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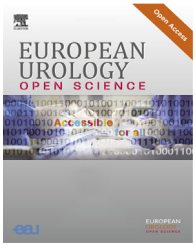

European Association of Urology

Prostate Cancer

Safety and Feasibility of Soractelite Transperineal Focal Laser Ablation for Prostate Cancer and Short-term Quality of Life Analysis from a Multicenter Pilot Study

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Abstract

Background: Soractelite™ transperineal focal laser ablation (TPLA) for the treatment of localized prostate cancer (PCa) using the Echolaser® system is a novel minimally invasive technique that has the potential to induce tissue ablation, while reducing treatment-related morbidity, when compared with robot-assisted radical prostatectomy (RARP) and radiotherapy.
Objective: To determine the short-term safety and feasibility of single or multifiber TPLA, its functional outcomes, and quality of life (QoL).
Design, setting, and participants: TPLA was performed in 12 patients, consecutively assigned to four treatment regimens, with localized PCa who were scheduled for RARP (''ablate and resect design''). The treatment regimens were as follows: (1) a single fiber at 3 W, (2) two fibers at 5 mm distance at 3 W, (3) two fibers at 10 mm distance at 3 W, and (4) a single fiber at 5 W. TPLA was scheduled 4 wk prior to RARP.
Intervention: TPLA using the Echolaser® system under local anesthesia at the outpatient clinic.
Outcome measurements and statistical analysis: Safety and feasibility were determined by the assessment of device-related peri- and postoperative adverse events (AEs), and length of hospital stay. Functional outcomes and QoL were measured using validated questionnaires. Feasibility of RARP was assessed by a questionnaire for the urologist.
Results and limitations: Patients were dismissed after a median (interquartile range) hospital admission of 3.25 (1.25) h. No device-related AEs occurred. AEs that occurred were mostly related to lower urinary tract symptoms and were mild (grade 1–2). Most AEs resolved within 1 wk. A QoL analysis showed no significant differences for all treatment regimens. Functional outcomes remained unchanged,

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except for erectile function after 1 wk, which returned to baseline after 4 wk. TPLA treatment did not compromise RARP, based on the questionnaires.

Conclusions: TPLA for the treatment of PCa at the outpatient clinic appears to be safe and feasible with good short-term QoL and functional outcomes; oncological results are awaited.

Patient summary: Focal treatment of localized prostate cancer can safely be performed in a daycare setting using a new technique, based on laser ablation, without compromising quality of life.

1. Introduction

Prostate cancer (PCa) is the second most frequently diagnosed malignancy in males and is considered the fifth leading cause of cancer-related mortality worldwide [1].

Low- and intermediate-risk PCa cases are nowadays preferentially actively monitored without immediate treatment. Yet, approximately half of PCa patients under active surveillance still require conversion to radical therapy with curative intent, because of upgrading and cancer progression [2]. Standard therapy for PCa with curative intent consists of radical therapy, for example, robot-assisted radical prostatectomy (RARP) or radiotherapy plus androgen deprivation therapy (ADT). Unfortunately, treatment-related morbidity is high. The ProtecT trial showed urinary incontinence rates of 3% and 20% and erectile dysfunction rates of 66% and 79% for radiotherapy and RARP, respectively [3]. In addition, rectal toxicity is observed in 2–15%, besides the side effects of ADT [4]. This results in a significant impact on quality of life (QoL) [5,6]. Ideally, treatment for these patients provides oncological cure, while preserving important functional anatomy and with few side effects (trifecta) [7,8]. Focal therapy is an alternative treatment that could fulfill these criteria for highly selected patients [9]. Moreover, fusion of transrectal ultrasound with high-resolution magnetic resonance imaging (MRI) may enable accurate image-guided focal therapy, as it is also advised for diagnostic prostate biopsy procedures [10]. Examples of established focal therapy modalities are irreversible electroporation, cryotherapy, high-intensity focused ultrasound, microwave therapy, photodynamic therapy, and laser ablation.

