Radiology

ORIGINAL RESEARCH • VASCULAR AND INTERVENTIONAL RADIOLOGY

MRI-directed Micro-US–guided Transperineal Focal Laser Ablation for Localized Prostate Cancer: A 1-year Follow-up Study

François Cornud, MD • Katelijne de Bie, MD* • Luigi van Riel, MD • Arnaud Lefèvre, MD • Philippe Camparo, MD • Marc Galiano, MD*

From the Departments of Radiology (F.C., A.L.) and Urology (M.G.), Clinique de l'Alma, 166 Rue de l'Université, 75007 Paris, France; Department of Urology, Amsterdam UMC location Vrije Universiteit Amsterdam, De Boelelaan 1117, 1081 HV Amsterdam, the Netherlands (K.d.B., L.v.R.); and Department of Pathology, i-Path Institut de Pathologie des Hauts-de-France, Amiens, France (P.C.). Received December 28, 2023; revision requested January 22, 2024; final revision received September 16; accepted September 24. **Address correspondence to** K.d.B. (email: *k.debie@amsterdamumc.nl*).

* F.C. and K.d.B. contributed equally to this work.

Conflicts of interest are listed at the end of this article.

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Background: MRI-guided focal laser ablation (FLA) is a promising treatment in localized prostate cancer (PCa). MRI-guided micro-US FLA shows potential for outpatient use, but its clinical application remains unexplored.

Purpose: To evaluate the safety, feasibility, and 12-month functional and oncologic outcomes of MRI-guided micro-US transperineal FLA in localized PCa and to assess the accuracy of micro-US in showing lesions depicted at MRI with Prostate Imaging Reporting and Data System (PI-RADS) score of 3 or higher.

Materials and Methods: This prospective, single-center observational study (July 2020 to June 2023) included participants with localized low- or intermediate-risk PCa and PI-RADS 3 or higher lesions (≤20 mm). Single- or multifiber FLA was performed at 1064 nm, guided by MRI-delineated image fusion. At 12 months, recurrence rates, complications, erectile function scores, and urinary symptom scores were assessed. Mann-Whitney *U* and Wilcoxon tests were used for comparisons.

Results: Fifty-five male participants (median age, 70 years; IQR, 62–74 years) with 58 lesions that were PI-RADS 3 or higher underwent transperineal FLA, with a 12-month follow-up for 33 participants. The median prostate-specific antigen level was 7.0 ng/mL (IQR, 5.6–9.0 ng/mL), 43 of 58 lesions (74%) had a Gleason score of 3 + 4, and 10 of 58 lesions (17%) had a Gleason score of 3 + 3. Single-fiber and multifiber FLA were used to treat 21 of 58 (36%) and 37 of 58 (64%) tumors, respectively. At micro-US, 53 of 58 (91%) tumors were successfully visualized. Multifiber FLA produced larger ablation volumes than did single-fiber treatment (median, 15 mL [IQR, 8–22 mL] vs 4.5 mL [IQR, 2.8–9.2 mL]; $P < .001$). At 12 months, biopsies in 35 treated tumors showed 17 recurrences (49%), including 13 in-field and four out-of-field recurrences. In-field recurrences occurred in 10 of 18 (56%) single-fiber and three of 17 (18%) multifiber cases. At 12 months, erectile function scores decreased compared with baseline (median International Index of Erectile Function score, 19 [IQR, 12–24] vs 21 [IQR, 15–24]; $P < .001$), whereas urinary function remained stable (median International Prostatic Symptom Score, 2 [IQR, 2–9] vs 6 [IQR, 3–11]; $P = .72$). One rectoprostatic fistula developed and required surgery.

Conclusion: Multifiber micro-US–guided FLA was safe and feasible, with 18% recurrence at 1-year follow-up.

Clinical trial registration no. NCT05163197

Supplemental material is available for this article.

Routine prostate-specific antigen testing has increased the diagnosis of low-risk prostate cancer (PCa), leading to more radical treatments. Although these treatments offer excellent long-term oncologic outcomes, they are often associated with adverse effects that impact quality of life (1). Active surveillance has been proposed as an alternative to radical treatment for indolent PCa (2). Approximately 76% of men with low-risk PCa remain untreated after 5 years of active surveillance, with 64% and 55% remaining untreated after 10 and 15 years, respectively (3). Tumors with a low-volume Gleason score (GS) of 3 + 4, not depicted at MRI, and no more than one D'Amico risk factor are now considered for active surveillance (4). Nevertheless, even a small risk of progression can cause anxiety in patients undergoing active surveillance, resulting in 33% of patients opting for radical prostatectomy or radiation therapy after the 1st year of follow-up (5).

Focal therapy offers a middle ground, selectively targeting the index tumor to halt disease progression while avoiding the adverse effects of radical treatment (6). Research has demonstrated the effective targeting of PCa foci using biparametric or multiparametric MRI, enabling MRI-guided focal therapy (7,8). Various focal therapy modalities have been shown to be safe and feasible, but the results regarding efficacy and mid- to long-term functional and oncologic outcomes vary (9). Additionally, challenges persist in establishing an adequate imaging follow-up protocol. Presently, high-intensity focused US is the most commonly applied focal therapy method. However, needle-based focal laser ablation (FLA), guided by MRI or US, shows promise, with cognitive or software-based transrectal US and MRI fusion aiding accurate needle placement (10,11). Notably, laser fibers (Elesta), validated for use in focal therapy, offer high visibility at US (11). Another advantage of FLA is the potential implementation of

Abbreviations

FLA = focal laser ablation, GS = Gleason score, PCa = prostate cancer, PI-RADS = Prostate Imaging Reporting and Data System

Summary

Multifiber micro-US–guided focal laser ablation in participants with localized prostate cancer was safe and feasible, with 18% recurrence at 1-year follow-up.

