Tumor Ablation Treatment Planning Coupled to Robotic Implementation: A Feasibility Study

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The technical development described herein was undertaken to create a tumor ablation treatment system that consists of a software component and a robotic hardware component. First, the software treatment planning system enables applicator placement planning before tumor ablation. For example, it allows creation of overlapping ablations with the goal of treating larger tumors. Second, the robotic hardware system allows accurate applicator placement. The combined treatment system integrates treatment planning with treatment execution by taking the coordinates dictated by the planning system and feeding them to the robotic system for implementation. The feasibility of this system was tested in two patients with large hepatic metastases that required overlapping ablations.

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Abbreviation: RF = radiofrequency

THERMAL ablation of tumors is gaining clinical acceptance as a therapeutic option in patients with a variety of tumors who are not candidates for surgical resection (1–3). However, despite good initial results, challenges still exist. Two such challenges in the achievement of better outcomes are the treatment of intermediate and large tumors and the achievement of accurate and reproducible applicator placement.

The challenge of treating intermediate and large tumors has repeatedly been shown as a predictor of treatment failure. Five-year survival rates for patients with hepatoma treated with radiofrequency (RF) ablation have been reported at 84% in tumors 2 cm or smaller, whereas a 5-year survival rate of only 34% was reported in tumors greater than 5 cm in size (4).

One method for the creation of larger, more complete zones of ablation is to use multiple, overlapping ablations. This requires multiple, precise applicator placements such that the ablation zones overlap. Currently, this is being practiced freehand, and therefore the procedure varies from operator to operator. Dodd et al (5) performed computer modeling that showed the high precision required to create overlapping ablations. They also acknowledged how seldom this rigorous, mathematically based approach is practiced.

Another limitation to widespread community use of percutaneous, image-guided thermal ablation has been the operator dependence of the technique. Good results are dependent on precise and accurate placement of the ablation applicator. This is especially true when overlapping ablations are required.

Robots have been applied in surgery to precisely control instruments and reduce the variations among operators. More recently, they have been applied to real-time, percutaneous, image-guided interventions such as fluoroscopically guided nephrostomy tube placement and computed tomography (CT)–guided biopsy and thermal ablation (6,7).

In the current report, a system was implemented that permitted treatment planning before overlapping tumor ablations followed by robotic assistance in applicator placement at the prescribed treatment planning coordinates.

MATERIALS AND METHODS

Treatment Planning Software

Customized software was developed that enables the user to overlay the predicted zones of ablation from two commercially available RF ablation applicators on CT images of a patient's tumor. These planning CT images are acquired while the patient is on the table for the procedure. Conversely, if images obtained earlier were to be used, these images would have to be registered with the patient's current table position, which was not performed in the current study. Two LeVeen needle electrodes (Boston Scientific, Natick, MA; diameters of 3.5 cm and 4.0 cm) were the first two applicators incorporated into the software. The ablation zones were pro-

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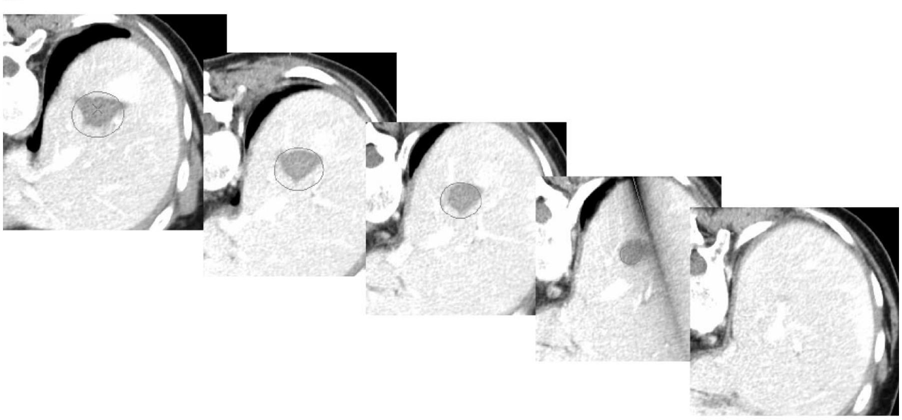
a.



