Devices and Equipment in Interventional Oncology and Their Operation

11

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Abstract

This chapter focuses on ablation devices, equipment, and their operation. It exhibits less the principles of ablation than it does with the principal features of the technologies that are employed by the physician-user. These features include the device's "applicator" (or probe) and the user interface. Applicator is a general term given to that element of the overall system that delivers the therapeutic agent to the tumor. The user interface is that with which the physician interacts to control the system to govern the treatment and to monitor the ablation based on feedback from the display.

Ablation can be divided into two main categories: (a) thermal and (b) nonthermal. Thermal ablation is a general term referring to a focal treatment involving an energy exchange with tissue that results in raising or lowering the temperature of the target. Various physical agents can be used as pyrogens and cryogens. Nonthermal ablation involves neither heating nor freezing. Nonthermal approaches include chemical ablation via intratumoral injection, intravenously injected drug-based ablation, and high-voltage electroporation.

Introduction

This chapter focuses on ablation devices, equipment, and their operation. It exhibits less the principles of ablation than it does with the principal features of the technologies that are employed by the physician-user. Throughout the chapter, these features include (a) the applicator and (b) the user interface. (a) Here, applicator (also "probe") is a general term given to that element of the overall system that delivers the therapeutic agent to the tumor. Typically, the applicator is a tool manipulated by the physician and thus navigated through tissues by hand – placing the applicator's active element within the tumor. Of course, tumor identification and instrument navigation are usually performed under some noninvasive imaging modality (US, CT, PET/CT, MRI). (b) The user interface is typically the front panel/display of an electrically powered medical system; overall, the system governs the output of the therapeutic agent to the applicator. The physician interacts with the

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user interface to control the system further (setting/adjusting parameters or activating treatment) and to monitor the ablation based on feedback from the display. The limited feedback from the user interface is often complemented by intraprocedural radiologic images.

Ablation can be divided into two main categories: (a) thermal and (b) nonthermal. (a) Thermal ablation is a general term referring to a focal treatment involving an energy exchange with tissue that results in raising or lowering the temperature of the target. Various physical agents are used as pyrogens for heating tissues; these include electrical current (radiofrequency alternating current (AC)), electromagnetic (EM) radiation (laser light or microwaves), and mechanical waves (high-intensity ultrasound). Contemporary cryoablation devices use high-pressure gas as a cryogen to freeze tissues. The tip of the ablation applicator acts as a heat source to heat or heat sink to freeze; this creates extreme focal temperatures so that cytodestructive temperatures are achieved at a distance from the tip, thus treating a volume of tissue. Generally, a therapeutic effect (tissue destruction) is achieved at or above +60 °C (pyroablation) and at or below −40 °C (cryoablation). (b) Nonthermal ablation involves neither heating nor freezing. Nonthermal approaches include chemical ablation via intratumoral injection, intravenously injected drug-based ablation, and high-voltage electroporation.

Thermal Ablation

Radiofrequency Ablation (RFA)

Radiofrequency ac near 450 kHz has long been utilized as a means to heat tissue for ablation. The various clinical RFA systems involve an electrical circuit that includes a patient's tissues; an RF generator is wired to the RF applicator ("active" electrode) placed within the tumor. A high current density is established within millimeters of this electrode causing ionic agitation and resistive heating. This heat conducts to adjacent tissue creating a volume of ablation. The electrical circuit is closed by having the patient wired back to the RF generator. This is typically accomplished by placing large conductive "dispersive" electrodes ("grounding pads") on the patient, usually adhered to the patient's thighs; this allows the current to exit through the skin with a low current density as it is distributed over the large area of the pads.

In general, the active electrodes are sharp and rigid enough so as to pass through tissue. They are manufactured in a variety of configurations; the primary geometries are "needle" and "array" type. They are electrically insulated along their shaft up to the distal exposed segment whereby the current passes into the tissue; the length of the exposed segments allows for various sizes of ablation volume. Various overall shaft lengths allow for reaching various depths within the body from an insertion site on the skin.

Covidien Cool-tip RF Ablation System

Longstanding in the field is the Cool-tip RF ablation system (Covidien, Boulder, CO). See Fig. 11.1. The standard electrical generator provides up to 200 W of power and 2 A of current at 480 kHz [1]. The system features needlelike active electrodes that are internally water cooled. Cooling these electrodes (at ∼100 mL/min) allows a higher current density at the exposed tip (thus more heat and larger ablation volumes) and yet prevents the carbonization (charring) of tissues immediately adjacent to the tip which would impede current flow and limit the volume of ablation.

The basic "single" electrode (overall length, 10–25 cm) is a 17-G needle with exposed tips 0.7–3.0 cm long; a given length is selected based on the volume to be ablated. The "cluster" electrode combines three parallel single electrodes (each 2.5-cm tip) in one handle; these share the power, are activated simultaneously, and act synergistically. This concept of multiple electrodes for larger ablation volumes is extended with the Cool-tip Switching Controller, an add-on device that allows the use of up to three separate single electrodes (each with a 3.0-cm tip).

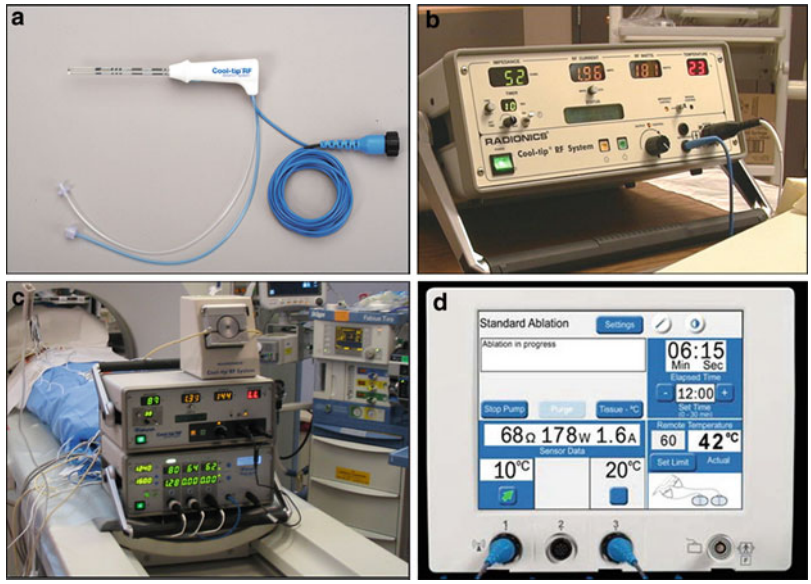

Fig. 11.1 Covidien Cool-tip RF ablation. (**a**) A "cluster" electrode comprised of three individual 17-G electrodes in one handle. *Light blue* and clear tubing provide for flow of coolant to and from electrode tips, respectively. (**b**) Standard Cool-tip generator powers one electrode. Control panel displays time, impedance, current, power, and temperature. (**c**) Standard generator atop switching controller provides power distribution for up to three single RF electrodes for multi-probe RFA. (The peristaltic pump, on top of the standard generator, is for pumping coolant.) (**d**) *Front panel* of the E-Series generator with inherent three-probe capability – connectors (1, 2, 3) seen along *bottom left of panel*. System also displays reading from optional Remote Temperature Probe (here, 42 °C) (Figure parts (**a**) and (**d**) courtesy Covidien, Boulder, CO)

The latter are manually set into tissue at ~1.5-cm distance from each other. Synergy is achieved by cycling full power to each at approximately 30-s intervals.

