The ClearPoint Prism® Laser Ablation System: A New Platform for Laser Interstitial Thermal Therapy (LITT) in Neuro-Oncology

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BACKGROUND AND OBJECTIVES: Laser interstitial thermal therapy (LITT) has advanced the surgical treatment of brain cancer. However, technical constraints in the first-generation laser ablation systems limit the full potential of this technology. The ClearPoint Prism® Laser Ablation System was developed to overcome many of these limitations, including a larger ablation window, a faster refresh rate for magnetic resonance thermometry, and integration with an MRI-compatible stereotactic system. This system was US Food and Drug Administration–cleared for neurosurgical use in 2022.

METHODS: As an IDEAL Stage 1 study, we prospectively followed the first 3 patients who underwent LITT using the ClearPoint Prism® Laser Ablation System in the United States to establish feasibility and safety of this technology platform.

RESULTS: Three patients underwent procedures involving MRI-guided needle biopsy followed by LITT. The radial error of stereotaxis relative to the intended target ranged from 0.8 to 1.6 mm (with a median of 1.0 mm). Definitive diagnosis was achieved in all cases. The average time required to establish the trajectories was 98.7 ± 16.6 minutes. The average time required to perform the biopsy and LITT was 110 ± 19.3 minutes. These times are not statistically different from our published results for comparable procedures using other available LITT systems. The average LITT time required to achieve ablation of >1 cm radius was 49 seconds (range: 29-133 seconds). There were no procedural complications. All patients were discharged home by postoperative day 3. The postoperative MRIs demonstrated expected ablation findings consistent with intraoperative thermometric assessment. With a median follow-up of 219 days (range: 185-259 days), there were no 30-day readmission, 90-day emergency visits, or wound complications.

CONCLUSION: In this study, we introduced the design rationale for the ClearPoint Prism® Laser Ablation System, theoretical considerations for its technical merits relative to other existing systems, and to share our initial experience.

KEY WORDS: Brain tumor, Glioma, Magnetic resonance laser-induced thermal therapy, Metastasis, Minimally invasive surgery

The introduction of stereotactic laser ablation (also known as laser interstitial thermal therapy [LITT]) has advanced neurosurgical care for patients with brain cancer. With an expanding literature documenting efficacy,[1-6] acceptance of clinical indications,[7,8] and a safety profile comparable with stereotactic needle biopsy,[6,9-11] there has been rapid adoption of this technology with an ~400% increase in cranial utilization between 2012 and 2018 relative to craniotomy.[12] However, several technical constraints of the two current laser ablation platforms, Visualase (Medtronic) and NeuroBlate (Monteris) Laser Ablation System, limit the full potential of LITT. For instance, with these systems, the safety and efficacy of ablation monitored through magnetic resonance (MR) thermometry and thermometric assessment require 8 seconds of data acquisition and processing, resulting in delayed readout.[13] In addition, both laser probe designs require cooling systems that compromise the efficiency of heat conduction.[14] Moreover, the total length of the laser window

ABBREVIATION: LITT, laser interstitial thermal therapy.

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is limited to 10 mm.[15,16] As such, ablation of regions greater than this window requires catheter repositioning followed by repeat ablation.

The ClearPoint Prism® Laser Ablation System (ClearPoint Neuro) was designed to address these limitations. The Prism® Laser (ClearPoint Neuro) probe has a fiberglass applicator tip that is designed to optimize heat distribution to surrounding tissue eliminating the need for a cooling system. This property of the applicator tip allows for achieving the same ablation as other cooled laser systems at a lower power. The properties of the Prism® Laser probe are compared with those of Medtronic Visualase (Medtronic) and Monteris NeuroBlate (Monteris) in Figure 1A. In addition, the ClearPoint Prism® Laser probe harbors a laser window up to 25 mm in length, a feature that is currently unavailable for other ablation probes (Figure 1B). Finally, the Prism laser probe was designed specifically to integrate with the MRI-compatible ClearPoint SmartFrame® (ClearPoint Neuro) stereotactic system to facilitate the ease of transition between navigation and LITT administration.[17-21]

A key benefit of the Prism® Laser system is its rapidity of thermometric measurements versus the standard 8 seconds to acquire and process temperature data.[13] The Prism® laser uses the Tranberg thermoguide workstation (Clinical Laserthermia Systems AB, Figure 1C) to acquire and process data in 3 seconds. The thermometry data are acquired in 2 planes with a spatial resolution of 1.6 mm × 1.6 mm × 3.0 mm (0.8 mm × 0.8 mm × 3.0 mm,

A

Features	ClearPoint Prism	Medtronic Visualase	Monteris Neuroblate
Cooling System	None	Saline	Liquid CO_2
Wavelength, Power	1064 nm, ≤4-7 W	980nm, ≤15 W	1064nm, ≤12 W (High, Medium, or Low)
Aperture Length	1 mm Radial 15 mm Diffuser 25 mm Diffuser	3 mm Diffuser 10 mm Diffuser	6 mm Diffuser and < 6 mm Sidefire
Thermometry	CEM 43	Arrhenius	CEM 43
TMAP	1-3 planes, any orientation.	2 planes, perpendicular to probe	3 coaxial planes 5 mm along the axis of the probe