Key Results

- In this prospective observational study of 55 participants with localized prostate cancer undergoing transperineal focal laser ablation (FLA), micro-US helped detect 91% (53 of 58) of lesions depicted at MRI with Prostate Imaging Reporting and Data System scores of 3 or higher.
- Twelve months after FLA, erectile function decreased compared with baseline (median International Index of Erectile Function, 19 vs 21, respectively; $P < .001$), whereas urinary function remained unaffected compared with baseline (median International Prostatic Symptom Score, 2 vs 6, respectively; $P = .72$).
- At the 12-month follow-up, the percentage of participants with in-field recurrence was 56% (10 of 18) for single-fiber FLA and 18% (three of 17) for multifiber FLA.

micro-US using high-frequency probes (29 MHz), which significantly increases spatial resolution (12). Consequently, MRI-directed micro-US enhances the visibility of the index lesion and the perilesional area, eliminating the need for US and MRI scan fusion (11,13). However, to the knowledge of the authors, the utility of MRI-directed micro-US in FLA remains unexplored. This study hypothesized that MRI-guided micro-US FLA would accurately target and treat PCa lesions with minimal complications. In addition, the procedure was expected to result in low recurrence rates and preserve functional outcomes. Thus, the aims of this study were to evaluate the safety and feasibility of MRI-guided micro-US FLA, functional and oncologic outcomes 12 months after FLA, and the accuracy of micro-US in visualizing MRI-depicted lesions with Prostate Imaging Reporting and Data System (PI-RADS) score 3 or higher.

Materials and Methods

Study Participants

This prospective, observational, single-center pilot trial was approved by the in-house ethics committee with an institutional review board waiver (Amsterdam UMC; Amsterdam, the Netherlands). All participants provided written informed consent before FLA treatment. The study is part of a multicenter retrospective registration study (Transperineal Laser Ablation for Prostate Cancer; ClinicalTrials.gov: NCT05163197). Participants were consecutively included from July 2020 to July 2023. Inclusion criteria were a life expectancy of more than 10 years, a tumor visible at MRI (PI-RADS ≥3) with a maximum tumor length of 20 mm or smaller (14), a prostate-specific antigen level of 15 ng/mL or less (<20 ng/mL for transition zone lesions), and a GS of 4 + 3 or lower on targeted biopsies. Participants were excluded if they had a GS of 4 or higher on systematic biopsies (Fig 1) (2).

MRI Protocol and Evaluation

Participants underwent MRI both before study inclusion and at follow-up to evaluate prostate lesions. Standard, diffusion-weighted, and contrast-enhanced MRI sequences were performed using a 1.5-T MRI scanner (Aera; Siemens) with a pelvic phased-array coil (Table S1). Contrast-enhanced MRI sequences were obtained only at follow-up. Imaging protocol details, including acquisition parameters, are provided in Appendix S1.

Lesions were graded using PI-RADS, version 2.1, with criteria by an experienced radiologist (F.C., with >35 years of experience). Lesions that were PI-RADS 3 or higher were considered suspicious for clinically significant PCa. Apparent diffusion coefficient values from diffusion-weighted imaging and early enhancement patterns from dynamic contrast enhancement were analyzed for lesion characterization. T2-weighted images provided detailed anatomic information regarding lesion morphologic structure and prostate zonal anatomy.

Micro-US Imaging and Biopsies

For localization of MRI-identified lesions (PI-RADS ≥3), micro-US imaging was performed using the ExactVu system (Exact Imaging) at 29 MHz. Lesions were visualized and biopsied with US guidance, with six to nine targeted biopsies obtained in the suspicious lesion and surrounding area and three to nine systematic biopsies obtained in areas farther than 10 mm from the lesion. Image fusion for biopsies was performed by an experienced interventional radiologist (F.C.). Biopsy results showed GS and maximum cancer core length after undergoing microscopic evaluation by a pathologist (P.C., with >20 years of experience). Micro-US protocol details are provided in Appendix S1.

FLA Protocol

FLA was performed with the EchoLaser system (Elesta), operating at 1064 nm, delivering 5 W of energy with a total dose of 1600–1800 J per fiber per cycle. The procedure was performed by an experienced urologist (M.G., with >15 years of experience) and a uroradiologist (F.C.). Participants were placed in the lithotripsy position after intravenous antibiotic prophylaxis and catheterization and then administered general anesthesia (15). Additional protocol and procedure details are available in Appendix S1.

Initially, a single-fiber mode was used, but due to a learning curve, the protocol changed to multifiber mode, with fibers spaced 7–8 mm apart and activated simultaneously to expand the ablation zone (16). For tumors close to the rectal wall, rectoprostatic hydrodissection ensured a 5–10 mm distance between the rectum and the prostate (Figs 2, 3) (14). Real-time micro-US was used to monitor ablation progress, indicated by increasing echogenicity from gas formation (Figs 4, 5). The procedure was completed when the entire target volume was covered, and participants were discharged within 2–6 hours, with catheter removal after 2 days.

Participant Follow-up

Follow-up included multiparametric MRI at 4 days, 6 months, and 12 months after ablation, with prostate-specific antigen tests at 6 and 12 months and biopsies performed at 12 months. In-field recurrence was confirmed by positive results from targeted biopsies or perilesional biopsies of the previously treated lesion. Out-of-field recurrence was confirmed with positive results from targeted biopsies of a new PI-RADS 3 or higher lesion beyond the treated area or by positive systematic biopsies.

Retreatment

Biopsy-proven in-field or out-of-field recurrences qualified for repeat FLA, but participants could choose radical treatment or continued follow-up if desired and acceptable to the physician (F.C.). Retreatment protocols, recorded parameters, and follow-up were similar to the initial FLA and were documented accordingly.

Functional Outcomes

Urinary and erectile function and quality of life were assessed using the International Prostatic Symptom Score and the International Index of Erectile Function questionnaires at baseline, 6 months, and 12 months.

Complications

Complications were assessed based on periprocedural, postprocedural, and device-related adverse events according to Common Terminology Criteria for Adverse Events, version 5.0 (16). FLA was considered safe if less than 10% of participants experienced a grade 3 adverse event.

Statistical Analysis

Baseline and follow-up characteristics were reported descriptively, with nonparametric data presented as medians and IQRs. The Mann-Whitney *U* test compared medians of ordinal data between independent groups, and the Wilcoxon signed rank test assessed paired continuous data. Statistical analysis was performed (K.d.B., with 4 years of experience) using SPSS, version 28.0 (IBM), and $P < .05$ indicated statistical significance. Tumor location (transition zone vs peripheral zone) was analyzed separately before FLA, and ablation parameters were presented by laser mode (single fiber or multifiber). Sample size was based on the total number of cases treated during the inclusion period.

Results

Participant Characteristics

In this study, 55 male participants (median age, 70 years; IQR, 62–74 years) underwent transperineal FLA (Fig 1). At baseline, the median prostate-specific antigen level was 7.0 ng/mL (IQR, 5.6–9.0 ng/mL) (Table 1).