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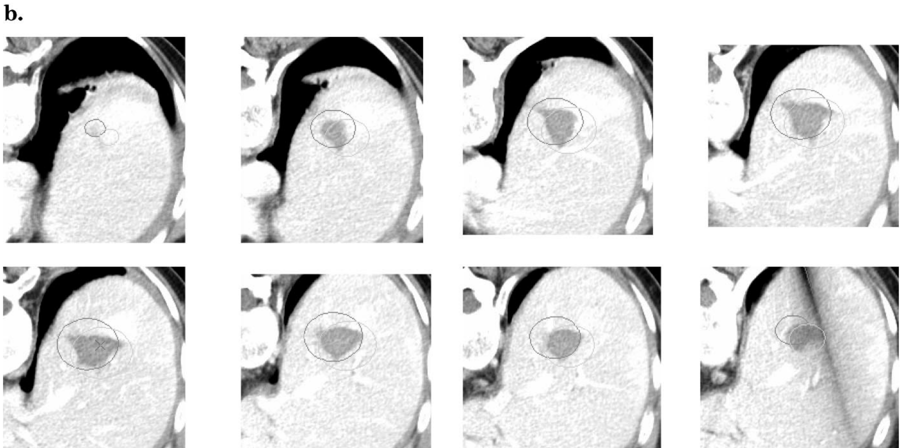

c.

Figure 1. **(a)** The treatment planning system interface allows the user to select from a palette of potential ablation zones. The user indicates the position of the applicator at the skin surface and the location of the destination for the applicator tip. This information is ultimately provided to the robot for implementation. **(b)** Preplanning software allows testing of the expected ablation ellipsoid area against the target tumor and shows the three-dimensional nature of the expected ablation volume. In this case, a single ablation procedure would not adequately cover the entire tumor. **(c)** Preplanning software shows the improved tumor coverage with two overlapping ellipsoid ablation areas.

vided by the manufacturer and were assumed to be ellipsoid with diameters of 3.0 cm × 3.5 cm × 3.5 cm for the 3.5-cm applicator and 3.5 cm × 4.0 cm × 4.0 cm for the 4.0-cm applicator. The user manually centers the ellipsoid area on the tumor seen on the CT image and then places additional overlapping ablation zones to create an appropriate margin of safety that avoids damaging critical structures while maintaining a margin beyond the tumor edge that includes normal tissue (**Fig 1**). The user can page through the multiple slices and observe the ablation coverage in three dimensions. When the user is satisfied with the ablation zone positions, the coordinates of each spheroid shape are transferred to the robotic system for appropriate applicator positioning.

Robotic System

The surgical robot, called AcuBot, presents a bridgelike structure comprising an XYZ cartesian stage and a robotic module connected through a passive arm with six degrees of freedom (8). The Remote Center of Motion module is capable of precisely orienting an instrument (ie, needle) around a fixed point distal to the mechanism.

The Percutaneous Access to the Kidney device is a needle driver originally designed for kidney applications that allows a needle to be inserted after alignment with the target. The instrument is loaded initially with its point at the fulcrum. The Percutaneous Access to the Kidney/Remote Center of Motion assembly is initially positioned with use of the passive arm

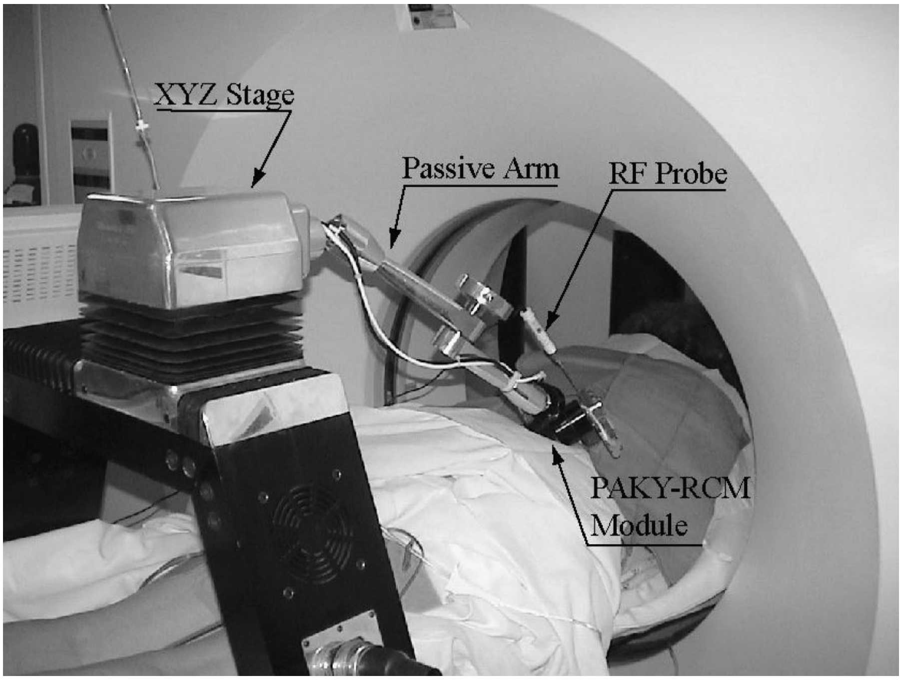

Figure 2. The robot is mounted on the CT table. The robot has an XYZ stage that can move in three dimensions. The passive arm is placed with the needle tip in the skin entry site. The Percutaneous Access to the Kidney/Remote Center of Motion module allows the RF applicator to move about the skin entry site to the correct trajectory as determined by the planning program.

such that the fulcrum is close to the desired entry point. The XYZ Cartesian stage can be used for small adjustments in the initial robot positioning until the point of the needle is at the skin entry site. This allows the robot to be positioned in close proximity to the target and provides the necessary stabilization for accurate needle advancement into the liver parenchyma.