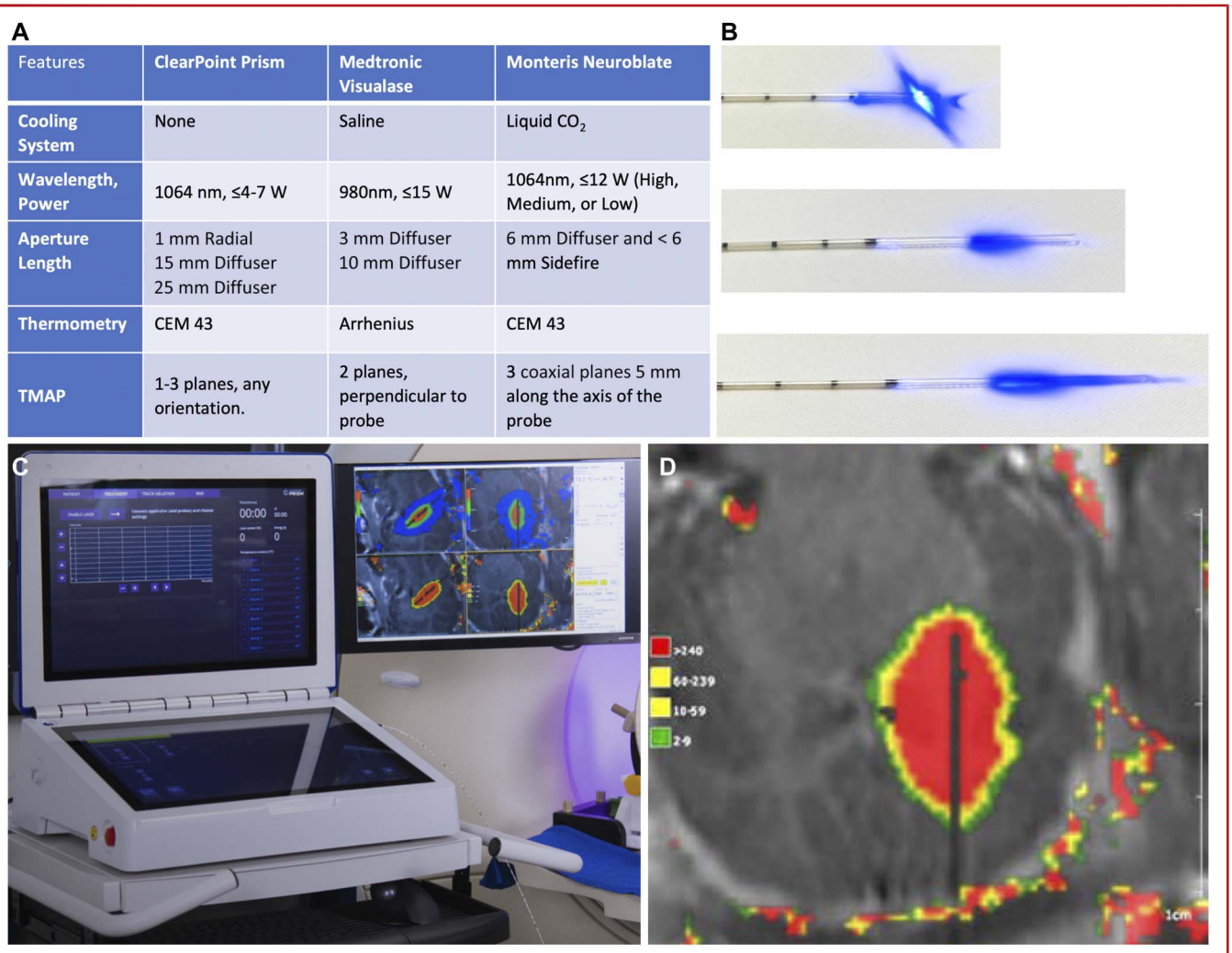

FIGURE 1. **A**, *Comparison of the characteristics of the ClearPoint Prism, Medtronic Visualase, and the Monteris NeuroBlate laser probes.* **B**, *The three sizes of the Prism fiber optic laser probe. Top: 1-mm radial probe; middle: 15-mm diffuser probe; bottom: 25-mm diffuser probe. Blue: light emitted on laser activation.* **C**, *The ClearPoint Prism Tranberg thermoguide workstation (Clinical Laserthermia Systems AB).* **D**, *Thermometry reference image. Damage prediction is expressed in CEM43. Green: equivalent to thermal exposure of 43° for >2 minutes; yellow: equivalent to thermal exposure of 43° for >10 minutes; orange: equivalent to thermal exposure of 43° for >60 minutes; red: equivalent to thermal exposure of 43° for >240 minutes. CEM, cumulative equivalent minutes.*

with interpolation, Figure 1D). Selection of correct reference baseline region of interest (ROI) is critical to accurate MR thermal imaging. The Tranberg thermoguide software (Clinical Laserthermia Systems AB) allows for the selection of a point or a mask as an ROI to compensate for normal phase drift of the MR system. The option of a larger baseline ROI such as a disk or a mask helps reduce the noise susceptibility. In addition, the software also allows the creation of up to 6 temperature guards, such as circle ROI, polygon, and points, that can be contoured around anatomy.