MRI and Micro-US Imaging

MRI findings showed a median prostate volume of 40 mL (IQR, 30–50 mL), with 58 tumors in 55 participants. Of these tumors, 35 of 58 (60%) were located in the peripheral zone and 23 of 58 (40%) were located in the transition zone. The median maximum tumor length was larger in tumors in the transition zone than in lesions in the peripheral zone lesions (median, 14 mm [IQR, 12–17 mm]

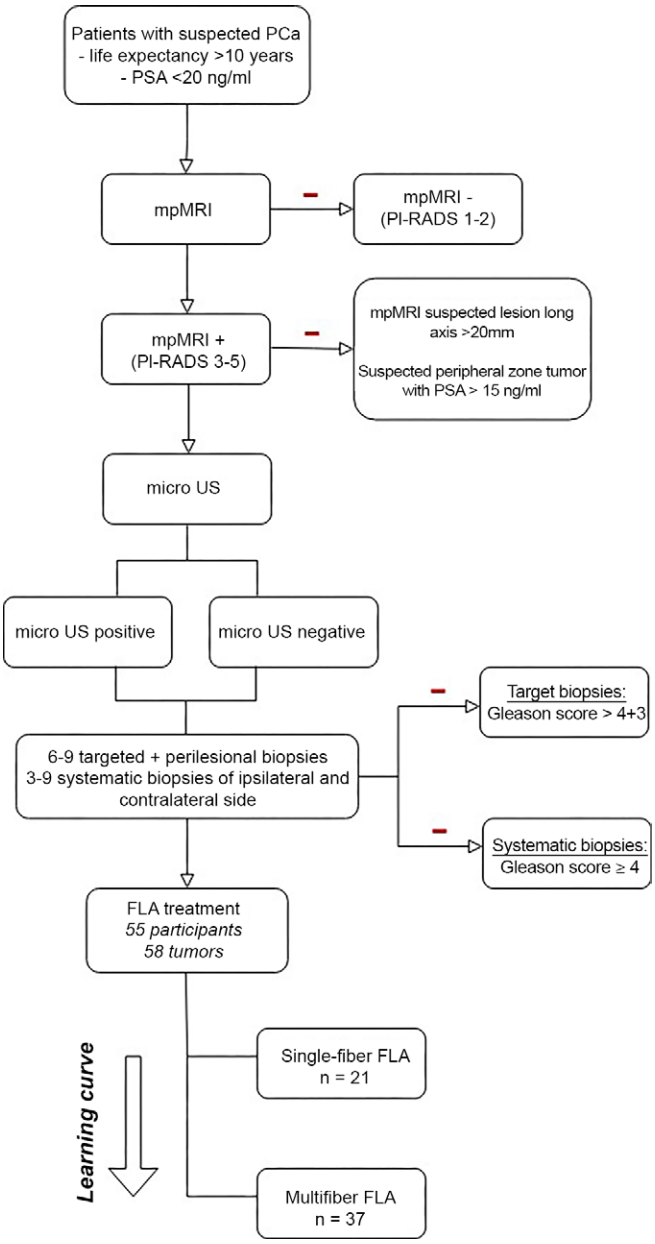

Figure 1: Flowchart of participant inclusion. FLA = focal laser ablation, mpMRI = multiparametric MRI, PCa = prostate cancer, PI-RADS = Prostate Imaging Reporting and Data System, PSA = prostate-specific antigen.

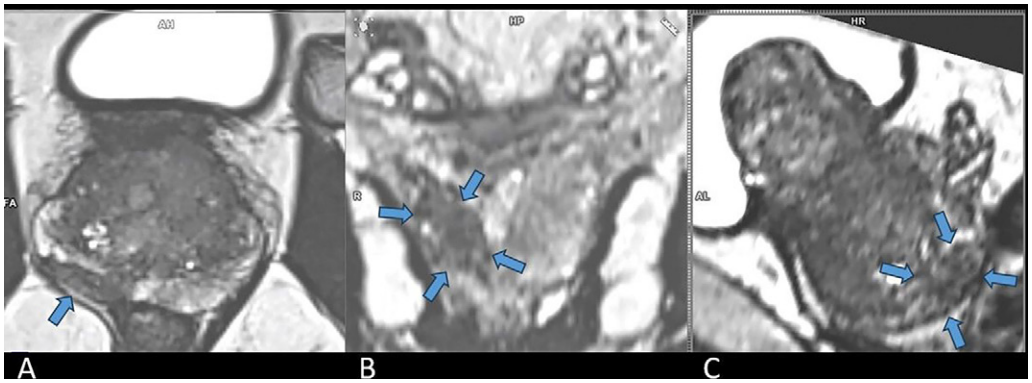

Figure 2: T2-weighted three-dimensional **(A)** axial, **(B)** coronal, and **(C)** sagittal prostate MRI scans in a 74-year-old male participant (initial prostate-specific antigen level, 8 ng/mL). The participant had a confined Prostate Imaging Reporting and Data System 5 lesion (arrows) in the right peripheral zone, with maximum tumor length of 20 mm. A Gleason score 3 + 4 lesion was diagnosed with targeted biopsies, with 10% Gleason score 4 tumor and a cribriform component of 0%. Note that the most medial part of the lesion is in contact with the rectal wall.

vs 11 mm [IQR, 10–15 mm]; P = .002), as shown in Table 2.

Micro-US showed 53 of 58 (91%) MRI-positive lesions. The median maximum tumor length differed between micro-US and MRI (median, 12 mm [IQR, 9–15 mm] vs 13 mm [IQR, 10–15 mm]; P = .002). Three transition zone tumors were not visible at micro-US because of tissue heterogeneity or shadowing from corpora amylacea (13). Additionally, two peripheral zone tumors (PI-RADS 4 lesions measuring 7 mm and 10 mm) were not visualized.