The Cool-tip RF system can be used in either of two operating modes. Ablation is most often performed in the "impedance control" mode in which the system automatically sets and adjusts the power output. The user selects the duration of the activation (usually 12 min; 16 min for multiple electrodes with the switching controller). The user interface of this system is the front panel of the generator. This offers a set of LED displays that continuously report the tissue impedance (ohms, Ω), current (amps), power (watts, W), elapsed time (minutes), and temperature (C) at the electrode's tip. Notable is that during a typical cooled-tip ablation, the temperature displayed is that of the chilled water. The tissue temperature is evident as the ablation is completed and the coolant flow is stopped. In "manual mode," the user sets the power and duration. This is typically selected when the electrode is purposefully not water cooled, and the user is interested in monitoring and controlling the tip temperature.

A new platform for the Cool-tip is the Covidien E-Series generator (CE cleared; FDA pending) [2]. This system can itself manage up to three individual electrodes. Added feedback features include a button-activated query of tissue temperature during a cooled-tip ablation; current and coolant flow are stopped to allow a read of the tissue temperature from the electrode's thermal sensor. Also, this system supports a separate 20.5-G needlelike Remote Temperature Probe (RTP) to monitor the temperature at the edge of the ablation zone or near a critical structure during ablation – warning the user at some user-defined temperature limit or shutting off the RF power directly. For non-cooled applications and

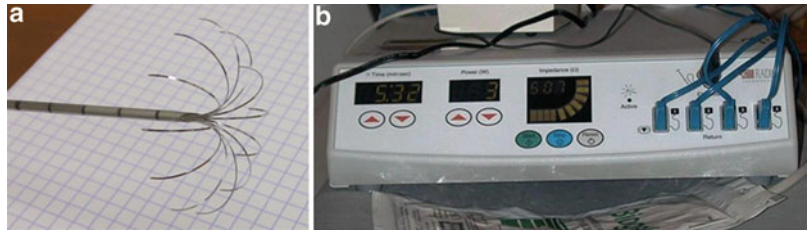

Fig. 11.2 Boston Scientific RF ablation. (**a**) The LeVeen RF electrode is shown with tines deployed forming a 4.0-cm-diameter array. (**b**) RF 3000 generator. From *left to right*, readouts on the front panel show elapsed time, power, and impedance. Rightmost on the panel are the electrical connections for the electrode (*black wire*) and the four grounding pads (*blue*). Time and power are set by the user; however, the display of the tissue impedance provides feedback to the user that serves as the clinical endpoint for the treatment

electrode-track coagulation, the E-Series offers automated self-regulation of electrode temperatures to a user-defined preset value.

Boston Scientific RF 3000 Radiofrequency Ablation System

The RF 3000 (Boston Scientific Corporation, Natick, MA) RFA system provides up to 200 W at 460 kHz. It is historically identified by its array-type LeVeen electrode and its use of tissue impedance as a clinical endpoint [3]. See Fig. 11.2. The electrode is not water cooled. Tissue charring is prevented by the distribution of the current over the multiple tines of the array and by a gradual ramping up of the power from a relatively low initial value.

The applicator is comprised of a sharp bevel-tipped, electrically insulated outer cannula (~13-G dia, 12–25-cm length). After inserting it into the tumor, the physician manipulates a mechanical plunger in the electrode's handle to deploy multiple non-insulated metallic tines out from the cannula's tip. The tines exit radially – though arcing back to form an umbrellalike array from which the current flows. A range of array diameters (2–5 cm) allow for various volumes to be ablated. The electrodes also come in a CoAccess™ version in which the insulated cannula is separate and provides a sharp handleless introducer to accommodate limited CT gantry clearance and can also provide a track through which pre-ablation needle biopsy or injection can be performed. The system also supports a single needle-type electrode (0.9-cm active tip, Soloist™) for small volume ablations.

The most prominent element of the user interface on the BSC RF 3000 generator is the display for the readout of the tissue impedance. At the outset of the ablation, the physician sets the power output to an initial value and then gradually increases it stepwise, manually. The initial power, increments, and maximum settings depend on the size of the array selected. During the ablation, the tissue impedance is monitored. The impedance is observed to rise suddenly by an order of magnitude, indicating tissue coagulation around the electrode; the power is shut off. After a brief pause, a second similar phase of power deposition is applied to assure a thorough ablation – again with the marked increase in tissue impedance as the endpoint for the ablation.

Angiodynamics StarBurst

The StarBurst® Radiofrequency Ablation System (AngioDynamics, Inc., Latham, NY) operates at 460 kHz and provides up to 250 W of power [4]. The system is known for its array-type electrodes and multipoint temperature feedback [5]. See Fig. 11.3. Exemplary is the StarBurst XL 5-cm-diameter array electrode. Housed in an insulated 14-G cannula (10-, 15-, 25-cm overall lengths), the non-insulated array is deployed via a mechanism in instrument's handle. It can be extended partially or fully to achieve a 3-, 4- or 5-cm-diameter ablation. Of its nine tines, five have thermal sensors in their tips. Separately notable is that the distal 5 mm of the cannula itself is non-insulated and can be activated during probe removal for track coagulation.

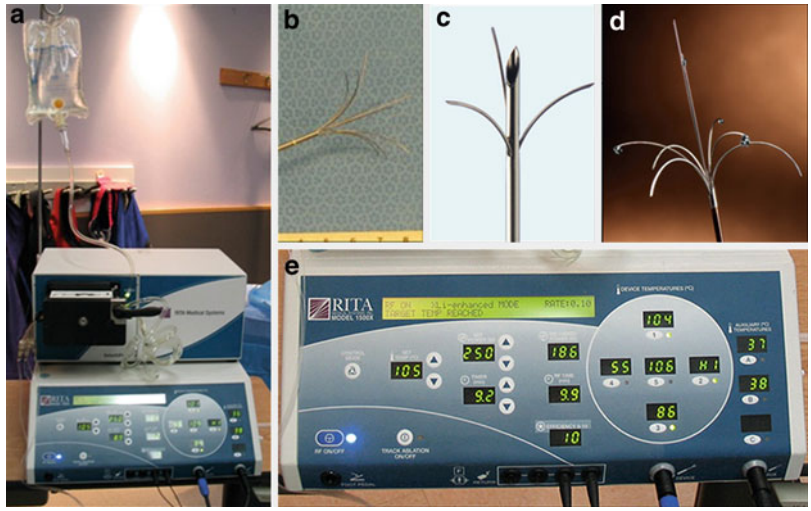

Fig. 11.3 AngioDynamics RF ablation. (**a**) The StarBurst RF ablation system is shown underneath its companion IntelliFlow pump which is connected to a small bag of saline suspended above. (**b**) The StarBurst array-type electrode shown with tines projecting forward from the insulated cannula. Thermocouples in the tips of alternating tines provide temperature readings during RFA. (**c**) The SDE or side-deployed array electrode offers, as its name suggests, an alternative to the standard forward projection of the tines. (**d**) The XLi version utilizes the pump seen in figure part (**a**). A slow perfusion of saline adds to the conductivity to the tissue. (**e**) The user interface of the AngioDynamics generator allows the user to set a desired average ablation temperature (far *left* display; here, 105 °C). Contained within the *circle on the right* are measured temperature values reported from the thermal sensors in the array (Figure parts (**c**) and (**d**) courtesy AngioDynamics, Inc., Latham, NY)