The Prism® Laser Ablation System was cleared for clinical use by the US Food and Drug Administration in September 2022. In this article, we describe the clinical outcome of the first 3 patients who underwent Prism®-mediated laser thermal ablation. The overall experience reflects the ease of integration with ClearPoint stereotaxis, fast ablation time, and a reassuring, pilot safety profile.

METHODS

Patient Population and Data Collection

The study was conducted under STUDY000069590 (University of Minnesota Human Research Protection Program). All patients included in the study provided informed consent for the included procedures. Basic clinical and demographic information was collected for the first 3 patients who underwent ClearPoint-guided biopsy and ClearPoint Prism® LITT after US Food and Drug Administration clearance of the system in 2022. Patients were selected for the study in the context of a multidisciplinary discussion at our institution's Brain Tumor Conference, attended by independent neurosurgeons, neuroradiologists, neuro-oncologists/oncologists, neuropathologists, and radiation oncologists before the procedure. Procedural complications, procedural time, perioperative neurological condition, 30-day readmission, 90-day emergency department visits, and wound complications were collected. There was no specific funding source allocated to this study.

ClearPoint Stereotaxis and Prism® Ablation

The procedural details of the SmartFrame stereotaxis were previously described.[17] Briefly, the patient was pinned under general anesthesia using the HFD100 head frame (intraoperative MRI system, Deerfield Imaging, Inc.) and positioned to prevent MRI bore collision. An MRI is taken after application of an adhesive grid containing MRI-visible fluid to determine the optimal entry point. The SmartFrame device was then mounted over the entry point. Multiple MRIs are taken to establish the desired trajectory. After confirmation of the entry site, a stab incision was made at the planned entry site and a 3.4-mm burr hole was made, followed by durotomy and corticectomy. An MRI-compatible Ad-Tech needle (Ad-Tech Medical) was measured to target depth and advanced to the target. Biopsies were then performed through this needle. The needle was removed, and the Prism® laser probe was inserted to the target point. Thermal ablation was performed under near-real-time MR thermometry. The ClearPoint Maestro® software (ClearPoint Neuro) calculates the distance between the target and the intersection of the device axis with the target plane as the radial error (Figure 2A). This radial error was collected for each trajectory (Figure 2B). Postablation MR images were uploaded into ClearPoint software. Subcortical structures were automatically segmented using ClearPoint Maestro® (**Supplemental Digital Content 1, Figure 1A**, http://links.lww.com/NS9/A11). All procedures were conducted by the senior author, who specializes in neurosurgical oncology. Procedures were performed at a major academic institution in the United States that serves as a quaternary referral center for a multistate catchment area. Patients were admitted to the Neurosurgical Intensive Care Unit after the procedure and were monitored in-house for at least 24 hours.

Procedural Time and Statistical Analysis

The stereotaxis time was defined as the time elapsed during the optimization of stereotactic trajectory. The procedural time was defined as the time required for the needle biopsy and the LITT. LITT was performed only after the frozen pathology became available. Statistical analysis was performed using the Student's *t*-test using R version 3.3.2.[22]

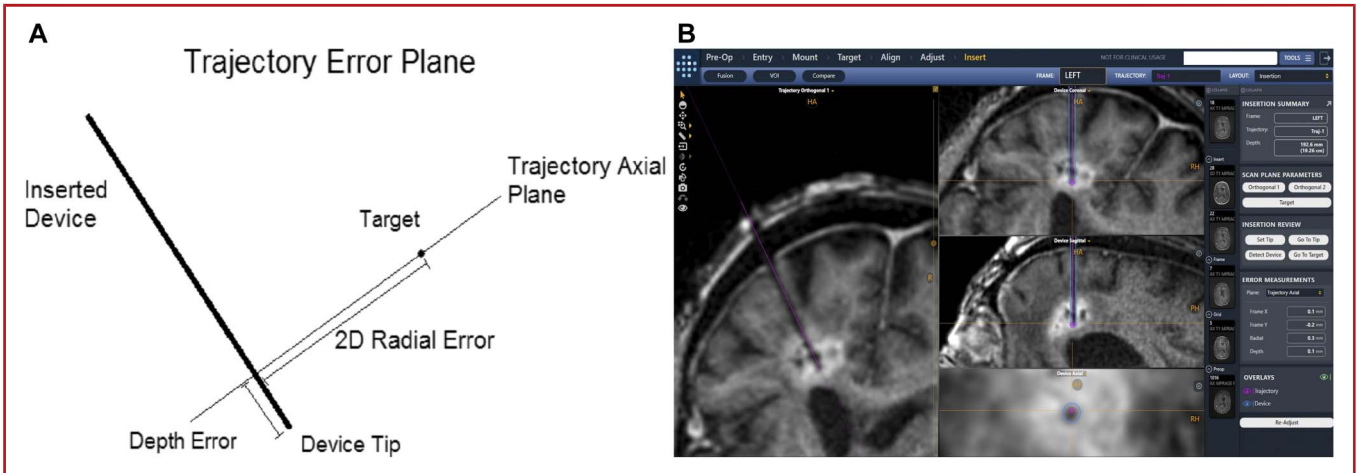

FIGURE 2. *Determination of radial error.* **A**, *The ClearPoint software calculates radial error as the distance between the target and the intersection of the device axis with the target plane.* **B**, *Illustrative example of radial error calculation. Pink: planned trajectory; blue overlaid on the signal void, corresponding to the location of the probe. The two-dimensional radial error was calculated to be 0.3 mm.*