Soractelite™ transperineal focal laser ablation (TPLA) using the Echolaser® system is a novel minimally invasive thermoablative technique based on laser-tissue interaction that induces cell death. It has already been shown that this technique can be performed safely in treating patients with lower urinary tract symptoms due to benign prostatic obstruction [11,12]. Moreover, several pilot studies showed that the procedure is feasible using single fiber focal laser ablation (FLA) systems for the treatment of PCa under general anesthesia [13–15]. Yet, the Echolaser® FLA system with a possibility for multifiber treatment settings has not been studied.

Therefore, we tested this system in a so-called "ablate and resect" design study in PCa patients who were scheduled for RARP. This study follows the IDEAL phase 2a for the assessment of novel techniques in a surgical environment [16]. This manuscript reports on short-term QoL, safety, and feasibility outcomes following different TPLA treatment regimens for PCa.

2. Patients and methods

2.1. Study design

This study is an investigator-initiated, prospective, multicenter, interventional pilot study aiming to include 12 patients, who are divided over four treatment regimens to evaluate possible variation in outcomes. The sample size was based on previous pilot studies for focal therapy of PCa [14,15,17]. The study was in accordance with the Declaration of Helsinki and was approved by the local institutional review boards under registry number NL69903.018.19. The study is registered on clinicaltrials.gov as "TPLA for PCa" (NCT04170478; https://clinicaltrials.gov/ct2/show/NCT04170478).

2.2. Study population

Men were eligible when the following criteria were met: ≥40 yr of age, histopathologically confirmed PCa, organ-confined PCa according to clinical T staging, prostate volume ≥40 ml, and scheduled for RARP with uni- or bilateral non–nerve sparing surgery. Patients were treated with TPLA on the side where nerve sparing was not intended. The exclusion criteria were a history of (hormonal) treatment for PCa, lower urinary tract surgery and bladder neck contracture, inability to undergo prostate MRI, contraindication for intervention with conscious sedation (significant cardiac or pulmonary disorder, and bleeding disorder), or known allergy for Sonovue. Participants were recruited from August 2020 until September 2021 at tertiary referral centers (Amsterdam University Medical Centers and Netherlands Cancer Institute). Written informed consent was obtained.

2.3. TPLA procedure

Two urologists with experience in TPLA procedures in patients with benign prostatic obstruction conducted the study intervention, as was reported previously in detail by van Kollenburg et al [18]. TPLA was performed in an outpatient setting. Participants underwent TPLA in a lithotomy position using local anesthesia of the perineal skin with lidocaine 2%, 8 ml, and a periprostatic block with lidocaine 2%, up to 15 ml, with optional conscious sedation. Antibiotic prophylaxis consisted of a single oral dose of ciprofloxacin 500 mg 1 h before the intervention. Proper urethra visualization was achieved by Foley catheter (16 Ch) placement. A biplane transrectal ultrasound scanner (TRT-33, MyLab Eight eXP; Esaote, Florence, Italy) with an external needle-guide kit was used. Pre-TPLA prostate MRI was performed according to standard clinical care. One lobe with histologically confirmed PCa tissue was targeted by (cognitive fusion of the MRI) and real-time grayscale ultrasound

images, while taking safety precautions into account. Laser fiber(s) was/were placed under ultrasound guidance using a 21-gauge trocar needle. Depending on the treatment regimen, one or two laser fibers were positioned in parallel at 5 or 10 mm distance (Table 1). Safety precautions included targeting of a non–nerve sparing side, a safety margin of 10 mm to the urethra and rectal wall, and a safety margin of 15 mm to the bladder neck. Thermometry measurements were performed during treatment at 0.5 Hz using in-house built software and a digital readout device. A wire thermosensor, containing 14 constantan-copper thermocouples evenly spaced at 10 mm, was inserted through the Foley catheter measuring urethral temperatures. A wire thermosensor in a sterile tube containing seven constantan-copper thermocouples evenly spaced at 10 mm was placed in the intraprostatic rectal space using a 15-gauge trocar needle. Laser ablation was conducted using the Echolaser X4 system (Elesta, Florence, Italy), of which one or two channels were used, out of a total of four independently adjustable continuous wave laser diodes operating at 1064 nm. TPLA was performed delivering 1800 J per fiber at 3 or 5 W power, according to the treatment regimen, which equals 6- or 10-min treatment duration.

