while the average time needed for the morcellation was 17.65 ± 3.42 min. No significant complications were observed intra- or post-operatively. The average hemoglobin drop was calculated to be 0.94 ± 0.71 g/dL.

Conclusions: All the operations were successfully and efficiently completed with the use of the FiberDust™ (Quanta System, Samarate, Italy) in ThuFLEP. Significant blood loss or major complications were not observed.

Key words: Benign Prostatic Hyperplasia; Enucleation; Prostate; ThuFLEP; Thulium.

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Introduction

Lower urinary tract symptoms (LUTS) constitute a major concern for many men over 50 years old. The symptoms may usually be caused by the presence of enlarged prostatic adenomas, a condition known as Benign Prostatic Hyperplasia (BPH). BPH constitutes a major healthcare burden, affecting almost one out of four men in their lifetime (1). The treatment options include both conservative and surgical approaches. Treatment decision-making process is based on the grade of the symptoms, the renal function, the prostate volume and the post-voiding residual urine (1).

Transurethral resection of the prostate (TURP) has been the milestone surgical option for BPH for many years despite the relatively high complication rates observed in patients with enormous prostatic volume (2). In the last decades, however, endoscopic enucleation of the prostate (EEP) techniques have been rapidly developed and implemented into the urological armamentarium. The main idea was to adjust the open procedure to the endoscopic approach. In addition, EEP techniques have been associated with improved outcomes in terms of the removed percentage of prostatic volume as well as minimized surgical intervention (3). Although EEP techniques evolved as a promising alternative to conventional TURP, they seem to show a steeper learning curve. According to current literature, the completion of the learning curve needs the performance of 40 to 60 cases (4).

Apart from the development of endoscopic surgical techniques, the simultaneous evolution of laser technology and laser devices has also played an important role in the expansion of EEP (5). The rapid development of the established holmium: Yttrium-Aluminum-Garnet (Ho: YAG) laser was followed by the integration of the Thulium Fiber Laser (TFL). TFL produces a wavelength of 1940 nm, while the penetration depth is 0.077 mm. The pulse energy ranges from 0.025 to 6 J, and the frequency may reach up to 2400 Hz (6). These technical aspects show a laser with a precise cutting function, which is convenient for the handling of soft tissues. This fact is also confirmed by experimental studies showing that TFL is associated with higher efficiency and safer profile in tissue application compared to Ho: YAG (7). Consequently, TFL has recently been widely integrated into EEP techniques (ThuFLEP).

The aim of the current study is to present our initial experience and early outcomes of ThuFLEP with the use of the FiberDust™ (Quanta System, Samarate, Italy) in patients with BPH.

Materials and methods

The current study is a retrospective single-center study conducted at the Urology Department of the University...
Hospital of Patras. The study was approved by the Institutional Ethics Committee. Informed consent was obtained from all the participants.

Study design
From June 2022 to April 2023, all patients with BPH treated at our department with ThuliumFLEX using the FiberDust™ (Quanta System, Samarate, Italy) were included in the study. A single expert surgeon with experience in EEP techniques conducted all the surgeries and the follow-up management of the participants. Patients with prostatic volume under 80 cm³, serious coagulation disorders, neurogenic bladder, concomitant bladder stones, or a history of urethral strictures were excluded from the study.

Data collection
The preoperative patients’ data included age, height, weight, and Body Mass Index (BMI). The preoperative use of alpha-1 adrenoreceptor antagonists (α-blocker) and 5-alpha reductase inhibitors (5-ARI) was recorded as well as the history of acute urinary retention (AUR) or permanent catheterization. All patients underwent abdominal ultrasound for the estimation of the prostate volume, uroflowmetry for the evaluation of the maximum flowrate (Qmax) and blood exams for the investigation of hemoglobin (Hgb) level. The International Prostate Symptom Score (IPSS) was used for the evaluation of symptoms’ severity. The perioperative data included the record of enucleation and morcellation time as well as the presence of intra- and postoperative complications. The volume of enucleated prostatic adenoma was estimated based on the histopathological report. Postoperatively, all patients underwent blood exams on the first post-operative day and afterwards in case any complication occurred. The catheter removal was scheduled on the first postoperative day if no hematuria was present and a trial without catheter (TWOC) was performed.