TABLE 1. Patient Demographics

Patient	Age (y)	Sex	Laterality	Location	Diagnosis	Trajectory	Approach
1	53	Male	Right	Insular	Glioblastoma	One	Frontal-insular
2	67	Female	Right	Thalamus	Melanoma recurrence	One	Frontal-thalamic
3	55	Female	Right	Frontal	Radiation necrosis	One	Frontal

RESULTS

Study Population

Basic patient demographics are shown in Table 1. The median age of the patients was 55 (range: 53-67) years. Two patients were female, and one patient was male. All patients underwent a single trajectory biopsy followed by LITT. The radial error of stereotaxis (the distance between actual device trajectory and planned target axis) ranged from 0.8 to 1.6 mm (with a median of 1.0 mm) (Table 2). Definitive diagnosis was achieved in all cases. The clinical histories of the study subjects are described below.

Case 1

A 54-year-old man presented with Isocitrate Dehydrogenase wild-type (Methyl-Guanine Methyl Transferase) promoter–methylated glioblastoma diagnosed 3 years before presentation. He was found to have a progressive enlarging, irregularly shaped contrast-enhancing lesion in the right insula. The patient underwent a biopsy and LITT of this lesion through a frontal-insular approach (Figure 3A), with pathology demonstrating active tumor growth. Eighty-five percent of the lesion was ablated (Figure 3B and 3C, **Supplemental Digital Content 1, Figures 1A and 1B**, http://links.lww.com/NS9/A11). At a 6-month follow-up, local control was maintained (Figure 3D); however, the patient unfortunately suffered multifocal progression thereafter.

Case 2

A 67-year-old woman presented with stage IV melanoma with progressive enlargement of a right thalamic brain metastasis 10 months after radiosurgery. The patient underwent a biopsy and LITT of this lesion through a Kocher point approach (Figure 4A), with pathology demonstrating active tumor growth. Because of the morphology of the lesion, a single pullback followed by a second ablation was required for achieving 100% coverage of the target lesion (Figure 4B and 4C, **Supplemental Digital Content 1, Figure 1C** [http://links.lww.com/NS9/A11]). The patient subsequently underwent consolidation radiosurgery treatment of this right thalamic lesion. At a 6-month follow-up, local control was maintained (Figure 4D) and the systemic cancer of this patient continues to be controlled on immunotherapy.

Case 3

A 55-year-old woman presented with stage IV esophageal cancer with progressive enlargement of a right frontal contrast-enhancing area 25 months after involved field radiation therapy. The patient underwent a biopsy and LITT of this lesion (Figure 5A), with pathology demonstrating radiation necrosis. The entirety of the lesion was ablated (Figure 5B and 5C, **Supplemental Digital Content 1, Figure 1D** [http://links.lww.com/NS9/A11]). At the 6-month follow-up, complete resolution of the contrast enhancement was observed (Figure 5D) and the patient continues to be well, off any systemic therapy.

Procedural Time

The average stereotaxis time (time required to establish the trajectories) was 98.7 ± 16.6 minutes, and the average procedural time (time required for biopsy and LITT) was 110 ± 19.3 minutes (Table 2). These times are not statistically different from our published results for comparable procedures using other available LITT systems (150 ± 40.4 minutes and 111.5 ± 16.5 minutes, respectively).[19] Of note, the procedural time included time

TABLE 2. Procedural Specifications

Patient	Radial error (mm)	Stereotaxis time (min)	Procedural time (min)	Laser time (s)	Laser window	LITT maximal radius (mm)
1	1.5	97	118	133	Diffuser 15 mm	15.5 × 22.7
2	0.8	83	88	29[a], 69	Diffuser 15 mm	9.5 × 12.5[a]; 15 × 11.5
3	1.6	116	124	49	Radial 1 mm	9.5 × 10

LITT, laser interstitial thermal therapy.
[a]Two ablations were performed, with an 8-mm pull back between the 2 ablations.