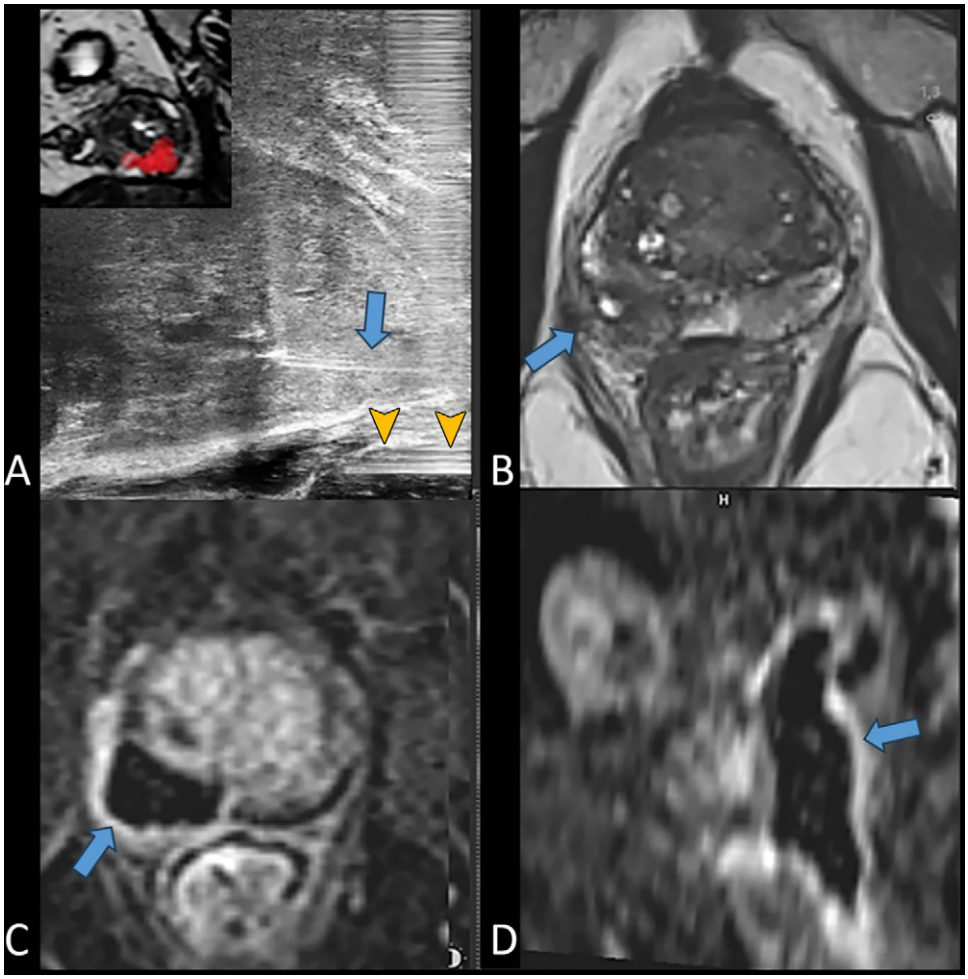

Figure 3: Treatment and follow-up images in a 74-year-old male participant (also in Fig 2). **(A)** Longitudinal micro-US image. The participant underwent rectoprostatic hydrodissection before focal laser ablation (FLA). A 21-gauge needle (arrow) was placed in the medial part of the lesion, which abuts the rectal wall. The needle inserted into the rectoprostatic space for hydrodissection (arrowheads) is used to inject hypertonic glucose serum to detach the prostate from the anterior surface of the rectum. The inset on the upper left quadrant of **A** shows the MRI scan fusion, with red tags delineating the boundaries of the target volume. **(B)** Three-dimensional transverse T2-weighted image obtained 4 days after FLA shows that the area of the lesion has a low-intensity signal (arrow). Fluid is visible centrally within the lesion. **(C, D)** Axial and sagittal dynamic contrast-enhanced images show that the ablation volume is avascular (arrow). The rectal wall, which is in contact with the medial part of the tumor, has a normal appearance. Note the basal and cranial extension of the ablation zone **(D)**, which provides an oncologic safety margin.

Prostate Biopsies

For the lesions depicted at MRI, a median of nine (IQR, seven to 10 biopsies) targeted biopsies were obtained, with similar numbers for peripheral zone and transition zone tumors (median, nine tumors [IQR, six to 11 tumors] vs nine tumors [IQR, seven to 10 tumors]; P = .46). Regarding GS, 43 of 58 (74%) were GS 3 + 4 tumors, whereas 10 of 58 (17%) were GS 3 + 3 tumors. A median of six systematic biopsies (IQR, four to six biopsies) were performed. Notably, one participant with a transition zone tumor of 16 mm, GS 4 + 4, who refused radical treatment was included. Further imaging and histologic characteristics can be found in Table 2.

Tumors that were GS 3 + 3 were considered clinically significant PCa due to their size, with a maximum tumor length at MRI of 16 mm (IQR, 11–18 mm) and a maximum cancer core length of 4–15 mm in five of 10 tumors. Among the five GS 3 + 3 tumors with a maximum cancer core length of 3 mm or more, four had a PI-RADS score of 4 and one had a PI-RADS score of 3 with a 15-mm maximum tumor length.

Focal Ablation

Focal ablation was performed in single-fiber mode in the first 21 tumors and multifiber mode in the last 37 tumors, with the multifiber mode delivering more median joules (median, 5400 J [IQR, 3600–6800 J] vs 4450 J [IQR, 3200–4800 J]; P < .001). However, the median laser time and procedure time were similar between the single-fiber and multifiber modes (median laser time, 11 minutes [IQR, 9–13 minutes] vs 11 minutes [IQR, 8–16] [P = .83]; median procedure time, 42 minutes [IQR, 38–45 minutes] vs 45 minutes [IQR, 40–60 minutes] [P = .19], respectively) (Table 3).

Follow-up 4 Days after Treatment

At the 4-day follow-up, all treated prostates showed nonperfused lesions that corresponded to the target volume. Multifiber-treated tumors had larger ablation zones than single-fiber-treated tumors (median, 15 mL [IQR, 8–22 mL] vs 4.5 mL [IQR, 2.8–9.2 mL]; P < .001) (Table 3). MRI showed no residual tumor in 55 of 58 (95%) treated tumors, whereas three of 58 (5%) treated tumors showed residual tumor at the margins of the treated area. The MRI-positive lesions were reevaluated at the 6-month follow-up.

Follow-up 6 Months after Treatment

Six-month follow-up data were available for 40 participants (43 treated tumors). The median prostate-specific antigen level was lower after FLA than before FLA (median, 3.0 ng/mL [IQR, 1.9–4.0 ng/mL] vs 7.0 ng/mL [IQR, 5.7–9.0 ng/mL], respectively; P < .001). MRI revealed no recurrence in 34 of the 43 (79%) tumors, whereas nine of 43 (21%) tumors had a PI-RADS score of 4. Biopsies for MRI-positive lesions were deferred to 12 months

due to decreased prostate-specific antigen levels (median, 6.0 ng/mL [IQR, 5.7–7.5 ng/mL] vs 4.0 ng/mL [IQR, 2.4–5.1 ng/mL]; P = .01). Scarring was observed at MRI (low-intensity T2 signal without enhancement or restricted diffusion) in 24 of 43 (56%) treated tumors.