Variations on the StarBurst include the Semi-Flex – the cannula of which has two sections: a distal rigid 12 cm for tissue penetration and a proximal 13 cm that is flexible. A bend of the flex portion can assist in situations with limited CT gantry clearance. Both the XL and the Semi-Flex electrodes are available in MRI-safe versions for magnetic field strengths of up to 1.5 T. The StarBurst "XLi enhanced," intended for treating large tumors, is a 7-cm-diameter saline-perfused array. An external pump provides a slow drip of saline into tissue from the tips of certain tines during the ablation to add conductivity to the tissue. (Note that the saline is not used for the purpose of cooling the XLi electrode).

The most prominent feature of the generator's front panel is the display of the five temperature readings from the thermal sensors in the tines of the array. Automatic temperature control (ATC) mode allows the user to define a target temperature (say, 95 °C) in the range 50–120 °C (instructions for use provide lookup tables for recommended temperature, duration, and power limit). On activation, the system ramps up the power until the temperatures average 95 whereupon the output is modulated to sustain that temperature. It is sustained for a preset duration (say, 7 min) to complete the ablation. If needed, individual thermal sensors in individual tines can be turned off so as not to contribute to the calculation of the average. Separately, (a) the device has automated-track coagulation mode for use during probe removal (tines withdrawn), and (b) the device can support the AngioDynamics 17-G UniBlate electrode intended for small tumor ablations. This is a needlelike electrode with a single thermal sensor. The tip has an adjustable active length (1–2.5 cm).

Celon Power System

The Celon *Power* System (Celon AG Medical Instruments/Olympus Surgical, Teltow, Germany) is a 470-kHz RF generator providing up to 250 W [6]. The system powers the needle-type Celon Pro *Surge* RFA electrode [7].

Fig. 11.4 Celon Power System RF ablation. (**a**) Three Pro Surge bipolar electrodes shown traversing a *thin plastic template* for proper inter-probe spacing. (**b**) Mobile cart transports generator (and optional laptop) and coolant pump system. (**c**) The system's front panel LED displays provide readouts of ablation power, energy, and time. Underneath the readouts are a socket for a footswitch and the plug-ins for up to three electrodes for multi-probe RFA (Images courtesy Celon AG Medical Instruments/ Olympus Surgical, Teltow, Germany)

See Fig. 11.4. In contrast to the monopolar RF applicators described above, the Pro *Surge* electrode is a bipolar device. That is, rather than having the current flow from the active electrode to the separate dispersive electrode(s) located remotely on the patient's body, the current flows between positive and negative elements located together on the needle tip. Grounding pads are not used with the Pro Surge electrodes.

The Pro *Surge* and the MRI-safe *Surge MRI* are 15 G in diameter and 10–25 cm long and are electrically insulated proximally along the shaft to the final few centimeters. The non-insulated active tip (2, 3, or 4 cm) is made up of two adjacent electrodes (one positive, one negative) separated from each other by a small spacer. For smaller and larger volumes of ablation, there is the *Micro Surge* applicator with a sub-cm active tip and the thicker *Surge Plus* at ten French for open procedures, respectively. All these devices are internally cooled with pumped (30 ml/min) room temperature water to prevent tissue charring adjacent to the probes.

The Celon system is a multi-probe system – with connections for up to three bipolar applicators for simultaneous use in treating large tumors. When two or three are used, current flows not only between the elements of an individual bipolar applicator but also between elements of separate probes in an alternating fashion. The system is typically run in its automatic RCAP (resistance controlled automatic power)

mode – whereby the system regulates the power output in response to its internal monitoring of the electrical resistance in the tissue. RCAP mode reduces power when tissue impedance exceeds program limits. RCAP can be turned off for manual power control for end-of-procedure track ablation. A lookup table for setting target RF power and duration is provided by the manufacturer. During treatment, the user interface displays the power, energy (Joules; W-s), and elapsed time; an audible tone provides added feedback about impedance status.

Cryoablation

In contrast with pyrogenic devices are cryogenic systems designed to focally ablate tissues by freezing. In general, contemporary clinical cryoablation systems use a high-pressure gas as a cryogen. The room temperature, high-pressure gas is circulated to multiple needlelike applicators (cryoprobes, cryoneedles). The gas flows from a regulated tank in the room through a micro-tube to the probe's tip where it exits the micro-tube into the small relatively low-pressure space within the probe's tip, and flows back out into the room. Freezing occurs at the site within the probe where the gas exits the micro-tube. This "throttling" of the gas and the resulting drop in temperature are in accord with the Joule-Thomson (J-T) effect. Certain gases such as nitrous oxide, carbon dioxide, and argon have a positive J-T coefficient at room temperature and are suitable cryogens for these clinical systems. (Gas is not released into the patient's body).

While gas-based systems predominate in the field, other cryogens offer alternative solutions. Technologies arriving in the market include the new IceSense3 (*IceCure Medical*, Caesarea, Israel) which uses low-pressure liquid nitrogen for freezing of a single cryoprobe. Separately, a work in progress of note is *CryoMedix, LLC* (Albuquerque, NM) development of refrigerated "single-phase" liquid cooling agents that are circulated in a closed loop offering the potential for adjustable cooling through both rigid and flexible catheters.

Galil Medical SeedNet

The SeedNet cryoablation system (Galil Medical, Arden Hills, MN) is an argon gas-based system [8]. See Fig. 11.5. It and its kin, the Presice and the MRI SeedNet, support the simultaneous independent activation of multiple (as many as 25) cryoprobes. While high-pressure (∼3,500 psi) argon gas is used as the cryogen, high-pressure helium gas (∼2,200 psi) can be used to warm the probes. (Helium has a negative J-T coefficient.) Thus, this two-gas configuration system can first freeze the tissue for treatment and then deliver an active thaw for a quick release of the probes from the frozen tissue. The Presice model is a single gas system that offers a helium-free thaw (i-Thaw) – using warmed low-pressure argon gas to actively thaw the probes after treatment.

The needlelike Galil cryoprobes are 17 G in diameter with an overall shaft length of 17.5 cm and are available with straight or right-angled handles. A thin lightweight gas line leads from the handle to one of the connection ports on the side of the main body of the system. Various probe models (i.e., IceSeed, IceSphere, and IceRod) provide various iceball sizes that can be used in multiple-probe applications to create larger or sculpted ice formations. MRI-safe versions of the IceSeed and IceRod cryoneedles are available for use with the MRI SeedNet system.