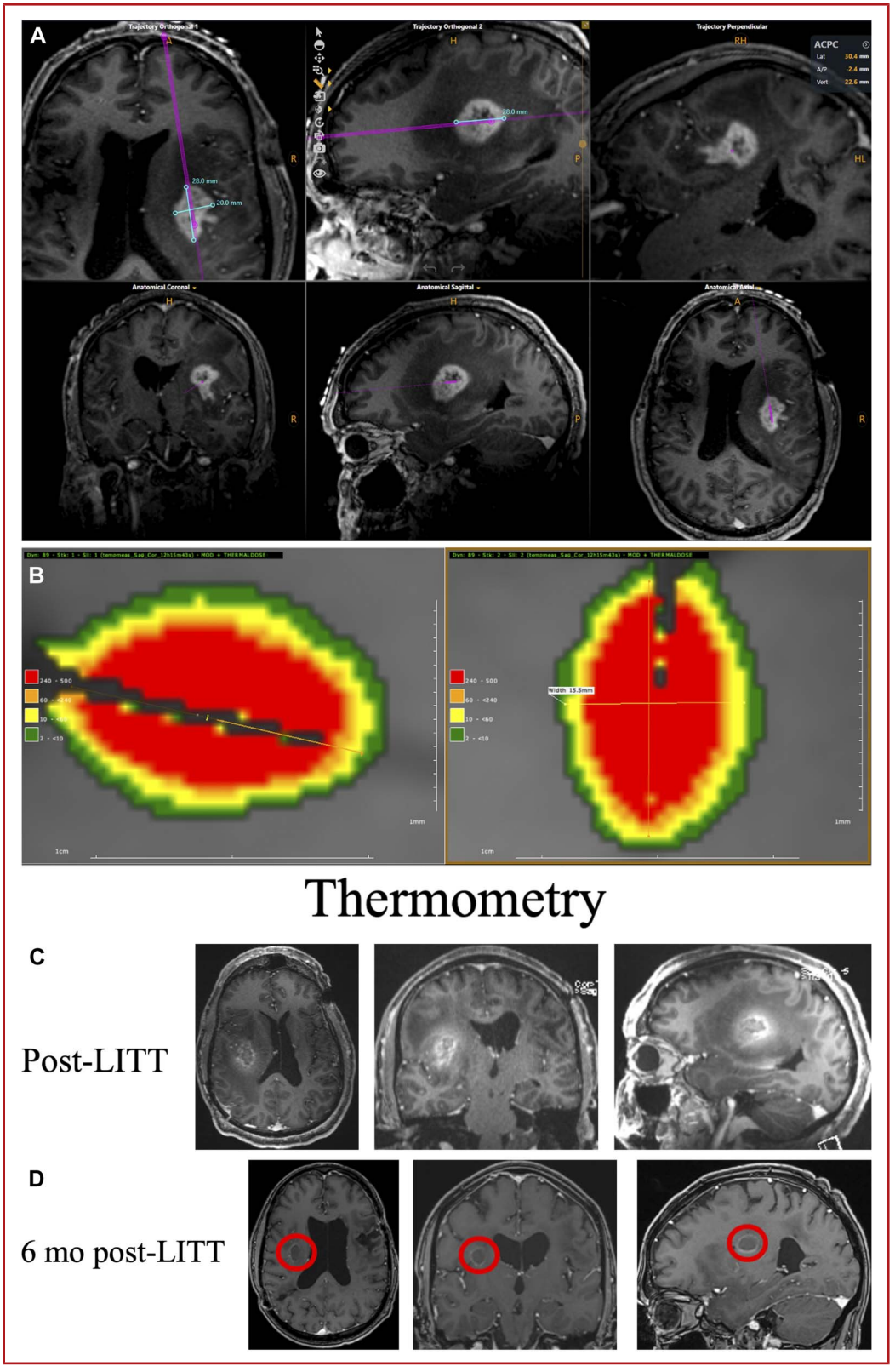
A
Trajectory Orthogonal 1
Trajectory Orthogonal 2
Trajectory Perpendicular
ACPC
Anatomical Coronal
Anatomical Sagittal
Anatomical Axial
B
Thermometry
C
Post-LITT
D
6 mo post-LITT

FIGURE 3. *A 53-year-old man with a 3-year history of glioblastoma (IDHwt, MGMTm) who was found to have a new, progressively enlarging lesion in the right insular cortex.* **A**, *Multiplanar postcontrast MRI images (T1 with gadolinium) demonstrating stereotactic localization and right frontal-insular approach to the target lesion. From right to left, top row: axial, sagittal, sagittal images; The top row shows the planned trajectory superimposed onto the anatomic images (purple). The blue lines indicate the dimensions of the contrast enhancement.* **B**, *Intraoperative thermometry with the 15-mm diffuser probe. The ablation cavity measured 15.5 × 22.7 mm, encompassing 100% of the target lesion. See Figure 1D for the color code in thermometric assessment.* **C**, *Immediate, postoperative axial, coronal, and sagittal MRI images (T1 with gadolinium) demonstrating expected ablation cavity.* **D**, *Six months postoperative postcontrast axial, coronal, and sagittal MR images (T1 with gadolinium). LITT, laser interstitial thermal therapy.*