Surgical technique
The surgical approach used was based on the description of the en bloc enucleation of the prostate by Saitta et al. (8). The patient was placed in lithotomy position under general or epidural anesthesia. The irrigation bags were placed 1 m above the surgical table. Cefuroxime was administered intravenously 1-hour preoperatively and afterward, twice a day during hospitalization. Urerocystoscopy with the use of a resectoscope (Karl Storz SE & Co. KG, Tutlingen, Germany) was conducted for the observation of the anatomical landmarks, the sphincter limits, the ureteral orifices and their distance from the adenoma and the possibility of any pathological finding in the urethral lumen and the bladder. The power settings used were 60 W (2Jx30Hz). Minor differentiations were used in a few cases with harder tissue and/or persistent hemorrhage. The diameter of the laser fiber used was 550 μm.

The initial incision was a marking of the external sphincter connecting 11 and 1 o’clock. A second incision between the fifth and seventh hour was conducted alongside the verumontanum. The next step was the connection of these initial incisions, aiming at the demarcation of the sphincter from the prostate apex. The importance of minimization of mechanical stress and the activation of the laser for the gentle tissue dissection after the early apical release of the prostate should be underlined as it is believed to contribute to the postoperative continence maintenance. The gradual deepening of the incisions until the prostate capsule was crucial. After the capsule was observed, the dissection became circumferential respecting the plane of enucleation starting from 6 o’clock with direction to 12 o’clock (Figure 1). The resectoscope was rotated for better placement of the laser fiber and avoidance of mechanical pressure for dissection. The same movements were followed for the gradual detachment of the adenoma. The proximal detachment of the prostate for the bladder entry was conducted through the anterior enucleation plane, followed by careful circumferential release of the adenoma. The ureteral orifices were reobserved before the final dissection of the prostate from the capsule near the bladder neck. The detached adenoma was then freely pushed into the bladder. Meticulous hemostasis was conducted exclusively with the use of the laser with no need for additional electrocautery use. The importance of this step should be underlined as clear view is crucial for the uneventful morcellation process. The final step of the procedure was the replacement of the resectoscope with a 26 Fr nephroscope (Karl Storz SE & Co. KG, Tutlingen, Germany). For maximal irrigation conditions and prevention of bladder collapse during morcellation, the inflow of irrigation fluid was facilitated simultaneously through the inflow and outflow lumens of the nephroscope. The morcellator (Quanta Blade, Quanta System, Samarate, Italy) was placed into the bladder through the working channel of the nephroscope. A 22 Fr 3-way urethral catheter was placed into the bladder, and bladder irrigation was used at least until the patient returned to the department.

Figure 1.
Start of the prostate enucleation from 6 o’clock and circumferential development towards 12 o’clock.
Follow-up
Post-operative evaluation was performed 1, 3, 6 and 12 months after the surgery. The follow-up examination included the record of incontinence or additional symptoms, ultrasonography of the urinary tract as well as $Q_{\text{max}}$ and IPSS measurement. The presence of incontinence was defined as the use of at least one pad per day.

Endpoints
The successful completion of the surgeries, the duration of the procedures (divided into enucleation and morcellation time), the volume of enucleated prostate and the documentation of complications based on the Clavien-Dindo classification were the primary endpoints of the study (9). Enucleation and morcellation time were defined as the time between the first and the last activation of the laser and the time between the first and the last activation of the morcellator, respectively. The secondary endpoints of the study were the hemoglobin decrease (the difference between the pre-operative and the last post-operative sample) and the differentiation of the $Q_{\text{max}}$ and IPSS pre- and post-operatively (as postoperative $Q_{\text{max}}$ and IPSS defined the values of the last follow-up). Additionally, the catheterization and hospitalization duration as well as the presence of postoperative incontinence were also evaluated.