Following the procedure, participants were discharged after a minimum of 1 h and a successful spontaneous void without significant residual urine. If patients developed urinary retention, an indwelling catheter was placed for 1 wk.

2.4. Follow-up

Participants were contacted by phone 1 d after TPLA, and an outpatient visit was scheduled at 1 and 4 wk after TPLA for monitoring of health status, questionnaires, and reporting of adverse events according to Common Terminology Criteria for Adverse Events version 5.0 (CTCAE v5.0) [19]. In addition, pre-RARP imaging (multiparametric MRI and contrast-enhanced ultrasound of the prostate) and post-RARP histological analysis of the prostate specimen were performed, which will be reported separately.

2.5. Safety and feasibility

Safety and feasibility of TPLA were evaluated prospectively by the number of periprocedural, postprocedural, and device-related adverse events according to the CTCAE v5.0. TPLA was considered safe when $\leq$10% of participants experienced grade $\geq$3 adverse events. TPLA treatment duration and length of hospital admission (h) were reported. Additionally, temperatures were registered in the urethra and near the rectal wall. Feasibility of RARP following TPLA was assessed by blood loss (ml), procedure time (min), and hospitalization duration (d), and by using a questionnaire that was completed by the surgeon (see the Supplementary material). This questionnaire determined TPLA-related complications (eg, hematoma, edema, fibrosis, or necrosis), feasibility of RARP, and whether the procedure was subjectively experienced similar to a standard RARP, on a 1–5 Likert scale.

2.6. QoL and functional outcomes

QoL regarding urinary, bowel, sexual, and hormonal status were determined by validated questionnaires: Expanded Prostate Cancer Index Composite (EPIC), International Prostate Symptom Score (IPSS), IPSS QoL score (IPSS-QoL), and International Index of Erectile Function (IIEF-15). Pain was measured by the visual analog scale (VAS). Functional outcomes were evaluated by uroflowmetry. Data were collected at baseline, and 1 and 4 wk after TPLA.

2.7. Statistical analysis

Baseline characteristics were reported descriptively. Functional outcomes, regarding nonparametric data of questionnaires and uroflowmetry between paired samples, were compared at baseline and at each follow-up visit, using the Friedman test with Dunn-Bonferroni post hoc test. Box plots of parameters were plotted to visualize data over the follow-up period. Statistical tests were performed using IBM SPSS statistics, version 26 (IBM SPSS, IBM Corp., Armonk, NY, USA), and a p value of <0.05 was set as a significant difference.

3. Results

Twelve patients were included between August 2020 and September 2021. Patient characteristics are displayed in Table 2. Eleven patients had a suspicious lesion on prebiopsy prostate MRI according to the Prostate Imaging Reporting and Data System version 2.0 (PIRADS v2.0) classification.

3.1. Periprocedural and immediately postprocedural outcomes

TPLA was performed using local perineal anesthesia only; optional conscious sedation was not needed. Patients were consecutively treated according to the assigned treatment regimen. The total mean (standard deviation [SD]) procedure time was 57 (3.8) min (Table 3). No machine failures occurred. The mean (SD) laser ablation duration was 9 (1.7) min. The median (interquartile range [IQR]) maximum temperature increase was 0.7 °C (0.14–1.83 °C) at the rectal wall and 2.8 °C (2.46–10.1 °C) in the prostatic urethra. Patients reported minor discomfort during ablation, mostly a burning sensation in the lower abdomen, and urgency. All patients completed the laser treatment. Patients were discharged on the same day after a median (IQR) of 3.25 (1.25) h. One patient at the age of 77 yr was discharged with an indwelling catheter for 7 d because of urinary retention. At baseline, this patient had a peak urinary flow of 6 ml/s with a postvoid residual of 71 ml, IPSS of 1, and a prostate volume of 67 cc. Another patient had already been performing clean-intermittent catheterization (CIC) three times a day prior to TPLA treatment and continued this after TPLA.