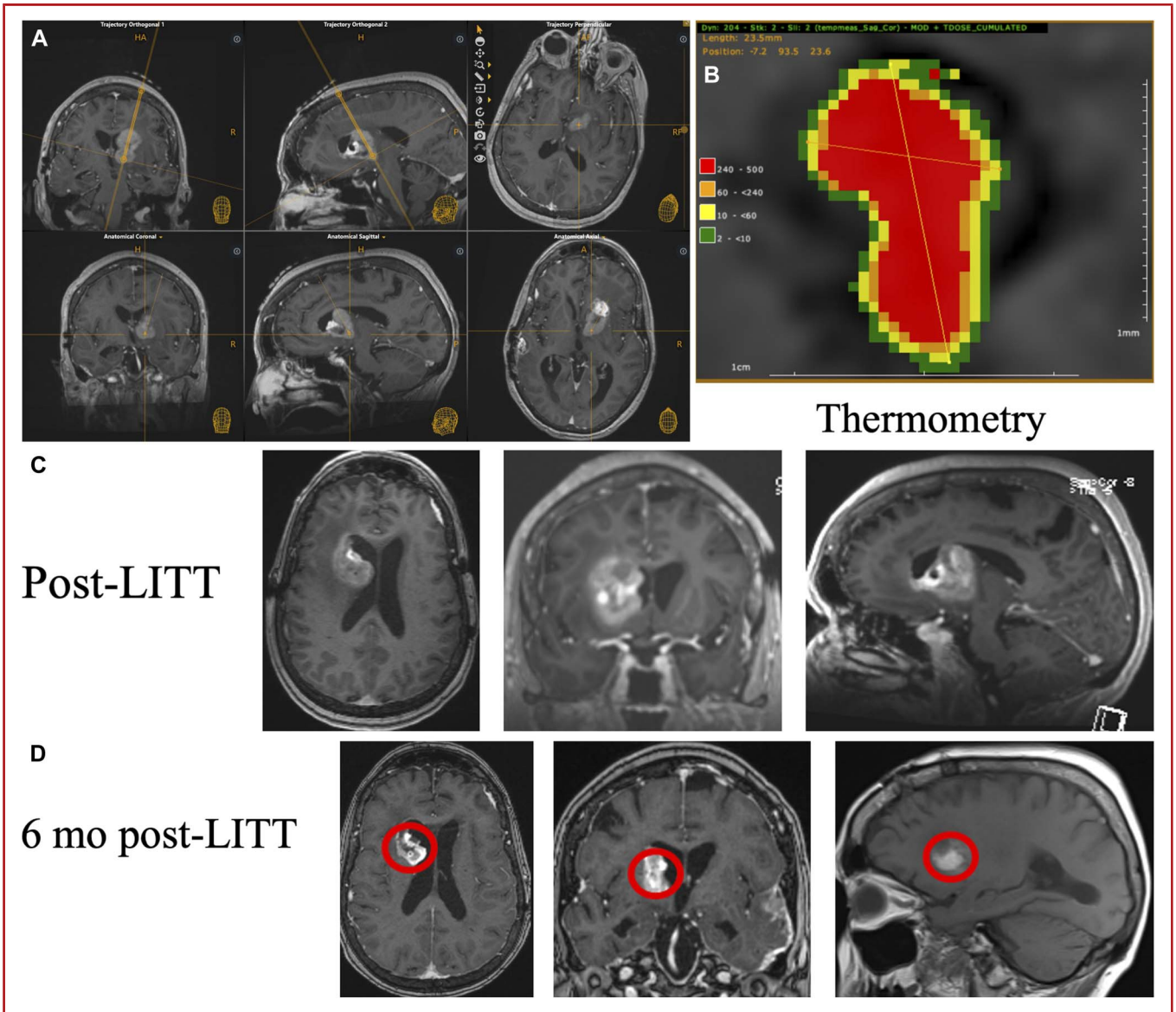

FIGURE 4. *A 67-year-old woman with a history of stage IV melanoma who was found to have progressive growth of a right thalamic lesion 10 months after radiosurgery.* **A**, *Multiplanar postcontrast MRI images (T1 with gadolinium) demonstrating stereotactic localization and right frontal-insular approach to the target lesion. From right to left, top row: axial, sagittal, sagittal images; the top row shows the planned trajectory superimposed onto the anatomic images (orange).* **B**, *Intraoperative thermometry with the 15-mm diffuser probe. Two ablations were performed in 2 serial depths. The ablation cavities measured 9.5 × 12.5 and 15 × 11.5 mm, encompassing 100% of the target lesion. See Figure 1D for thermometric assessment.* **C**, *Immediate, postoperative axial, coronal, and sagittal MRI images (T1 with gadolinium) demonstrating expected ablation cavity.* **D**, *Six months postoperative postcontrast axial, coronal, and sagittal MR images (T1 with gadolinium). LITT, laser interstitial thermal therapy.*