Statistical analysis
All the quantitative data are presented as mean values and standard deviations, while the qualitative variables are presented as numbers and rates.

Results
In total, 20 patients were included in the study. The mean follow-up was 10.2 ± 2.04 months. The participants had a mean age of 72.5 ± 6.4 years. The mean BMI was calculated to be 27.59 ± 3.53 kg/m². More specifically, the average height was 1.72 ± 0.08 m, while the mean weight was 81.1 ± 10.05 kg. In addition, the mean preoperative prostate volume as measured in the abdominal ultrasound was 112.75 ± 28.9 ml. Preoperatively, nine (45%) and eleven (55%) patients used 5-ARI and a-blocker, respectively. Additionally, six (30%) patients had a prior history of AUR, while seven (35%) patients were catheterized (Table 1).

The completion of all the procedures was successful without any intraoperative event. The mean time of enucleation was 45 ± 9.1 min. The average morcellation duration was calculated to be 17.65 ± 3.42 min. The mean hemoglobin decrease was 0.94 ± 0.71 g/dL (Table 2). The average catheterization and hospitalization duration were 1.15 ± 0.37 and 1.7 ± 1.38 days, respectively. Two patients presented persistent hematuria after the discontinuation of irrigation; thus, the catheterization was prolonged until the second postoperative day (Clavien-Dindo I). One patient presented postoperative AUR without hematuria. The catheter was placed again, and TWOC was successful during the second postoperative day (Clavien-Dindo I). Finally, two patients presented with fever 12 hours postoperatively. The antibiotic regimen was not modified, and the TWOC was not postponed and was performed successfully in both of them. Nevertheless, the hospitalization was prolonged until they were fit for discharge (Clavien-Dindo I) (Table 2). The mean volume of enucleated prostate was 76.85 ± 20.87 ml, while an average rate of 68.34 ± 11.43% of the prostate was enucleated. The mean pre- and post-operative $Q_{\text{max}}$ were 7.6 ± 3.35 ml/s and 21.75 ± 3.30 ml/s, respectively. The average increase of $Q_{\text{max}}$ was estimated to be 14.15 ± 4.43 ml/s. Concerning IPSS, the pre- and post-operative mean values were calculated to be 22.75 ± 2.22 and 9.2 ± 3.04, respectively. The average IPSS decrease was 13.55 ± 3.9. One (5%) patient presented with incontinence (use of one pad daily) (Table 3).

Table 1.
Demographic and preoperative data.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean ± SD)</td>
<td>72.5±6.4 years</td>
</tr>
<tr>
<td>Height (mean ± SD)</td>
<td>1.72±0.08 m</td>
</tr>
<tr>
<td>Weight (mean ± SD)</td>
<td>81.1±10.05 kg</td>
</tr>
<tr>
<td>BMI (mean ± SD)</td>
<td>27.59±3.53 kg/m²</td>
</tr>
<tr>
<td>Prostate Volume (mean ± SD)</td>
<td>112.75±28.9 ml</td>
</tr>
<tr>
<td>5-ARI (n, %)</td>
<td>9 (45%)</td>
</tr>
<tr>
<td>a-blocker (n, %)</td>
<td>11 (55%)</td>
</tr>
<tr>
<td>AUR (n, %)</td>
<td>6 (30%)</td>
</tr>
<tr>
<td>Permanent Catheterization (n, %)</td>
<td>7 (35%)</td>
</tr>
<tr>
<td>$Q_{\text{max}}$ (mean ± SD)</td>
<td>7.6±3.35 ml/s</td>
</tr>
<tr>
<td>IPSS (mean ± SD)</td>
<td>22.75±2.22</td>
</tr>
</tbody>
</table>

SD: Standard Deviation; BMI: Body Mass Index; 5-ARI: 5-alpha reductase inhibitor; a-blocker: Alpha-1 adrenoreceptor antagonist; AUR: Acute Urinary Retention; $Q_{\text{max}}$: Maximum Flow rate; IPSS: International Prostate Symptom Score.