The SeedNet's user interface is a computer screen with a touchpad mouse. The system manages the flow of gases to five groups of probes with as many as five probes per group. During treatment, the user can control the five groups independently, selecting from among options of freezing with a full flow of argon gas or actively thawing with helium. Also, the flow of argon to any of the probe groups can be reduced from 100 % to 80 % (or 60 %, 40 %, 20 %, 0 %) for control of ice growth. Additional feedback for the control of the ablation can be obtained using the thermal sensors (TS) and multi-point thermal sensors (MTS). The disposable 17-G sensors can be placed interstitially to provide single-point temperature readings (four separate readings for the MTS). These readings appear on the console to monitor user-defined critical temperatures and can also be used by the system in

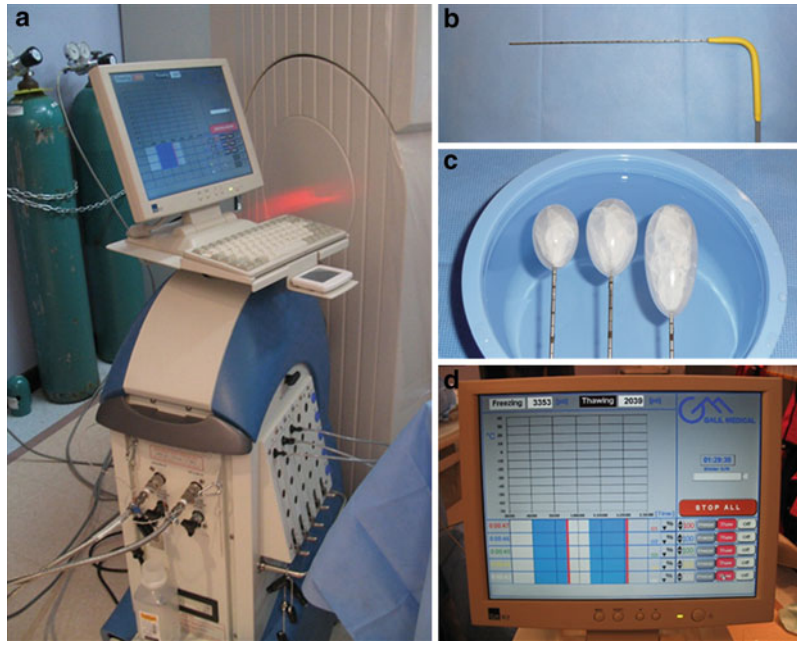

Fig. 11.5 Galil Medical cryoablation. (**a**) SeedNet system with swivel monitor and keyboard. The back of the system is in the foreground showing hoses for argon gas (for freezing) and helium (for active thawing) exiting the system and leading to gas source tanks (*green*) in the background. On the *right-hand side* of the system, the connections for multiple probes can be seen. (**b**) 17-G *right angle* "cryoneedle." (**c**) Sample iceballs formed in water at distal tips of IceSeed, IceSphere, and IceRod. (**d**) Lower half of screen displays treatment history of a freeze, thaw – freeze, thaw cycle (*blue*, *red*, *grey pattern*); probe status (percent flow, freeze, thaw, off) is shown toward the *right*

a controlled mode to automatically adjust gas flow to maintain/limit temperature in a TS' location. The Presice system offers additional on-screen features to the user for treatment planning in kidney and prostate procedures including visualization of intra-procedural US images.

Microwave Ablation (MWA)

Microwave energy delivery for ablation is distinct from RFA. Unlike an RF electrode from which electric current flows into tissue, the MWA applicator is an antenna, electrically driven, that emits electromagnetic (EM) radiation – essentially broadcasting from its tip into the surrounding tissue. No grounding pads are necessary for MWA since the antenna itself is a complete circuit. While the microwave portion of the EM spectrum is broad, ranging from 300 MHz to 300 GHz, clinical MW ablation systems typically operate at one of two frequencies: 915 MHz and 2.45 GHz. Contemporary antennae are all needlelike and range from 17-G thin to 13-G thick. The microwaves are generated by a magnetron within the MWA system and fed to the antenna. Currently marketed systems provide power connections for 1–3 antennae. When activated, dielectric tissue heating occurs – the electric dipole moment of molecules in the tissue (primarily H_2O) oscillates rapidly with the EM waves, transferring energy to adjacent nonpolar molecules.

Most MWA systems, though not all, employ a circulating liquid- or gas-cooling mechanism to prevent the shaft of the probe from overheating; this cooling is to protect the patient and healthcare personnel from burns. The shaft can heat up due to power that is reflected back from tissue during activation of the antenna in turn due to an "impedance mismatch" between the metal antenna and the tissue.

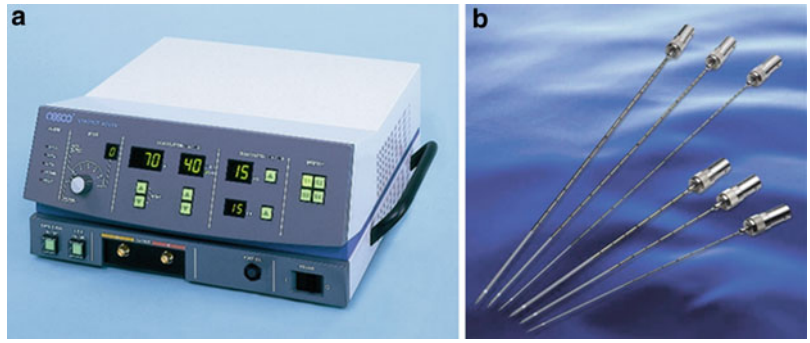

Fig. 11.6 Alfresa Pharma microwave ablation. (**a**) The Microtaze microwave generator provides up to 110 W at 2.45 GHz. Model shown (AZM-520) allows for two antennae to be used simultaneously. The system can have several user-defined preset patterns of ablation power and duration. (**b**) Various needle-type -coated antennae for percutaneous MWA (Images courtesy Alfresa Pharma Corporation, Osaka, Japan)

Alfresa Pharma Corporation AZM-550

The Microtaze AZM-550 MWA system (Alfresa Pharma Corporation, Osaka, Japan) generates 10–110 W of power at a frequency of 2.45 (±50) GHz [9]. See Fig. 11.6. Antennae with various tip geometries are available for hemostasis, tissue resection, and tissue coagulation in open and laparoscopic surgical settings as well as for percutaneous tumor ablation. The system includes a unique "dissociation" feature that is intended to prevent a probe tip from adhering to the ablated tissue – a small direct current is used so as to pull water molecules toward the probe by electroosmosis and thus to soften the coagulum.

The percutaneous MW ablation applicators are needlelike dipole MW antennae. They are available in a disposable version, NESCO Percu-Pro DP, with diameters of 1, 1.6, and 2 mm and overall shaft lengths of 15 and 25. Sterilizable, reusable antennae for interstitial ablation are also available. The probe shafts are not cooled; the manufacturer recommends applying saline to the skin insertion site during ablation to cool the site. The distal tips of the Percu-Pro series are coated in Teflon to provide a nonstick surface which obviates the need for the system's electrical dissociation feature as might be used with other probes. Coaxial cables carry power to the antennae from the system/generator. The AZM-550 can power a single antenna (the 550's predecessor, the AZM-520, powers two antennae simultaneously).