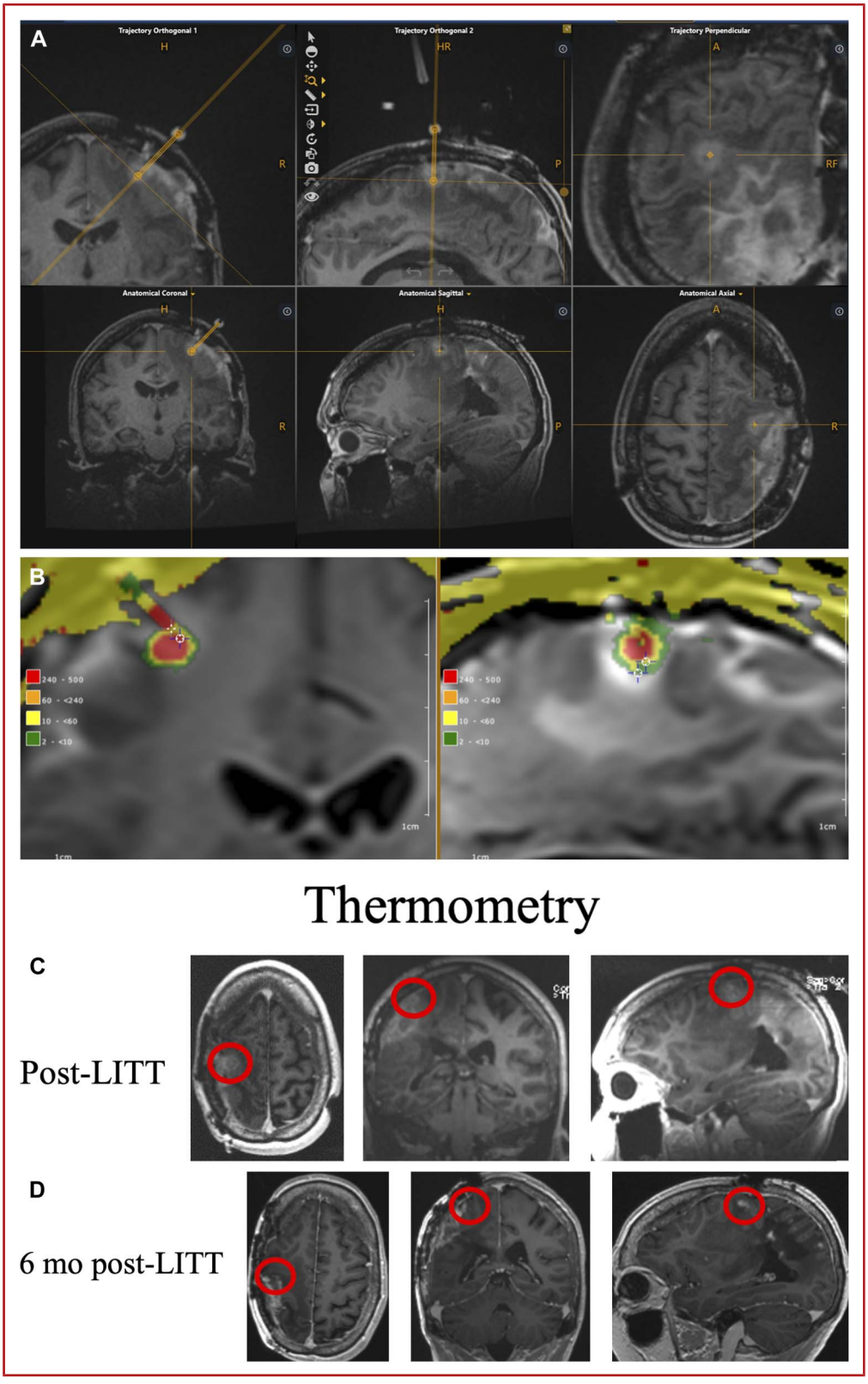
A
Trajectory Orthogonal 1
Trajectory Orthogonal 2
Trajectory Perpendicular
Anatomical Coronal
Anatomical Sagittal
Anatomical Axial
B
240 - 500
60 - <240
10 - <60
2 - <10
1cm
Thermometry
C
Post-LITT
D
6 mo post-LITT

FIGURE 5. *A 55-year-old woman with stage IV esophageal cancer with progressive enlargement of a right frontal contrast-enhancing area 25 months after involved field radiation therapy.* **A**, *Multiplanar postcontrast MRI images (T1 with gadolinium) demonstrating stereotactic localization and right frontal-insular approach to the target lesion. From right to left, top row: axial, sagittal, sagittal images; The top row shows the planned trajectory superimposed onto the anatomic images (orange).* **B**, *Intraoperative thermometry with the 1-mm radial probe. The ablation cavity measured 9.5 × 10 mm, encompassing 100% of the target lesion. See Figure 1D for thermometric assessment.* **C**, *Immediate, postoperative axial, coronal, and sagittal MRI images (T1 with gadolinium) demonstrating expected ablation cavity.* **D**, *Six months postoperative postcontrast axial, coronal, and sagittal MR images (T1 with gadolinium). LITT, laser interstitial thermal therapy.*

awaiting the result of the frozen pathology findings. For the Prism® laser probe, the average LITT time required to achieve ablation of >1 cm radius was 49 seconds (range: 29-133 seconds). As we had not previously recorded such LITT time for other laser ablation systems, quantitative comparisons between ablation systems are not possible at this time.

Clinical Outcome

Periprocedurally, there were no changes in neurological examination. There were no procedural complications. Two patients were discharged home on postoperative day 1, and 1 was discharged on postoperative day 3. Postoperative MRIs showed expected ablation findings consistent with intraoperative thermometric assessment for all patients (Figures 3-5). With a median follow-up of 219 days (range: 185-259 days), durable local control and expected resolution of radiation necrosis were observed on the 6-month follow-up MRIs (Figures 3-5). There were no 30-day readmissions, 90-day emergency department presentations, or wound complications (Table 3).