Follow-up 12 Months after Treatment

Twelve-month follow-up data were available for 33 participants (35 treated tumors). Biopsies showed 17 recurrences (n = 35; 49%), including 13 in-field and four out-of-field recurrences (Table 4). Most in-field recurrences occurred after single-fiber treatment (10 of 13; 77%). Among the in-field recurrences, biopsies revealed GS 3 + 4 disease in seven lesions, GS 4 + 3 disease in one, and GS 3 + 3 disease in five. Notably, three biopsy-proven in-field recurrences were not detected by MRI. Out-of-field recurrences included three diagnosed by targeted biopsies (GS 3 + 4) and one by systematic biopsies (GS 3 + 3). Six participants with histologic analysis–proven PCa recurrence underwent repeat FLA, eight participants opted for active surveillance, and three participants chose radical treatment.

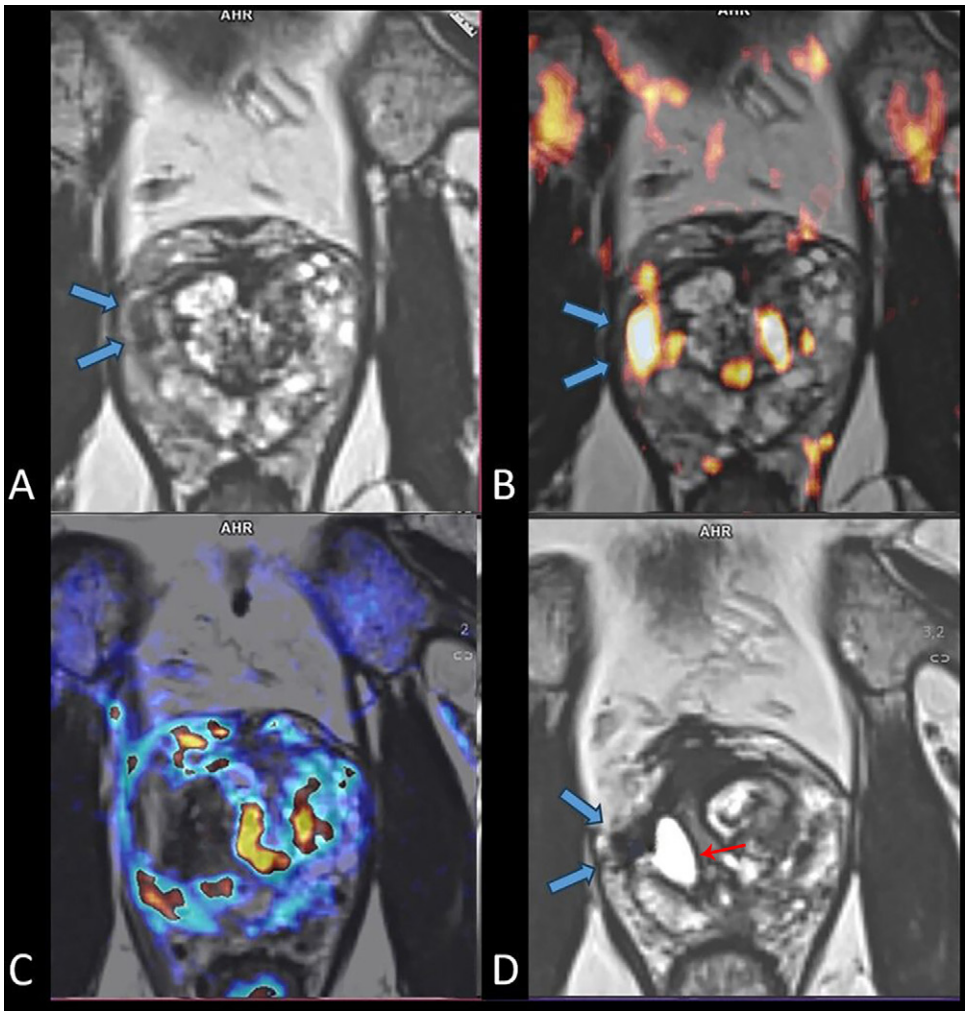

Figure 4: T2-weighted three-dimensional MRI scans in a 62-year-old male participant (initial prostate-specific antigen level, 7.6 ng/mL) with a Prostate Imaging Reporting and Data System (PI-RADS) 4 lesion (blue arrows) in the anterior sector of the right peripheral zone (maximum tumor length, 11 mm). A Gleason score 3 + 4 lesion was diagnosed with targeted biopsies, with 20% grade 4 tumor and a cribriform component of 0%. **(A, B)** T2-weighted transverse images show a PI-RADS 4 lesion in the anterior sector of the right peripheral zone (arrows). **(C)** T2-weighted transverse image superimposed with contrast-enhanced image acquired 4 days after focal ablation shows the treated area, which is avascular. The absence of vascularization extends beyond the outer edge of the prostate, reflecting the transcapsular extension of thermal necrosis. **(D)** T2-weighted transverse image acquired 12 months after focal ablation shows an avascular scar with a low T2-weighted signal intensity in the treated lesion (blue arrows). Medially, a fluid cavity (red arrow) secondary to thermal necrosis is visible.

Retreatment

Repeat FLA was performed in four participants with in-field and two with out-of-field recurrences. The treated lesions were visible on MRI scans, with targeted biopsies showing a GS of 3 + 4 in four lesions and a GS of 3 + 3 in two lesions. Two fibers were used for each treatment, with a median total dose of 3600 J (IQR, 3200–3900 J) and a median ablation volume of 11 mL (IQR, 3.5–19 mL).

Twelve-month follow-up data after repeat FLA were available for five of six (83%) participants and showed a 27% reduction in prostate-specific antigen levels (Table 4). Biopsies were negative in four participants, whereas one participant required a third FLA treatment due to positive findings in targeted biopsies with a GS of 3 + 4.