The prominent display components on the front panel of the Alfresa's Microtaze system are the MW "coagulation" power and duration; these can be set at between 10–110 W and 0–15 min, respectively. A separate display shows values of the dissociation current and its duration of between 0–20 mA and 0–60 s, respectively. Typical settings could be 70 W for 60-s coagulation and 15 s at 15-mA dissociation. The coagulation and dissociation can be set to alternate or to run simultaneously; patterns and the repetition of patterns can be selected from preset modes or user-defined cycles that can be stored in memory for frequent use. There is also a slow coagulation function that automatically ramps up the power slowly from zero to a preset value.

Covidien Evident

The Evident Microwave Ablation System (Covidien, Valleylab, Inc., Boulder, CO) operates at 915 MHz and can power a single dipole MW antenna at up to 60 W [10, 11]. See Fig. 11.7. The single-use antennae are available in both a 13-G surgical (VTS series) and a 14-G percutaneous (VT) version. The radiating section of the VTS is 3.7 cm long (shaft length 17 cm), while that of the percutaneous VT (shaft lengths 12, 17, 22 cm) is available as 3.7 as well as 2.0 cm. The shaft of the percutaneous antennae is water cooled during energy deposition from a small reservoir by an external peristaltic pump. A thin power cable exits the handle of

Fig. 11.7 Covidien Evident microwave ablation. (**a**) Sample 14-G antenna for percutaneous ablation at 915 MHz. (**b**) Pair of generators for multi-probe ablation. Display on each shows planned and elapsed durations as well as power setting(s). A single peristaltic pump for antennae shaft cooling sits atop both generators; the small tubular reservoir for the coolant hangs suspended to the *left* of the pump

the probe and leads back to the generator. This electric cable (and the inflow-outflow water tubing in the case of the percutaneous VT) is guarded by an accordion-like thin plastic guide intended to serve as a spacer and protective shield should the cable heat up.

The user interface of the evident generator primarily allows the user to set the power to the antenna and the duration. The timer can be set for up to 30 min. The system indicates when the unit is active and displays the elapsed time. Note that the percutaneous antennae are limited to 45 W and 10 min. Utilization of multiple probes for a procedure requires multiple generators, one for each probe. The peristaltic pump can provide sufficient flow to accommodate three antennae. For multi-probe procedures, small templates are available that can be placed at the skin insertion sites to establish a set spacing between probes, that is, a 1.5-cm distance for the VT probes. Single- and multiple-probe configurations warrant various power-time combinations depending on the desired size of the ablation – the manufacturer's lookup tables provide recommended combinations for planned ablation sizes.

HS Medical AMICA

The HS AMICA, an acronym for Apparatus for Microwave Ablation, is a 2.45-GHz microwave ablation system (HS Hospital Service SpA., Aprilia, Italy) that delivers up to 140 W to a single needle-like MW antenna, the AMICA-PROBE [12].

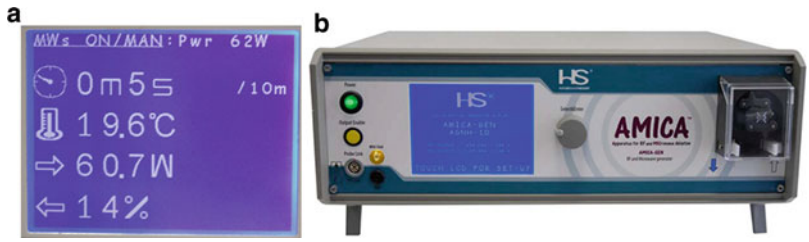

Fig. 11.8 HS Medical microwave ablation. (**a**) Liquid crystal display and touch screen for the HS Medical AMICA-GEN AGN-3.0 2.45-GHz MWA system. Here, the interface reports on elapsed time, probe coolant temperature, output power, and reflected power. (**b**) The new hybrid AMICA AGN-H-1.0 offers 200 W at 450 kHz to a needlelike cooled-tip RF electrode in addition to the MWA capabilities of the AGN-3.0 2.45-GHz MWA device (Images courtesy HS Hospital Service SpA., Aprilia, Italy)

See Fig. 11.8. The AMICA-PROBE is a coaxial dipole microwave antenna, available as 11, 14, and 16 G for surgical and percutaneous applications. A flexible 2.5-mm-diameter probe is available for endoscopic ablation. Probe heating due to reflected power is addressed structurally in the probe's manufacture by a "quarter-wave coaxial 'choke'" at the probe tip which electrically suppresses reflected power, although, in addition, the probe shaft is water cooled by a closed circuit of pump-driven water.

The AMICA-GEN, the system's MW power source and control unit, comes in 100-W (AGN-2.1) and 140-W (AGN-3.0) versions, the latter having an integrated coolant pump rather than an external peristaltic pump (AMICA-PUMP). An LCD touch screen and control/select knob serves as the user interface. The operator can select from manual and automatic modes. A lookup table for power settings and ablation durations is available when selecting the manual mode in which these parameters are user defined. In the automatic mode, a target tissue temperature can be selected, and the device will modify its output based on an internal thermal sensor in the tip. Also, a separate external thermal sensor can be connected to the device to assist in monitoring tissue adjacent to the ablation zone. The user can define a maximum allowable temperature for the thermal sensors or set limits on treatment duration or power output. The LCD screen reports on elapsed time, power, and probe temperature.

In a unique recent development, HS Medical has released, in Europe, a dual modality system that is a hybrid relative to the AMICA-GEN – a single unit that offers a selection of either RFA at 450 kHz or MWA at 2.45 GHz.

NeuWave Medical Certus 140

The Certus 140 2.45-GHz Ablation System (NeuWave Medical, Madison, WI) is equipped with a microwave generator that provides for up to three antennae that can be used simultaneously [13]. See Fig. 11.9. The "triaxial" needlelike antennae (consisting of three concentric longitudinal elements) are manufactured so as to be "tuned" to specific tissues for ablation efficiency (i.e., less reflected power) [14, 15]. These include the 17-G Certus^{LK} for the liver and kidney and the Certus^{LN} antenna for the lung. The radiating segment at the distal tip of either probe type is available as 2.0 or 3.7 cm in length (15 or 20 cm in overall shaft length; with a 13-G 25-cm antenna also available).