3.2. Complications and adverse events

No serious (CTCAE grade $\geq$3) adverse events occurred during 4-wk follow-up. On the 1st day following treatment, urinary complaints were noted by nine patients, which included mild painful micturition and urgency (CTCAE

Table 1 – Overview of treatment regimen followed according to laser settings

Regimen	No. of fibers	Wattage (W)	Energy per fiber (J)	Distance (mm)	No. of procedures
1	1	3	1800	–	3
2	2	3	1800	5	3
3	2	3	1800	10	3
4	1	5	1800	–	3

Table 2 – Patient characteristics at baseline

	Value
Age (yr), median (IQR)	69 (12)
PSA (ng/ml), median (IQR)	11.9 (12.3)
Prostate volume (ml), median (IQR)	44 (9.8)
PIRADS, *n* (%)	
2	1 (8.3)
3	2 (16.7)
4	3 (25)
5	6 (50)
Size of PIRADS lesion (mm), median (IQR)	16 (6)
Total biopsy cores, median (IQR)	11.5 (3.5)
Number of positive cores, median (IQR)	4 (1)
ISUP grade group, *n* (%)	
2	3 (25)
3	7 (58.3)
4	1 (8.3)
5	1 (8.3)

IQR = interquartile range; ISUP = International Society of Urological Pathology; PIRADS = Prostate Imaging Reporting and Data System; PSA = prostate-specific antigen.

Table 3 – Perioperative outcomes of TPLA treatment

Details	Value
Procedure duration (min), mean (SD)	57 (3.8)
Laser ablation duration (min), mean (SD)	9 (1.7)
Anesthetic used, *n* (%)	
Local anesthesia of perineal skin and prostate	12 (100)
Conscious sedation	None
Maximum temperature increase (°C), median (IQR)	
Rectal wall	0.7 (0.14–1.83)
Prostatic urethra	2.8 (2.46–10.1)
Hospital admission (h), median (IQR)	3.25 (1.25)

IQR = interquartile range; SD = standard deviation.

grade 1). In eight patients, complaints resolved after 1 wk. For one patient, symptoms lasted 4 wk following TPLA. One patient developed a perineal hematoma after 1 wk (CTCAE grade 1), which had resolved after 4 wk. One patient who performed CIC prior to TPLA was unable to perform CIC 1 wk after TPLA treatment, which required an indwelling catheter until RARP. RARP surgery for two patients and follow-up were delayed until 8 wk after treatment due to an unrelated pulmonary infection ($n = 1$) and at the request (not related to TPLA treatment) of a patient ($n = 1$). No further adverse events were observed. Moreover, hematuria, hematospermia, frequency, incontinence, and erectile dysfunction were not reported. No rectal toxicity was observed; specifically no rectourethral fistula or rectal injury was reported. Table 4 provides an overview of adverse events by grade and point in time following TPLA treatment.

3.3. QoL and functional outcomes

No differences were observed in the urinary, bowel, or hormonal function domains of the EPIC questionnaire at baseline, and 1 and 4 wk following the procedure. Sexual function domain scored significantly ($p = 0.024$) lower at 1 wk, when compared with baseline. At 4 wk, no significant difference was observed anymore, when compared with baseline. IPSS QoL remained stable over time, with a mean of 1.67, 1.92, and 2.17 at baseline, 1 wk following treatment, and 4 wk following treatment, respectively.

The mean (SD) TPLA treatment-related pain score (VAS) was 1.1 (1.6) after 1 wk. After 4 wk, one patient reported a VAS of 2, while no pain was experienced by the remaining 11 patients. No significant differences in VAS scores over time were found.

Erectile function measured by the IIEF-15 questionnaire total score was significantly ($p = 0.013$) lower at 1 wk than at baseline. At 4 wk, no significant difference was observed anymore, when compared with baseline. No changes over time were found in IIEF-15 subset scores. IPSS remained stable at both follow-up moments when compared with baseline. Qmax and postvoid residual showed no significant differences. An overview of QoL and functional results is shown in Figure 1.