Functional Outcomes

At the 6-month follow-up, erectile function was assessed in 33 participants, as seven participants abstained from sexual intercourse. The median International Index of Erectile Function score was lower than that at baseline (median, 19 [IQR, 11–24] vs 22 [IQR, 16–24], respectively; P < .001), with no change from baseline in median International Prostatic Symptom Score (median, 5 [IQR, 2–9] vs 6 [IQR, 3–11], respectively; P = .63) or quality of life (median, 1 [IQR, 1–3] vs 2 [IQR, 1, 3], respectively; P = .46).

At the 12-month follow-up, erectile function was assessed in 29 participants. The median International Index of Erectile Function score remained lower than that at baseline (median, 19 [IQR, 12–24] vs 21 [IQR, 15–24], respectively; P < .001). There was no difference in the median International Prostatic Symptom Score (median, 2 [IQR, 2–9] vs 6 [IQR, 3–11], respectively; P = .72) or quality of life (median, 1 [IQR, 1–3] vs 2 [IQR, 1–3], respectively; P = .69) compared with baseline.

Complications

One severe complication (Common Terminology Criteria for Adverse Events grade 3), a rectoprostatic fistula, developed 7 days after FLA treatment of a bilateral peripheral zone tumor; three fibers

delivering 11 000 J were used (Fig 6). Despite hydrodissection, MRI performed 4 days after treatment showed rectal wall involvement, requiring surgical intervention.

Minor complications (Common Terminology Criteria for Adverse Events grade 1–2) occurred in 10 of 58 (17%) participants and included urinary retention, infection, and transient stress incontinence and were resolved with alpha blockers or antibiotics. Suprapubic catheters were placed for urinary retention. In addition, two participants experienced retrograde ejaculation.

Discussion

MRI-guided focal laser ablation (FLA) is a promising treatment of localized prostate cancer (PCa), but the clinical use of MRI-guided micro-US FLA has not been evaluated. The objective of this study was to evaluate the safety, feasibility, and 12-month functional and oncologic outcomes of MRI-guided micro-US transperineal FLA for localized PCa. In addition, we aimed to evaluate the accuracy of micro-US in visualizing lesions depicted at MRI that are Prostate Imaging Reporting and Data System score of 3 or higher. Because of a learning curve, we switched from single-fiber treatment to multifiber treatment after 21 ablations. Micro-US helped show 53 of 58 (91%) lesions depicted at MRI. At 12 months, biopsies of 35 treated tumors revealed 17 recurrences (49%), 13 in-field and four out-of-field, with 10 in-field recurrences occurring after single-fiber treatment. Erectile function scores were slightly lower at 12 months (median International Index of Erectile Function, 19 [IQR, 12–24] vs 21 [IQR, 15–24]; $P < .001$). There was one severe complication, a rectoprostatic fistula, which required surgery.

Our study confirmed that micro-US can help to effectively localize PCa tumor foci before focal therapy and guide transperineal interventional prostate procedures (11,13). Lughezzani et al (17) reported similar detection rates at micro-US in a prospective study of 320 participants. The high tumor detection rate may be due to the high resolution of 29 MHz, which provides a real-time spatial resolution of 70 μm, resulting in a threefold increase in resolution compared with conventional 9–12-MHz transrectal US probes (18). However, MRI scan fusion proved valuable during the planning phase of the FLA, allowing for precise needle position adjustment for optimal target volume coverage.

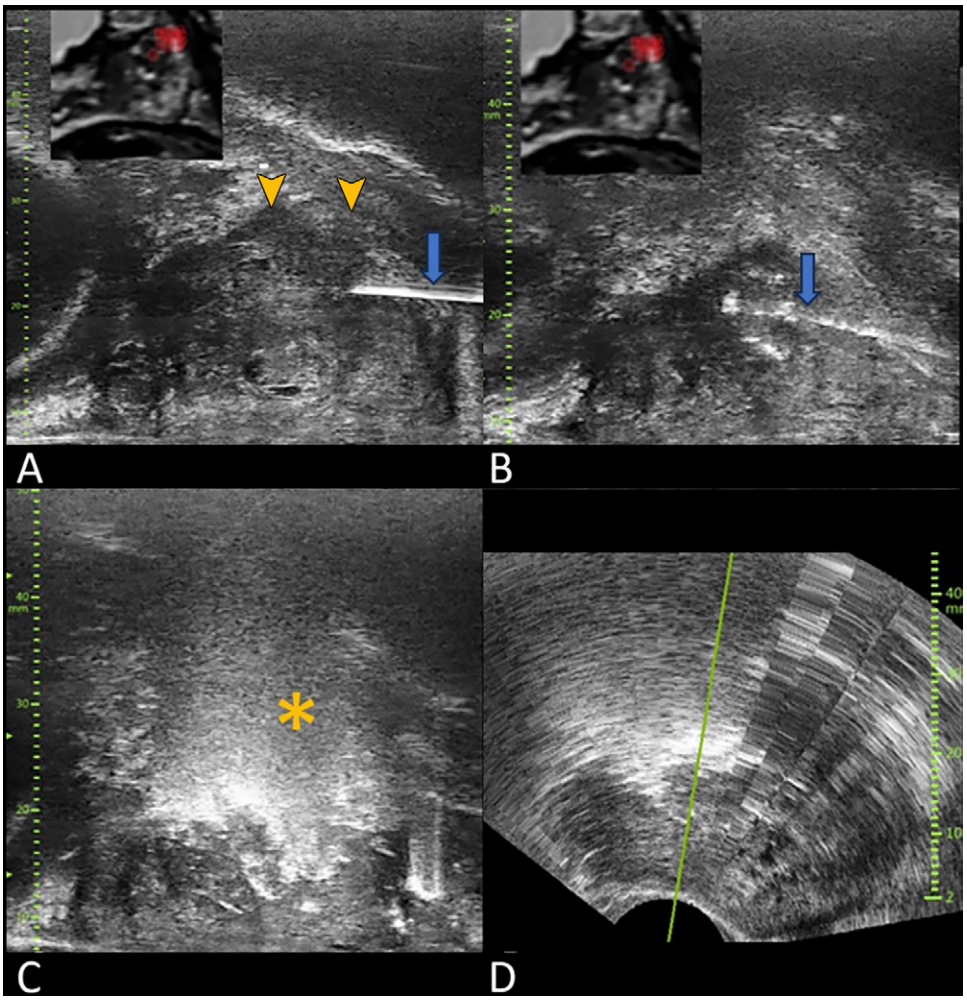

Figure 5: US images show monitoring of focal laser ablation (FLA) in a 62-year-old male participant (initial prostate-specific antigen level, 7.6 ng/mL) with a Prostate Imaging Reporting and Data System (PI-RADS) 4 lesion. **(A)** Longitudinal image shows placement of a 21-gauge needle (arrow). The PI-RADS 4 lesion is clearly visible (arrowheads), and its location is confirmed by image fusion and is visible on an MRI scan inset in the upper left quadrant of the image. Image fusion (red tags) delineates the limits of the target volume. **(B)** Longitudinal image shows start of ablation. Laser fiber (arrow) is visible inside the lesion. Several hyperechogenic foci are visible around the laser fiber, indicating that ablation has started. **(C)** Longitudinal view shows the echogenic area (*), corresponding to gas formation, which indicates that the target volume, visible on MRI fusion scans (top left corners on **A** and **B**), has been covered by FLA. The laser fiber is minimally visible. **(D)** Transverse micro-US reconstruction shows the extent of the ablation zone.