The probes connect into the compact Power Distribution Module which can be attached to the patient table (but remains tethered to the generator); this offers plug-in near the interventional field while keeping the main body of the system relatively remote. Each MW antenna shaft is cooled by a CO_2 gas system using the J-T effect instead of flowing water. In addition to a deep cooling that allows for more power to be applied, the CO_2 gas can get as cold as −10 °C so as to freeze part of the distal end of the probe to enable the user to lock it in place, the Tissu-Loc function. Each probe is equipped with three thermal sensors: one to monitor the temperature of this

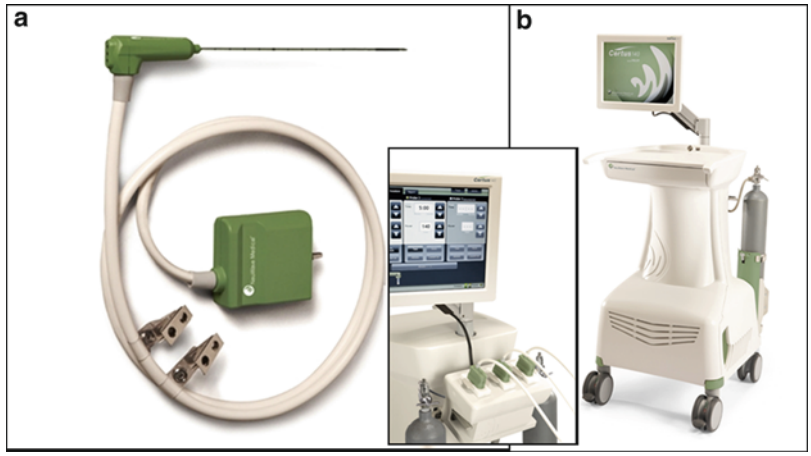

Fig. 11.9 NeuWave Medical microwave ablation. (**a**) NeuWave 17-G Certus antenna. (**b**) Certus 140 system at 2.45 GHz with adjustable computer screen for user interface. Cart supports the small CO_2 tanks (*grey*) for probe cooling during ablation, *inset*. Power Distribution Module on back of cart (shown between CO_2 tanks with three antennae plugged in) can be detached from the back of the cart and attached to CT table near the interventional field (Images courtesy NeuWave Medical, Madison, WI)

Tissu-Loc feature, one in the tip at the site of ablation, and one in the handle for user safety.

As noted above, the system has multi-probe capability. It provides up to a maximum of 140 W of power for a single-antenna ablation. If three probes are used, the generator can deliver a total output of up to 195 W with each channel receiving up to 65 W. The system is controlled and monitored via a computer touch-screen user interface; power and duration are set based on the number of probes and as per lookup tables provided by the manufacturer (i.e., 140 W for 5 min with one probe, 65 W for 10 min with three probes). Visual cues on the control screen as well as on the probe handle itself alert to user to the active delivery of MW energy. The device also features a cauterize mode for needle-track coagulation.

MedWaves AveCure

The AveCure (MedWaves, Inc., San Diego, CA) microwave ablation system features proprietary software that monitors tissue temperature and reflected power during ablation to optimize power delivery to result in more transmitted energy into tissue. See Fig. 11.10. This involves adjustments to the operating frequency over a range of 902–928 MHz (centered at 915 MHz) [16]. The system is designed to power a single monopole antenna at up to 32 W. No cooling of the shaft is required.

The needlelike antennae are 12, 14, and 16 G in diameter with shaft lengths of 15–30 cm. They include integrated temperature sensors. The system can thus be run in a temperature control or power control mode in which the device uses data to modulate MW output to maintain a constant user-defined temperature or power for a prescribed time. A typical ablation protocol is 32 W set for 10 min.

Microsulis Acculis

The Acculis Sulis V^{pMTA} ablation system Control Unit (Microsulis Medical Ltd., Hampshire, UK) provides up to 180 W at a frequency of 2.45 GHz to a single MW applicator [17]. See Fig. 11.11. The system can also support certain surgical applicators such as the 5.6-mm-diameter Accu5i antenna intended for open procedures. The Accu2i is Microsulis' percutaneous dipole antenna: 1.4-cm active tip, 1.8-mm diameter, water cooled, and with overall shaft lengths of 14 and 29 cm. The system monitors the reflected energy back to the antenna as well as the

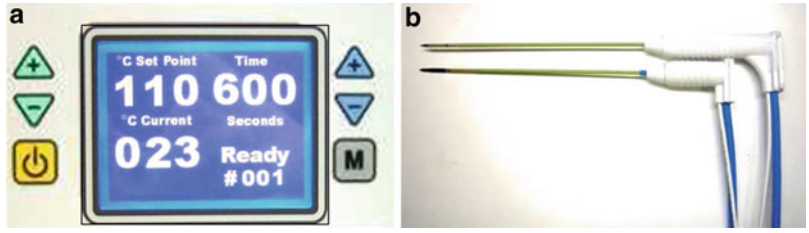

Fig. 11.10 MedWaves microwave ablation. (**a**) Liquid crystal display for the single-antenna MedWaves AveCure 915-MHz system. In temperature control mode, a target temperature (here 110 °C) for the antenna tip can be preset. (**b**) Sample antennae (range 12–16 G) (Images courtesy MedWaves, Inc., San Diego, CA)

Fig. 11.11 Microsulis microwave ablation. (**a**) The 2.45-GHz Sulis V system powers a single MWA antenna. The control panel allows the user to set and monitor ablation duration and power. The bottom row of the panel shows temperature readouts from up to two separate 18-G thermal sensors that can be placed adjacent to ablation volume for added feedback on tissue status (Images courtesy Microsulis Medical Ltd., Hampshire, UK)

temperature of the probe shaft and that of the water coolant. These readings provide feedback to the device for automatic shutdown should values fall outside of a prescribed range.

The control unit houses a touch-screen user interface. Here, the duration and power can be set for a given ablation. Manufacturer's instructions include lookup tables that list desired ablation diameters as functions of power, time, and tissue type (liver, muscle, kidney), that is, a typical liver setting is 120 W for 6 min. During ablation, the touch screen reports time, power, and temperatures. Notably, the unit can support up to two independent 18-G thermal sensors (MTA temperature probes) which can be placed near the ablation field to help in tissue monitoring.

BSD MicroThermX

The MicroThermX Microwave Ablation System (BSD Medical Corporation, Salt Lake City, UT) operates at 915 MHz [18]. See Fig. 11.12. It offers the simultaneous use of up to three probes at a time. When two or three antennae are activated, they operate in a "synchronous" mode such that the electromagnetic waves from each probe have not only the same 915-MHz frequency but also the same phase. Superimposing