3.4. Feasibility of RARP following TPLA

RARP was performed in all patients, combined with pelvic lymph node dissection in six patients. Nerve-sparing surgery at the contralateral side of TPLA treatment was performed in ten patients. RARP were performed by four experienced urologists. No TPLA treatment-related complications occurred during or after RARP; specifically, no rectal injury, hematoma, necrosis, or fibrosis was observed. All surgeons reported that the surgical feasibility of RARP following TPLA was not compromised and stated that it was equal to standard RARP, with a mean (SD) Likert score of 4.67 (0.62). The characteristics of RARP are shown in Table 5.

4. Discussion

This study on safety and feasibility and QoL of Soractelite™ TPLA focal treatment at the outpatient clinic for PCa patients who were scheduled for radical prostatectomy showed that single- or multifiber ablations at 5- and 10-mm distance using the Echolaser® device can be performed

Table 4 – Treatment-related toxicity and adverse events in accordance with CTCAE v5.0

Grade	Description		Day 1	Week 1	Week 4	Patients affected, *n* (%)
1	Mild	Painful micturition	*n* = 8	*n* = 1	–	8 (66.7)
		Urgency	*n* = 1	*n* = 2	*n* = 1	2 (16.7)
		Perineal hematoma	–	*n* = 1	–	1 (8.3)
2	Moderate	Urinary retention	*n* = 1	*n* = 1	–	1 (8.3)
		CIC failure due to fausse route	–	*n* = 1	–	1 (8.3)
3	Severe		–	–	–	–
4	Life threatening		–	–	–	–
5	Death related to AE		–	–	–	–

AE = adverse event; CIC = clean-intermittent catheterization; CTCAE v5.0 = Common Terminology Criteria for Adverse Events version 5.0.