Table 1: Baseline Characteristics of Participants Undergoing Initial FLA Treatment

Characteristic	Initial FLA Treatment (n = 55)
Age (y)	70 (62–74) [52–82]
Initial PSA level (ng/mL)	7.0 (5.6–9.0) [2.1–21]
Prostate volume (mL)*	40 (30–50) [18–100]
Previous treatment	
Active surveillance	4/55 (7)
Transurethral resection of the prostate	1/55 (2)
None	50/55 (91)

Note.—Quantitative variables are expressed as medians, with IQRs in parentheses and ranges in brackets. Qualitative variables are expressed as numerators/denominators, with percentages in parentheses. FLA = focal laser ablation, PSA = prostate-specific antigen.

* Calculated with an ellipsoid formula: width × height × length × π/6.

Because of numerous in-field recurrences after single-fiber treatment, our study involved a learning curve, leading us to switch to multifiber ablations (19). Compared with the single-fiber mode, the multifiber mode resulted in a larger ablation volume, with fewer in-field recurrences at 12 months. Our results are comparable to those of Walser et al (14), who investigated in-bore MRI-guided FLA using a 980-nm wavelength laser at 17 W for 3 or 4 minutes and achieved higher joules with one fiber (3060–4860 J) than we did (1800 J). They reported an 18% 12-month recurrence rate, which is similar to our outcomes with multifiber ablation. However, their recurrence rate was lower than our single-fiber results, possibly due to differences in laser properties and overlapping of the treatment area to ensure adequate treatment margins.

One severe complication occurred in our study: a rectoprostatic fistula requiring surgical intervention. The fistula was not amenable to closure, necessitating prostatectomy and coloanal

Table 2: MRI and Histologic Characteristics at Baseline

Characteristic	Peripheral Zone (*n* = 35)	Transition Zone (*n* = 23)	*P* Value
Prostate volume (mL)*	40 (30–54)	38 (30–50)	.67
MRI tumor length (mm)†	11 (10–15)	14 (12–17)	.002
Sextant			…
Apex	4 (11)	7 (30)	
Midline	26 (74)	16 (70)	
Base	5 (14)	0	
Sector			…
Posteromedial	23 (66)	1 (4)	
Posterolateral	7 (20)	22 (96)	
Anterior	5 (14)	0	
PI-RADS score			…
3	4 (11)	4 (17)	
4	28 (80)	15 (66)	
5	3 (9)	4 (17)	
Gleason score			…
3 + 3	5 (14)	5 (22)	
3 + 4	28 (80)	15 (65)	
4 + 3	1 (3)	2 (9)	
4 + 4	1 (3)	1 (4)	

Note.—Included were 58 tumors treated in 55 participants. Qualitative variables are expressed as proportions with percentages in parentheses. Quantitative variables are expressed as medians with IQRs in parentheses. Statistical analysis was performed using SPSS, version 28.0 (IBM), and $P < .05$ indicated statistical significance. The Mann-Whitney *U* test was used to compare the medians of two independent groups. PI-RADS = Prostate Imaging Reporting and Data System.

* Calculated with an ellipsoid formula: width × height × length × π/6.

† Tumor size: the largest tumor diameter measured on the coronal, sagittal, or axial plane.

Table 3: Parameters of Focal Laser Ablation

Characteristic	Single-Fiber Mode (*n* = 21)	Multifiber Mode (*n* = 37)	*P* Value
Cycle			…
One	4 (19)	14 (38)	
Two	6 (29)	20 (54)	
Three	8 (38)	2 (5)	
Four	3 (14)	1 (3)	
Fiber			…
One	21 (100)	0	
Two	0	24 (65)	
Three	0	6 (16)	
Four	0	6 (16)	
Five	0	1 (3)	
Total delivered energy (J)	4450 (3200–4800)	5400 (3600–6800)	<.001
Ablation volume (mL)	4.5 (2.8–9.2)	15 (8–22)	<.001
Laser duration (min)	11 (9–13)	11 (8–16)	.83
Procedure duration (min)	42 (38–45)	45 (40–60)	.19

Note.—Included were 58 tumors treated in 55 participants. Qualitative variables are expressed as proportions with percentages in parentheses. Quantitative variables are expressed as medians with IQRs in parentheses. Statistical analysis was performed using SPSS, version 28.0 (IBM), and $P < .05$ indicated statistical significance. The Mann-Whitney *U* test was used to compare the medians of two independent groups.

Table 4: Twelve-month Follow-up of Participants after Initial FLA Treatment and after Repeat FLA for In-Field or Out-of-Field Recurrences

Application Mode	No. of Treatments	Initial PSA (ng/mL)	PSA after FLA (ng/mL)	Decrease in PSA (%)	Positive Findings in Targeted Biopsies	Positive MRI Findings*
FLA (*n* = 35)						
Single fiber	18/35 (51)	6 (5–8)	3.4 (1.7–4.4)	44	10/18 (56)	9/10 (90)
Multifiber	17/35 (49)	8 (6–10)	2.8 (2.3–4.5)	65	3/17 (18)	1/3 (33)
Repeat FLA (*n* = 5)						
Single fiber	0					
Multifiber	5/5 (100)	3 (2–11)	2.2 (0.7–7.2)	27	1/5 (20)	1/1 (100)

Note.—Quantitative variables are expressed as medians with IQRs parentheses; qualitative variables are expressed as numerators/denominators with percentages in parentheses. FLA = focal laser ablation, PSA = prostate-specific antigen.