Table 2.
Intra- and perioperative outcomes.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enucleation time (mean ± SD)</td>
<td>45±9.1 min</td>
</tr>
<tr>
<td>Morcellation time (mean ± SD)</td>
<td>17.65±3.42 min</td>
</tr>
<tr>
<td>Hemoglobin drop (mean ± SD)</td>
<td>0.94±0.71 g/dL</td>
</tr>
<tr>
<td>Catheterization duration (mean ± SD)</td>
<td>1.15±0.37 days</td>
</tr>
<tr>
<td>Hospitalization duration (mean ± SD)</td>
<td>1.7±1.38 days</td>
</tr>
<tr>
<td>Complications (n, %)</td>
<td>5 (25%)</td>
</tr>
<tr>
<td>Clavien-Dindo I</td>
<td>5 (25%)</td>
</tr>
<tr>
<td>Clavien-Dindo II</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Clavien-Dindo &gt; II</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

SD: Standard Deviation.

Table 3.
Postoperative and functional outcomes.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enucleated Prostatic Volume (mean ± SD)</td>
<td>76.85±20.87 ml</td>
</tr>
<tr>
<td>Mean Enucleation Rate (mean ± SD)</td>
<td>68.34±11.43%</td>
</tr>
<tr>
<td>$Q_{\text{max}}$ Increase (mean ± SD)</td>
<td>14.15±4.43 ml/s</td>
</tr>
<tr>
<td>IPSS Decrease (mean ± SD)</td>
<td>13.55±3.9</td>
</tr>
<tr>
<td>Incontinence (n, %)</td>
<td>1 (5%)</td>
</tr>
</tbody>
</table>

SD: Standard Deviation; $Q_{\text{max}}$: Maximum Flow rate; IPSS: International Prostate Symptom Score.
In the present clinical study, we presented our retrospectively collected data of 20 patients regarding the surgical treatment of BPH. The advantages of the enucleation technique have been thoroughly analyzed and a promising trend in outcomes has been revealed.

DISCUSSION
The wide adoption of lasers in the urological field is partially due to their great hemostatic properties (10). Various laser devices and a plethora of surgical techniques’ modifications have gradually been developed and enriched the enucleation process, making it an appealing and efficient treatment option for BPH. In this clinical retrospective study, we aimed to present our operative and functional outcomes. Twenty ThuFLEP procedures in patients with enlarged prostate glands (> 80 cm³) were performed. A sphincter preservation technique with a high-power laser device was adopted and modified. The surgeries were completed successfully. The enucleation and morcellation times were 45 ± 9.1 min and 17.65 ± 3.42 min, respectively. Postoperatively no significant hemoglobin drop was detected. Despite the reported complication rate of 25%, all of them were Clavien-Dindo 1 and consequently, the mean catheterization and hospitalization durations were not influenced. Additionally, on average 68.34 ± 11.43% of the total prostatic volumes were enucleated while the postoperative functional outcomes were encouraging. Fraundonfer and Gilling described the first EEP using laser, followed by morcellation in 1998, developing the enucleation technique described by Hiraoka et al. (11, 12). The initial description of laser enucleation of the prostate was the 3-lobe detachment including 14 patients. Lasers’ adaptation and rapid evolution played a major role in the implementation of multiple techniques and the gradual evolution of the original one (13). The early recognition and preservation of the sphincter and the easier development and safe dissection of the surgical plane have led to increased popularity of the en bloc technique. The enrichment of the technique with several modifications has also minimized the residual prostatic volume (8, 14). The latest addition and adjustment of TFL devices have significantly contributed to the wider EEP implementation. One of the main advantages of TFL is the greater efficiency regarding the management of hemorrhage. This is partially because of the shallow tissue penetration and the pulsed wavelength delivery (15). Nevertheless, Holmium lasers have been widely used and investigated in terms of safety and efficiency for EEP. The comparison between the two lasers has been the ground for many studies and discussions between surgeons and researchers. According to Hartung et al., recent bibliography on EEP suggests that both laser types are associated with great and comparable outcomes in terms of the LUTS improvement and the pattern of voiding characteristics after the surgery (16). In compliance with the structural function of TFL, Hartung et al. noticed that Holmium laser enucleation of the prostate (HoLEP) was found to be partially inferior to ThuFLEP regarding the postoperative incontinence rates and hemostasis. In their randomized controlled trial, Enikeev et al. compared TFL and TURP in terms of efficiency (17). The superiority of ThuFLEP in terms of resection percentage, grade and frequency of complications and duration of hospital stay was demonstrated. The experience and convenience of the urologist as well as the availability of surgical means in each setting are the factors that determine the surgical treatment of BPH.