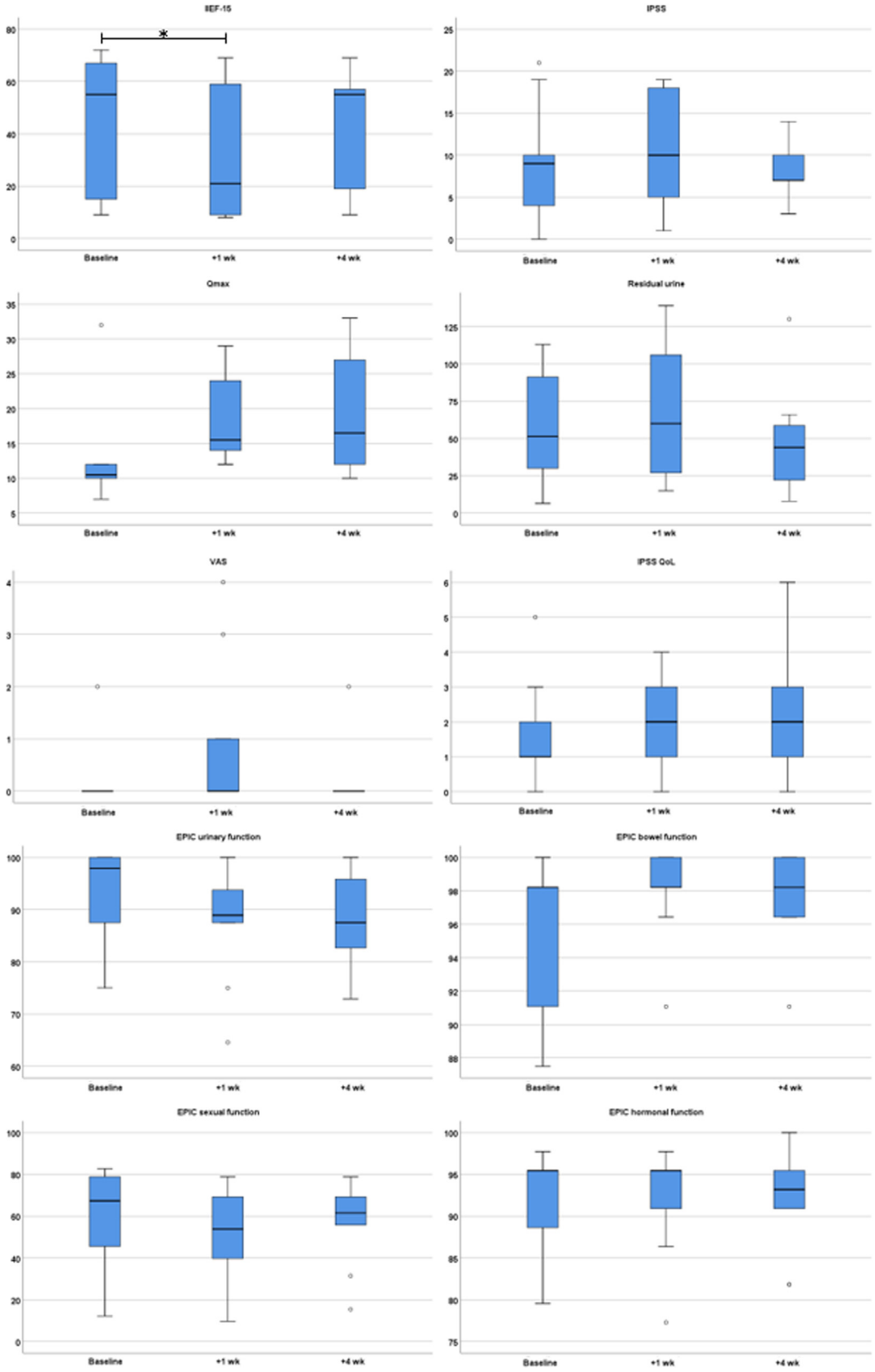

Fig. 1 – Overview of quality of life (VAS, IPSS QoL, and EPIC quality of life domain scores) and functional outcomes (IIEF-15, IPSS scores, Qmax [ml/s], and residual urine [ml]) at baseline, and 1 and 4 wk following treatment. Circle symbols represent outliers and the asterisk symbol represents a significant change ($p < 0.05$). EPIC = Expanded Prostate Cancer Index Composite; IIEF-15 = International Index of Erectile Function; IPSS = International Prostate Symptom Score; QoL = quality of life; VAS = visual analog scale.

Table 5 – Characteristics and feasibility of radical prostatectomy surgery following TPLA treatment

Details	Value
Surgical approach, *n* (%)	
RALP	6 (50)
RALP + PLND	6 (50)
Non–nerve sparing surgery, *n* (%)	
Unilateral	10 (83.3)
Bilateral	2 (16.7)
Blood loss (ml), mean (SD)	199 (104)
Operation time (min), mean (SD)	147 (32)
Surgical feasibility following TPLA	
Complications	None
RALP following TPLA is similar to a standard RALP (Likert scale: 1 = not similar to 5 = similar)	4.67 (0.62)

PLND = pelvic lymph node dissection; RALP = robot-assisted laparoscopic prostatectomy; SD = standard deviation; TPLA = transperineal focal laser ablation.

safely using local anesthesia. Patients were discharged on the same day, and only mild (grade 1 and 2) adverse events occurred during 4 wk of follow-up. The adverse events resolved mostly between the 1st day and 1st week following TPLA. A short-term QoL analysis following TPLA treatment showed no significant differences over time. Functional outcomes remained stable following ablation, except for erectile function after 1 wk, which returned to baseline after 4 wk. Possibly this is caused by the reduced sexual activity of patients directly following treatment, as was subjectively reported by patients.

Surgical innovations need proper safety evaluation before routine application in clinical practice, according to the IDEAL recommendations [16]. This study is in line with earlier pilot studies on safety for focal therapy for PCa [14,15,17,20]. Despite its promising safety and short-term functional results, the study is limited by the small sample size. Moreover, several safety precautions were implemented, especially because TPLA was performed without curative intent in this trial. Patients were eligible only if their prostate volume was $\geq$40 ml in order to be able to meet safety margins. Additionally, patients were treated with TPLA at the side where nerve sparing surgery was not intended. Notably, in this report, we did not reflect on the histological result of the RARP specimens, as this analysis is studied separately.