* Positive MRI findings are expressed as the number of participants who underwent MRI (denominator) and the number of participants who had a suspected recurrence at MRI (numerator).

anastomosis. This complication highlights the safety concerns of multifiber FLA without real-time temperature feedback, as provided by MRI-guided treatments. Simultaneous monitoring of multiple treatment sites with micro-US is challenging, especially in posteromedial peripheral zone tumors. To reduce this risk, we recommend rectoprostatic hydrodissection to prevent thermal damage to the rectum. The fistula occurred early in the learning curve, and with precautions such as limiting to two activated fibers, micro-US can safely monitor even difficult tumors. Although rare, rectoprostatic fistulas induced by focal therapy have been previously reported, with management ranging from conservative approaches to surgery (14,20–24). In the other participants, the treatment was shown to be safe, with minor complications resolved by medical intervention or temporary catheterization.

We observed a small decrease in erectile function at the 6- and 12-month follow-up examinations. This finding contrasts with those of Walser et al (14) and Eggener et al (25), who reported no difference 1 year after FLA (P = .51 and .38, respectively). The reasons for these differences are unclear but may be related to variations in treated lesion locations, which were not reported in other studies, preventing direct comparison with our results.

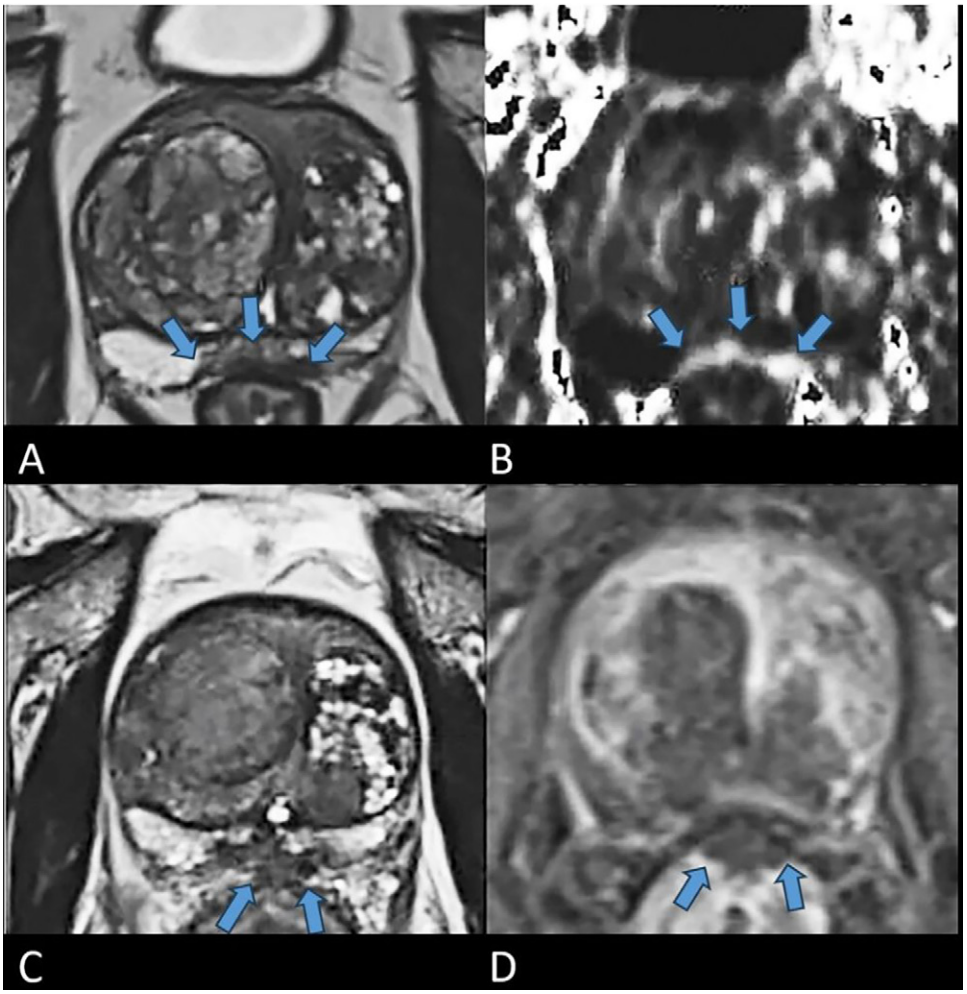

Figure 6: T2-weighted three-dimensional MRI scans in a 66-year-old male participant (initial prostate-specific antigen level, 6.3 ng/mL) with a Prostate Imaging Reporting and Data System 4 lesion in the peripheral zone, on the midline, predominating on the right side and at the apex. Prostate volume was 100 mL. The targeted biopsies were Gleason 3 + 4, the percentage of grade 4 was 40%, and the cribriform component was 0%. The **(A)** transverse T2-weighted and **(B)** diffusion-weighted images show that the tumor is bilateral and centered by the median line (arrows), abutting the rectal wall on both sides. **(C)** Transverse T2-weighted and **(D)** dynamic contrast-enhanced images acquired 4 days after focal laser ablation (FLA) show the hypointense lesion bulging into the rectoprostatic fat on the T2-weighted image (arrows, **C**). **(D)** On the dynamic contrast-enhanced image, thermal necrosis involves the rectal wall (arrows). FLA was followed by the occurrence of a rectoprostatic fistula 7 days after focal ablation, which was treated surgically.

Our study had several limitations. First, the sample size was small, with limited assessment of oncologic outcomes beyond 12 months. Second, the data were analyzed at the tumor level, rather than at the participant level, but the small number of participants with multiple tumors was unlikely to have caused data clustering. Third, the lack of thermosensors to monitor temperature during laser application limited insights comparable to those of MRI thermometry at in-bore MRI-guided FLA. However, micro-US–guided FLA has advantages, such as no need for MRI-compatible materials or equipment, making it a low-cost, outpatient alternative that can be performed even while the patient is undergoing local anesthesia (16). Further studies with larger cohorts are needed to define the role of US-guided FLA treatments and to compare them with MRI-guided treatments.

In conclusion, the safety and efficacy of the multifiber mode in micro-US–guided focal laser ablation performed with hydrodissection were demonstrated. Single-fiber treatments were associated with 12-month recurrence rates in slightly more than half of the participants. Caution is advised for posteromedial lesions, which require hydrodissection and adequate monitoring. A small decrease in erectile function was observed at the 12-month follow-up.

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