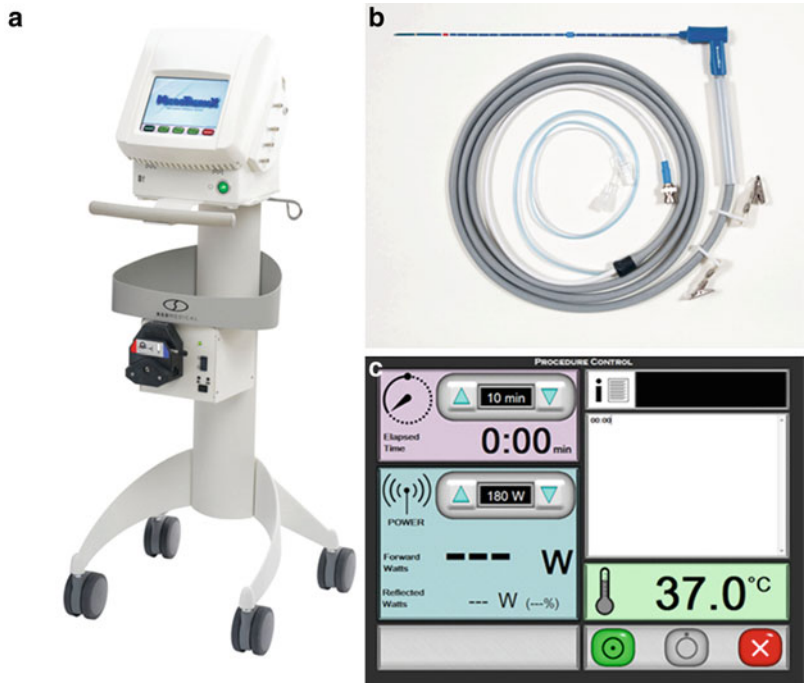

Fig. 11.12 BSD MicroThermX microwave ablation. (**a**) The mobile MicroThermX 915-MHz MWA system. The head of the system includes the touch-screen control panel. On the *right-hand side* of the head are seen connectors for up to three MWA antennae. Just below the waist of the cart in the front is the pump for water cooling of probe shafts during ablation. (**b**) Sample SynchroWave antenna with electrical connection for power and tubing for coolant flow in and out. (**c**) Control panel close-up. Duration and power can be set and monitored on the *left side* of the screen; this includes a report of reflected power. The *right-hand side* of the screen has an information field and readout of the optional 18-G thermal sensor (Images courtesy BSD Medical Corporation, Salt Lake City, UT)

waves with the same phase contribute to constructive interference – whereby the waves add together to enhance power deposition in tissue.

The 14-G SynchroWave antennae are needle-like with a 5-cm active length. Overall shaft lengths range 10–25 cm. These probes are internally cooled with sterile saline via a peristaltic pump to control heating due to power reflected back along the shaft. The generator provides 180 W, up to 60 W to each of three probes. An ablation zone chart provided by the manufacturer guides the user as to probe spacing and parameters. The latter can be set by the user via the procedure control screen which also displays power, time, and temperature during the ablation. Also, there is an optional 18-G TempSure Temperature Sensor that can be used to perform a point measurement of temperature during ablation to monitor adjacent structures. The antenna can perform tract coagulation for coagulating the probe tract on removal post-ablation.

Laser Ablation (ILT, LITT, ILP)

LASER is an acronym for Light Amplification by Stimulated Emission of Radiation. Laser is the noun used to refer to the device whereby the LASER process occurs, and the light energy emitted from a laser is EM radiation. Laser light is typically characterized by its wavelength in microns or nanometers (as opposed to it frequency in Hz as referred to above in discussing microwaves). Depending on the laser system, a range of wavelengths are possible: from the invisible ultraviolet to the invisible far infrared with the visible colors in between. The wavelength of the light that is selected for a medical

application is due to the absorption characteristics of the tissue involved (water content, presence of blood, other chromophores) and the desired endpoint. For interstitial tissue ablation, lasers that emit are the near infrared which are most common – such as the neodymium-doped yttrium aluminum garnet (Nd:YAG) laser at 1,064 nm or diode laser at 980 nm. These wavelengths typically allow for a deeper penetration in tissue. The photons are absorbed and the energy is converted into heat. The light is delivered to tissue by means of a fiber optic cable from the output of the laser system to the distal end. For effective delivery over a volume of tissue and to help prevent charring, the working end usually involves a light-diffusing element whereby the light is emitted radially over the distal few centimeters of the optic. It is possible to use multiple fibers by splitting a primary beam or by using multiple laser systems. For higher energy throughput, the fiber can be cooled (such as by pumped water) so that a higher photon density can be achieved and charring avoided. A historic mainstay for the interstitial delivery of laser light is the water-cooled MR Power Laser Application catheter (Somatex Medical Technologies GMBH, Teltow, Germany), also available in a non-cooled and non-MR versions). More recent to market with an MRI focus on LITT is the Visualase Thermal Therapy System (Visualase, Inc., Houston, TX) [19] and, separately, the AutoLITT (Monteris Medical Inc., Winnipeg, MB Canada). See Fig. 11.13.

Ultrasound Ablation

High-frequency sound waves can serve as mechanical agents of thermal ablation. In procedures commonly dubbed high-intensity focused ultrasound ablation (HIFU) or focused ultrasound surgery (FUS), mechanical waves are transmitted through and absorbed by tissues. In a most common configuration, for transcutaneous treatment, the HIFU energy source is an ultrasonic transducer with a large surface area (*low-intensity* US) that is extracorporeal and is acoustically coupled to the patient's skin "above" the target. The physical shape of the transducer and its associated electronics can focus the transmitted ultrasound beam like a lens to a focal spot (*high-intensity* US) within the body. Further, the transducer can be tilted and translated, and the beam delivery parameters can be modified such that the energy can be delivered as a single (small or large) ellipsoidal focus (a "sonication") or as a timed combination of multiple sonications whereby a volume can be treated.

Important to the delivery of therapeutic levels of ultrasound energy for heating or disrupting tissues is radiological imaging for control of the spatial distribution of the effects. As seen in the sections that follow, MRI can serve to target and monitor the ablation. Alternatively, ultrasound itself can play the roles of both diagnostic and therapeutic components of an ablation system. The latter is exemplified in the Haifu JC Focused Ultrasound Therapeutic System (Chongqing Haifu (HIFU) Technology Co., Ltd., Chongqing, China).

Under a separate paradigm, ultrasound technology can be rendered into an interstitial or intraluminal ablation modality. One promising example is a work in progress (Profound Medical, Inc., Toronto, Canada) utilizing a linear array of small planar ultrasound transducers in an applicator thin enough for transurethral ablation in the prostate. The device adds spatial selectivity to ablation by varying the wavelength of the ultrasound waves applied and can be monitored and controlled by MR imaging feedback.

InSightec ExAblate

The ExAblate magnetic resonance image-guided focused ultrasound surgery (MRgFUS) system (Model 2000 and 2100, InSightec Ltd., Tirat Carmel, Israel) integrates the FUS system with a General Electric MRI scanner (1.5 or 3.0 T) whereby imaging can assist in both targeting the tumor and monitoring the tissue heating [20]. See Fig. 11.14. The FUS system's workstation can communicate with the MRI scanner for control of image acquisition and image data transfer.