The needle driver, which is radiolucent and can be rendered sterile, is used to guide and actively advance a needle or RF applicator in percutaneous procedures. In the needle driver, the needle is tightly held near the skin, and a rolling dowel mechanism is used to create a friction transmission system that allows needle advancement. The current design of the needle drive occasionally results in stripping of the insulation when used with RF applicators. As such, in this study, the RF applicator was manually advanced at a predetermined distance as calculated by the robotic planning system after the applicator was maneuvered by the robot to the correct insertion angle. The applicator was secured by the needle driver along its barrel near the tip to minimize deflection or bowing of the unsupported length of the needle during passage through various tissue planes.

The user interface includes an LCD mounted on the bridge adapter together with a joystick and an emergency stop button. The manipulator is controlled with an industrial PC fitted with a PCX-DSP card (Motion Engineering, Santa Barbara, CA). The manipulator can be attached to a CT table or an operating room table with special adapters (**Fig 2**).

When the accepted coordinates are transferred from the treatment planning system to the robot, the robot maneuvers the applicator to the correct insertion angle and indicates the required depth necessary to meet the treatment plan. The aim of the needle positioning is to place the ellipsoid area at the prescribed coordinates. In the case of the 3.5-cm LeVeen applicator, for example, the tip would be 1.9 cm from the deep portion of the ellipsoid area to account for the typical ablation zone carrying further forward than just the needle tip's location. When the ablation is complete, the applicator can be withdrawn and reinserted according to the overlapping ablation treatment plan.

Registration

Robotic registration of the image space with the physical space is performed with use of the laser light that is incorporated in the slice-selection component of all CT scanners. The mechanical arm with the sterilized needle holder is manually placed so the tip of the RF applicator is in the skin incision site. The applicator shaft is moved to reflect the CT laser light, and this point is noted on the computer. A second position with the applicator tip still in the entry site is then selected. This second position is selected to also reflect the laser light along the applicator shaft and was also noted to the computer. Therefore, the two applicator positions that reflect the laser light are used to identify a plane for image registration. The third coordinate comes from the position of the CT scanner table.

Target Selection

Next, a single-breath-hold image is obtained that shows the tip of the applicator at the skin. The breath-hold is performed as a suspension of quiet breathing rather than a deep inspiration or expiration. Because only a single image is required, suspension of breathing is not very long. The image is transferred to the computer workstation. With the computer mouse, the physician indicates the tip of the needle and the shaft. Then, the overlapping ablation spheroids that were selected with the treatment planning software are indicated to the computer. These spheroids dictate the destination coordinates of the RF applicator tip.

Needle Insertion

The robot maneuvers the RF applicator to the ideal insertion angle to reach the target coordinates while the applicator tip remains fixed at the skin entry site. The computer indicates the necessary distance to reach the target, and the applicator is manually inserted to the specified depth based on markers on the applicator. The insertion is performed with use of the same breath-suspension technique used during the image acquisition for targeting. The needle is observed during advancement by CT fluoroscopy to guarantee appropriate targeting during suspended respiration.

Patients

Proof of principle was confirmed with two patients with hepatic lesions larger than 3.0 cm that required overlapping ablations. Informed consent was obtained. The study was performed with institutional review board approval and in compliance with the Health Insurance Portability and Accountability Act. The first patient was a 69-year-old woman with metastatic esophageal cancer. She had a new solitary hepatic metastasis that measured 3.7 cm × 3.2 cm × 4.5 cm after an earlier scan was negative for liver metastasis. The second patient was a 60-year-old woman with metastatic renal-cell carcinoma and a biopsy-proven liver metastasis measuring 3.1 cm × 2.6 cm × 3.5 cm. Both patients were treated under conscious sedation with fentanyl and midazolam administered intravenously and titrated to achieve pain relief. No postprocedural analgesic treatment was necessary. Both patients were discharged the same day the procedure was performed.