DISCUSSION

The ClearPoint Prism® laser probe harbors design specifications representing technical advances over current laser systems, including elimination of need for a cooling system, shorter delay in thermometric assessment, ablation window of up to 25 mm in length (Figure 1B), higher spatial resolution, and a design that affords improved integration with an MRI-compatible stereotaxis system (ClearPoint SmartFrame®, ClearPoint Neuro), leading to ease in transition between navigation and biopsy/LITT therapy. We were cautious in evaluating this system, with planned treatment of the first 3 patients treated under the Institutional Review Board and at the 6-month follow-up before consideration for adoption. In this article, we share our experience. We found the procedural and the safety profile of the Prism® system reassuring, no technical or clinical complications. A radial error of <2 mm was achieved in the accuracy of stereotaxis (Table 2). Postoperative MRIs showed expected ablation findings consistent with the thermometric assessment.

For these three Prism® procedures, the time required to achieve the intended trajectories (98.7 ± 16.6 minutes) was not significantly different from those we had previously published for MRI-ClearPoint®–guided needle biopsies,[15] highlighting the design integration between the laser ablation system and the stereotactic system. The postoperative MRI of all 3 patients exhibited expected MR changes in the regions corresponding to the areas of anticipated ablation based on the MR thermometry, suggesting validity of the thermometry. The shortened delay in thermometry from 8 seconds to 3 seconds should in principle enhance the safety of the LITT procedure. Excluding the third case involving a region characterized by pathology findings consistent with radiation necrosis, the times required for achieving an ablation of >1 cm radius in regions infested with tumor were 29, 69, and 133 seconds. This is, in the senior author's experience, shorter than that typically required to achieve a similar tumor ablation using Visualase or NeuroBlate. If the probe design affords enhanced heat convection efficiency, the Prism® probe could potentially expand the window of ablation, especially with the 25-mm probe.

Pertaining to thermometry, Thermoguide allows for the creation of points of interest (a.k.a. temperature points), at which

TABLE 3. Outcomes

Patient	Follow-up (d)[a]	Hospital stay (d)	Morbidity/ mortality	Clinical condition	30-day readmission	90-day ED presentation	Wound complication
1	259	1	None	Stable	None	None	None
2	219	3	None	Stable	None	None	None
3	185	1	None	Stable	None	None	None

ED, emergency department.
[a]Follow-up duration measured from time of the laser ablation.

temperature can be measured, similar to that available for Visualase or Monteris. In addition, Thermoguide allows free-form creation of regions of interest in which the average temperature can be measured (a.k.a. temperature regions). These regions of interest can be contoured to the patient's tumor and the surrounding anatomy. These temperature points/regions are used to monitor temperature, or they can be used to control the laser unit as a "temperature guard." Thermoguide additionally requires 1 High-Temp Guard (85-90°C) to be placed near the center of the laser applicator window. Finally, the shorter delays in Thermoguide thermometry allow the treating neurosurgeon to make decisions in a less time-delayed manner. The combination of these features, in principle, allows the treating surgeon to monitor thermal propagation in near real-time and adjust surgical decisions accordingly.

There are several options in multitrajectory procedures. There are 2 ClearPoint stereotaxis frames available currently—XG and Array. With the XG frame (ClearPoint Neuro), the surgeon can modify the angle and/or entry point without having to remount the frame itself and achieve multiple trajectories. The frame allows for ±3 mm to change the entry point in the X or Y direction. With the Array frame (ClearPoint Neuro), the surgeon has an option to select from 7 channels (one center and six around the circumference), each 3 mm apart. The user can select different channels for different trajectories. In addition, the surgeon also has the option of mounting multiple SmartFrames, as long as the entry points are far enough to accommodate the footprint of the SmartFrame. Alternatively, the user can remove and remount the stereotactic frame at a different entry point if needed. In z-axis trajectory adjustment (ie the depth of the inserted probe), manual adjustment is currently required. The laser fiber has markings every 1 cm along its entire length. In addition, 5-mm depth stops are provided. These features allow the surgeon to accurately retract the laser probe. Robotic advancement of the probe in the Z-axis is currently under development for the Prism.

CONCLUSION

In conclusion, the ClearPoint Prism® laser probe provides technical advances over other currently available laser systems while also providing a reassuring safety profile in our initial experience. As a pilot safety study, the conclusion of this study is therefore limited in scope. The goal of our study was to introduce the field to the design rationale for the Prism system, theoretical considerations for its merits relative to other existing systems, and to share our initial experience—with a greater than 6-month follow-up. Future studies are needed to definitively establish the relative merits of the Prism system relative to the existing platforms. The safety profile and ease of ablation, in our opinion, are sufficient to warrant these future investigations.

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Disclosures

Clark C. Chen is a consultant for ClearPoint Neuro. The other authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

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Supplemental Digital Content 1. Figure 1. Segmentation of the ablation volume relative to the tumor volume. **(A)** Automatic segmentation of subcortical structures for patient 1 using ClearPoint Maestro®. **(B)** Segmentation of the target tumor volume (white) and ablation cavity (red) for patient 1. **(C)** Segmentation of the target tumor volume (white) and ablation cavity (red) for patient 2. **(D)** Segmentation of the target tumor volume (white) and ablation cavity (red) for patient 3. 85%, 100%, and 100% coverages of the contrast-enhancing target lesion were achieved for patients 1, 2, and 3, respectively.