Several other FLA systems that have been studied before showed safety, feasibility, and stable short-term functional outcomes. Lindner et al [14] performed a phase 1 pilot study and treated 12 men with low-risk PCa using the Indigo Optima FLA system using one or two laser sources, operating at 830-nm wavelength. Yet, FLA procedures were performed under general anesthesia. Several other phase 1 studies performed FLA safely under local anesthesia and conscious sedation using the Visualase system, which operates at 980-nm wavelength. However, this FLA system only allows for single fiber treatment, and requires fiber replacement to create a larger ablation zone and subsequent longer treatment duration [15,20,21]. This is exemplified by Oto et al [20], who reported a procedure duration of 2.5–4 h and a mean duration of ablation of 4.3 min.

When comparing Soractelite™ TPLA treatment using the Echolaser® device with the aforementioned minimally invasive FLA techniques, it has several potential advantages. We showed that ultrasound-guided multifiber TPLA of the histologically confirmed PCa lesion on prostate MRI can be performed as a real minimally invasive treatment, using only local anesthesia. In addition, it can be applied in an outpatient setting, without an anesthesiologist, while discontinuing all anticoagulant medications except acetylsalicylic acid. This is potentially cost effective [22]. Additionally, it works with four independently adjustable continuous wave laser diodes. This allows for shaping of the ablation zone and an increasing treatment volume dependent on the size of the lesion, which could potentially improve oncological control. Moreover, it operates at a 1064-nm wavelength, which has increased penetration depth, in comparison with the lasers operating at 830 or 980 nm.

Focal therapy of PCa is considered investigational and has a risk of recurrence [13,23]. Therefore, it is crucial that TPLA treatment does not jeopardize salvage therapy. Our cases showed that RARP at 4–8 wk following TPLA was performed without any complications; especially no rectal injuries, necrosis, hematoma, or fibrosis was observed perioperatively. Surgeons reported that RARP following TPLA was very similar to standard RARP. It was hypothesized that 4 wk following TPLA would suffice for the sterile inflammation process to mitigate, which seems to be confirmed by current results.

These promising short-term results show that TPLA treatment for PCa is a minimally invasive treatment that preserves QoL, continence, and erectile function with low morbidity. However, in order for TPLA to be a focal therapy alternative, oncological control needs to be assessed in future studies.

5. Conclusions

TPLA treatment for PCa at the outpatient clinic with single- or multifiber ablation is a safe and feasible technique, requiring only local perineal anesthesia. Adverse events are mild (grade 1–2) and transient. Short-term QoL assessment shows no significant changes. Functional outcomes remain stable over time, except for a temporary reduction of erectile function. Oncological control needs to be assessed in future studies.

***Author contributions*:** Luigi A.M.J.G. van Riel had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: van Riel, de Reijke, de Bruin, Oddens.
Acquisition of data: van Riel, van Kollenburg, de Reijke, Oddens.
Analysis and interpretation of data: van Riel.
Drafting of the manuscript: van Riel.
Critical revision of the manuscript for important intellectual content: van Riel, van Kollenburg, Vis, van Leeuwen, de Reijke, de Bruin, Oddens.
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Supervision: de Reijke, Oddens.
Other: None.

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***Data sharing*:** The data that support the findings of this study are available upon reasonable request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.euros.2022.02.012.