RESULTS

Two patients with metastatic hepatic malignancies larger than 3.0 cm were included in this feasibility study. The treatment planning system was used to develop an overlapping ablation treatment plan, which was then implemented by a single physician, with two overlapping ablation zones for each patient performed. In both cases, the overlapping ablations could be performed through the same skin entry site. In each patient, both applicator positions were used with a single pass, even though intermittent imaging was performed with incremental advancement as a safety precaution. Setup time for the robot was approximately 7 minutes, and procedure time was approximately 50 minutes from the time the patient was ready until the time the applicator was removed. The planning phase of ablation zone prescription added approximately 10 minutes to the procedure. Contrast material–enhanced spiral CT images after ablation showed the expected overlapping ablation zones that subjectively appeared to match the prescribed plan. In both cases, ablation zones were larger than the original tumors: the respective measurements in one patient were 3.7 cm × 3.2 cm × 4.5 cm and 4.2 cm × 3.5 cm × 5.0 cm, and those in the other patient were 3.1 cm × 2.6 cm × 3.5 cm and 3.5 cm × 3.5 cm × 4.0 cm. No evidence of local recurrence (ie, nodularity or foci of contrast enhancement) was apparent on CT images at 6 months after treatment.

DISCUSSION

Although percutaneous tumor ablation has shown great promise, several challenges still exist. Two such challenges are treatment of intermediate and large tumors (>3.0 cm in diameter) and accurate applicator placement. The development described herein aimed to meet these two challenges by using overlapping ablations to create larger ablations and by using robotic control to permit accurate applicator placement for the overlapping plan. The current study demonstrated the use of a treatment planning system and its implementation via a robotic device.

Given the desire to improve outcomes in cases of large tumors, several approaches have been taken. These efforts have included (i) reducing the "heat-sink" effect by reducing the interference of incoming "cool" blood in the heating process (ie, the Pringle maneuver or temporary vascular occlusion balloon), (ii) combined therapy with arterial embolization, and (iii) improved electrode design (eg, saline solution injection, bipolar electrodes, multiple electrodes, or pulsed electrodes) (9–13). Some of these techniques have been helpful, but the challenge of treating larger tumors still exists.

One method for the creation of larger ablation areas is to perform multiple overlapping ablations. Khajanchee et al (14) studied the geometric requirements for ideal overlapping ablation zones and concluded that the challenge of creating overlapping ablations is not trivial and that a nonintuitively large number of ablations are required to optimize the overlapping ablation. Chen et al (15) then applied a polyhedron mathematical model for the performance of overlapping ablations in 121 liver tumors, with improved results compared with similar nonsimulated patients. Butz et al (16) similarly showed the value of simulation planning in the performance of ablation. However, although all these groups showed the importance of simulation and planning ablation, none applied the precision of planning to the actual procedure. In each of these cases, the ablation applicator placement was still performed manually. The purpose of the current study was to integrate the ablation simulation with the applicator placement by using the coordinates determined during the simulation to dictate the robotic placement of the applicator.

Although treatment planning systems are universally used in radiation therapy systems, such systems are not generally used in thermal therapy. The current feasibility system still uses manual decision-making in overlapping ablations, but it makes sense that future software improvements would use computer models to determine the ideal overlapping ablation plan. Similarly, these models could be made more complex by accounting for nearby vascular heat-sinks or critical structures to avoid.

The fact that the overlapping ablations in these two patients created ablation zones that were only barely larger than the lesions and did not match the manufacturer's expectations of ablation size probably most likely reflects the impact of the heat-sink effect on the actual ablation size. This highlights the need for a better understanding of the physiology affecting ablation size and how different tissues and different locations will lead to different outcomes. Ultimately, this understanding could be integrated into a much more sophisticated treatment planning system.

A current challenge of the manual performance of overlapping ablations is that there are few reliable imaging cues of where the first ablation was performed that can guide applicator placement for the second overlapping ablation. Robots may be particularly helpful in solving this problem. Because the robotic system described herein is based on coordinates, improved positioning for overlapping ablations should be obtainable despite the lack of visual cues of previous ablation zones.

The limitations of the current work include its lack of error validation between the applicator placement and the predicted overlapping plan. Larger patient numbers are needed to verify the utility of the current engineering development. Additionally, the lack of respiratory motion compensation may lead to inaccuracy in ablation zone overlapping. The present study involved attempted placement of the applicators during the same stage of the respiratory cycle as the initial images. However, improved respiratory tracking methods may improve the outcomes.

The current feasibility study shows the coupling of a treatment planning system and a robotic applicator positioning system to address two of the major challenges of tumor ablation. The use of overlapping ablations may improve the results of thermal ablation of larger tumors. The use of robotics may improve delivery of the lethal thermal therapy. The current system describes a method for the precise creation and delivery of overlapping ablations. Percutaneous tumor ablation began as a simple single-applicator, single-ablation technique, and there is now a need to advance to more sophisticated and complex planning and delivery systems. The current system describes an initial step in that direction.

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