In the present clinical study, we presented our retrospectively collected data of 20 patients regarding the outcomes of ThuFLEP using FiberDust™. A comparative study including 234 participants was published by Pirola et al. (18). The researchers conducted a retrospective match-pair analysis, dividing the 234 patients’ sample into 117 participants who underwent HoLEP and 117 who were treated with Thulep for BPH. The authors reported that the median enucleation time was 70 min (58.0-87.3 IQR) and 70.5 min (58-104 IQR) for the ThuLEP and the HoLEP group, respectively. In addition, they observed that the median morcellation time was 45 ± 9.1 min, and the average morcellation duration was 17.65 ± 3.42 min. In addition, the HoLEP group demonstrated an intraoperative complication rate of 5.7% and the ThuLEP group 7%. The hemoglobin decrease was 0.9 g/dl (range: 0.3-1.67) and 0.5 g/dl (range: 0.3-1.1) for the holmium and the thulium groups, respectively. In the current study, no intraoperative complication was observed and the average hemoglobin decrease was 0.94 ± 0.71 g/dL. The follow-up evaluation (IPSS, Qmax and incontinence rates) presented similar results in the two studies. In addition, in the current one, it was calculated that 68.34 ± 11.43% of the adenoma was removed. A retrospective clinical study including 125 patients with prostate volume larger than 80 ml was conducted by Chang et al. (19). The patients were treated with ThuLEP by a single experienced surgeon. The authors reported that the mean prostate volume before surgery was 106.80 ± 45.77ml and it was reduced by about 74.17 ± 11.27% after the treatment. Additionally, the authors demonstrated that IPSS postoperatively was 7.35 ± 5.89 and Qmax at the three-month follow-up was 23.20 ± 6.87ml/s. In the current study, the mean postoperative IPSS and Qmax were 9.2 ± 3.04 and 21.75 ± 3.30 ml/s, respectively. Enikeev et al. demonstrated the efficiency of ThuFLEP by conducting a prospective study including 130 patients with prostate volume over 80 ml and comparing EEP to open prostatectomy (20). Similar operation duration but significantly less hospitalization in favor of EEP were described. In addition, the incontinence rate was 1.1% for the ThuFLEP group which is in agreement with our results. Besides, a mean hemoglobin drop of 1 g/dl was demonstrated, while the catheter was successfully removed during the first 24 hours after the operation in 79% of the patients.

The present study included 20 cases with BPH treated with ThuFLEP. Nevertheless, the current study is not without limitations. Firstly, the urologist who conducted all the procedures was an experienced surgeon, who specializes in EEP and has conducted more than 100 cases before the initiation of the study. Therefore, the learning curve could not be evaluated. Additionally, the sample size was relatively small and further prospective studies with larger cohorts and longer follow-up are deemed necessary to confirm our findings. However, the objective of the study was to present our initial experience and patients’ outcomes with the ThuFLEP in BPH. The advantages of the enucleation technique have been thoroughly analyzed and a promising trend in outcomes has been revealed.
CONCLUSIONS
We presented the surgical and early functional outcomes of ThuFLEP with the use of FiberDust™ (Quanta System, Samarate, Italy) in patients with BPH. All the cases were successfully completed without intraoperative complications, major postoperative complications, or significant blood loss. The functional outcomes reported are in agreement with the current literature.

REFERENCES

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