References

[1] Sung H, Ferlay J, Siegel RL, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin 2021;71:209–49.
[2] Hamdy FC, Donovan JL, Lane JA, et al. 10-Year outcomes after monitoring, surgery, or radiotherapy for localized prostate cancer. N Engl J Med 2016;375:1415–24.
[3] Donovan JL, Hamdy FC, Lane JA, et al. Patient-reported outcomes after monitoring, surgery, or radiotherapy for prostate cancer. N Engl J Med 2016;375:1425–37.
[4] Wilt TJ, MacDonald R, Rutks I, Shamliyan TA, Taylor BC, Kane RL. Systematic review: comparative effectiveness and harms of treatments for clinically localized prostate cancer. Ann Intern Med 2008;148:435–48.
[5] Sanda MG, Dunn RL, Michalski J, et al. Quality of life and satisfaction with outcome among prostate-cancer survivors. N Engl J Med 2008;358:1250–61.
[6] Wei JT, Dunn RL, Sandler HM, et al. Comprehensive comparison of health-related quality of life after contemporary therapies for localized prostate cancer. J Clin Oncol 2002;20:557–66.
[7] Lindner U, Lawrentschuk N, Weersink RA, et al. Focal laser ablation for prostate cancer followed by radical prostatectomy: validation of focal therapy and imaging accuracy. Eur Urol 2010;57:1111–4.
[8] Hubner N, Shariat SF, Remzi M. Focal therapy of prostate cancer. Curr Opin Urol 2018;28:550–4.
[9] van den Bos W, Muller BG, Ahmed H, et al. Focal therapy in prostate cancer: international multidisciplinary consensus on trial design. Eur Urol 2014;65:1078–83.
[10] Mottet N, van den Bergh RCN, Briers E, et al. EAU-EANM-ESTRO-ESUR-SIOG guidelines on prostate cancer—2020 update. Part 1: screening, diagnosis, and local treatment with curative intent. Eur Urol 2021;79:243–62.
[11] Frego N, Saita A, Casale P, et al. Feasibility, safety, and efficacy of ultrasound-guided transperineal laser ablation for the treatment of benign prostatic hyperplasia: a single institutional experience. World J Urol 2021;39:3867–73.
[12] Pacella CM, Patelli G, Lapicca G, et al. Transperineal laser ablation for percutaneous treatment of benign prostatic hyperplasia: a feasibility study. Results at 6 and 12 months from a retrospective multi-centric study. Prostate Cancer Prostatic Dis 2020;23:356–63.
[13] Eggener SE, Yousuf A, Watson S, Wang S, Oto A. Phase II evaluation of magnetic resonance imaging guided focal laser ablation of prostate cancer. J Urol 2016;196:1670–5.
[14] Lindner U, Weersink RA, Haider MA, et al. Image guided photothermal focal therapy for localized prostate cancer: phase I trial. J Urol 2009;182:1371–7.
[15] Natarajan S, Raman S, Priester AM, et al. Focal laser ablation of prostate cancer: phase I clinical trial. J Urol 2016;196:68–75.
[16] McCulloch P, Altman DG, Campbell WB, et al. No surgical innovation without evaluation: the IDEAL recommendations. Lancet 2009;374:1105–12.
[17] Natarajan S, Jones TA, Priester AM, et al. Focal laser ablation of prostate cancer: feasibility of magnetic resonance imaging-ultrasound fusion for guidance. J Urol 2017;198:839–47.
[18] van Kollenburg RAA, van Riel L, Bloemen PR, et al. Transperineal laser ablation treatment for lower urinary tract symptoms due to benign prostatic obstruction: protocol for a prospective in vivo pilot study. JMIR Res Protoc 2020;9:e15687.
[19] US Department of Health and Human Services NIoH, National Cancer Institute. Common Terminology Criteria for Adverse Events (CTCAE) version 5; 2017.
[20] Oto A, Sethi I, Karczmar G, et al. MR imaging-guided focal laser ablation for prostate cancer: phase I trial. Radiology 2013;267:932–40.
[21] Bomers JGR, Cornel EB, Futterer JJ, et al. MRI-guided focal laser ablation for prostate cancer followed by radical prostatectomy: correlation of treatment effects with imaging. World J Urol 2017;35:703–11.
[22] Altok M, Kim B, Patel BB, et al. Cost and efficacy comparison of five prostate biopsy modalities: a platform for integrating cost into novel-platform comparative research. Prostate Cancer Prostatic Dis 2018;21:524–32.
[23] Walser E, Nance A, Ynalvez L, et al. Focal laser ablation of prostate cancer: results in 120 patients with low- to intermediate-risk disease. J Vasc Interv Radiol 2019;30:401–409 e2.