The treatment source for the ExAblate is a 10-cm-diameter 211 multielement phased-array transducer (1.61 MHz) located in a dedicated

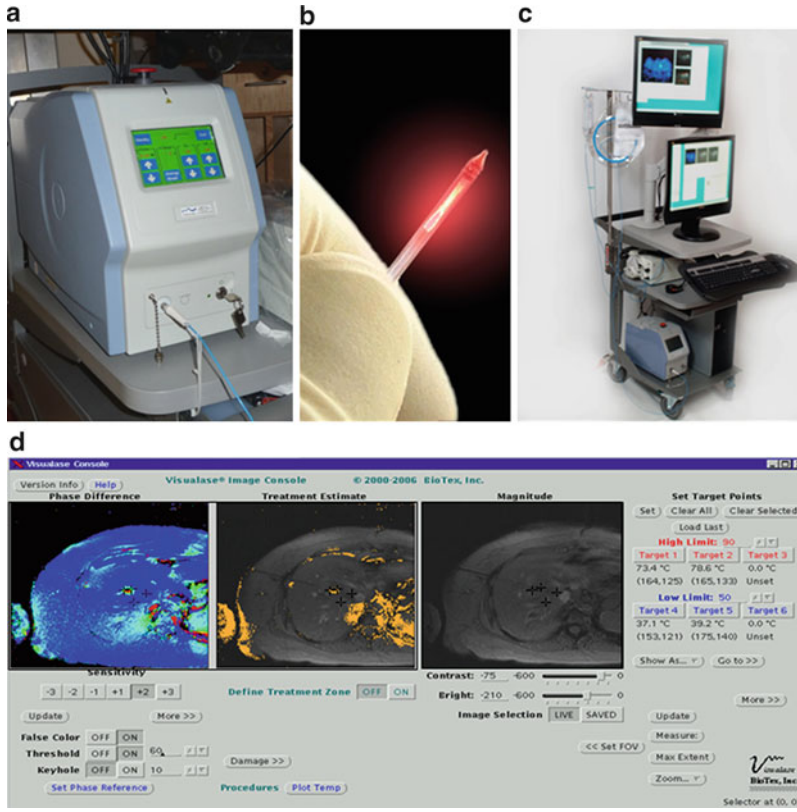

Fig. 11.13 Visualase laser ablation. (**a**) The PhoTex 30 diode laser provides up to 30 W of near-infrared light (980 nm) to a single fiber. A touch control screen provides access to set-up features and for setting output power and duration. (**b**) Visible (*red*) aiming beam illustrates the light-diffusing fiber tip; the sharp catheter in which the fiber is contained is water cooled to prevent charring. (**c**) The complete Visualase system includes a computer workstation for communicating with MRI scanner for thermal mapping during ablation. The laser is seen on the cart's *bottom* shelf. (**d**) The system displays MRI-based temperature map (*left image*) and total thermal dose (*center image*). The user can mark individual voxels in the image for numeric display of temperatures at points in or near the ablation field (Figure parts (**b**), (**c**), and (**d**) courtesy Visualase, Inc., Houston, TX)

MRI patient table and controlled by the FUS system computer workstation near the MRI control console. Images can be acquired prior to and during sonications. The location of the sonications can be adjusted by manipulating the angle (and pitch and roll) of the transducer. Computerized control of the multiple elements of the array provides electronic control over the size of the focal spot (ranging $\sim 2 \times 2 \times 4$–$10 \times 10 \times 35$ mm) and also the depth of the focal spot into tissue (5–20 cm). A sample set of parameters for a sonication is 70 W for 20 s over a $5.6 \times 5.6 \times 28$ mm focus. Multiple adjacent foci can be delivered to ablate a volume of tissue.

The FUS workstation provides a user interface for managing parameters and monitoring the treatment. It receives images from the scanner for treatment planning that help the user assess suitable beam paths and to select input parameters such as acoustic power, duration, interval between sonications, and focal spot size. The user can also fine-tune the energy deposition with modifications to the selected frequency to adjust for defocusing of the beam due to various tissues in the path. The FUS workstation provides image feedback during treatment that includes thermal maps calculated from the thermally sensitive MRI scans acquired during sonication and thermal dose maps based on time-temperature profiles.

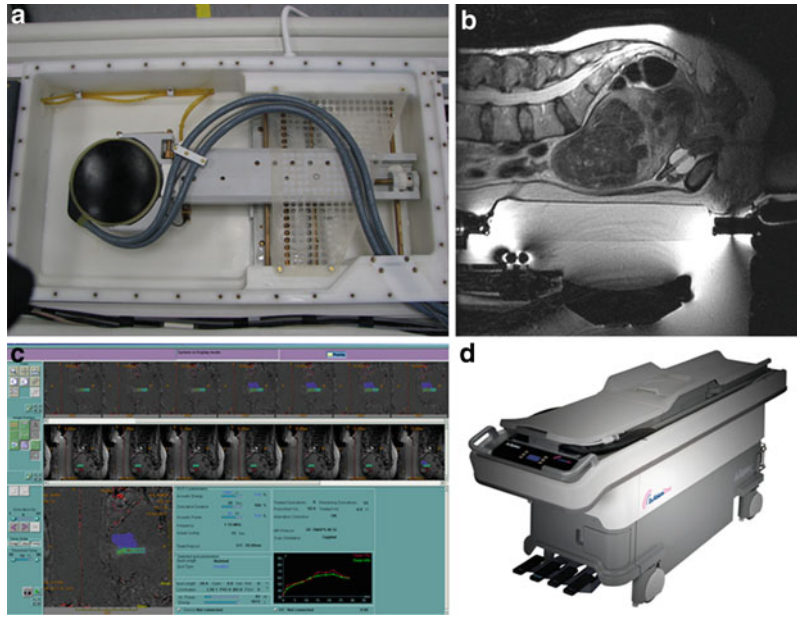

Fig. 11.14 InSightec ExAblate focused ultrasound surgery. (**a**) Multielement 10-cm-diameter phased array transducer built into MRI scanner's patient table. Computer control provides translation and angulation of the treatment beam. (**b**) MRI image illustrates relative position of anatomy above and FUS transducer (seen in cross section as *curved black silhouette*) below. (**c**) Computer software displays MRI-derived heat and dose maps. Lower *left image* displays temperature of current sonication (*green*) with background of previous treated regions (*blue*). (**d**) ExAblate one table replaces standard MRI scanner table (Figure parts (**a**), (**c**), and (**d**) courtesy InSightec Ltd., Tirat Carmel, Israel)

Philips Sonalleve

The Sonalleve MR-guided high-intensity focused ultrasound (MR-HIFU) system (Philips Medical Systems, Andover, MA) is an option that is available for the Philips 1.5- and 3.0-T Achieva MRI scanners [21]. See Fig. 11.15. The HIFU source is a 13-cm-diameter spherically shaped ultrasound transducer that operates at a primary frequency of 1.2 MHz and is composed of 256 individual elements. It is incorporated into a special add-on MRI scanner tabletop and can be mechanically moved within the confines of the tabletop by horizontal and vertical translation and tilting. Computerized control of the transducer's elements and its position within the table allow for individual sonicated volumes of ablation, "treatment cells," of various diameters (4, 8, 12, 16 mm). Larger cells can be treated in a "volumetric" sonication in which the US beam follows a spiral "trajectory" outward from the cell center.

The user interface for the Sonalleve is a computer workstation that provides the user with a selection of sonication modes and parameters of power, duration, and limits. MRI images identify the orientation of the transducer in the table, and thus, the ultrasound beam path can be reviewed by the user. The path and planned treatment cells can be adjusted to avoid critical structures and optimize the treatment. During sonication, temperature data (calculated from the MRI image data) can be updated rapidly (∼every 3.5 s or less). In addition to this temperature feedback, thermal dose maps based on time and temperature can be displayed to view cumulative effects. An individual sonication's duration can also be controlled automatically by this MRI-temperature feedback – whereby the beam can be made to advance to another part of the target based on some preset limit on temperature or dose. The system also reports on various parameters such as reflected power to assist in assessing efficacy and safety.

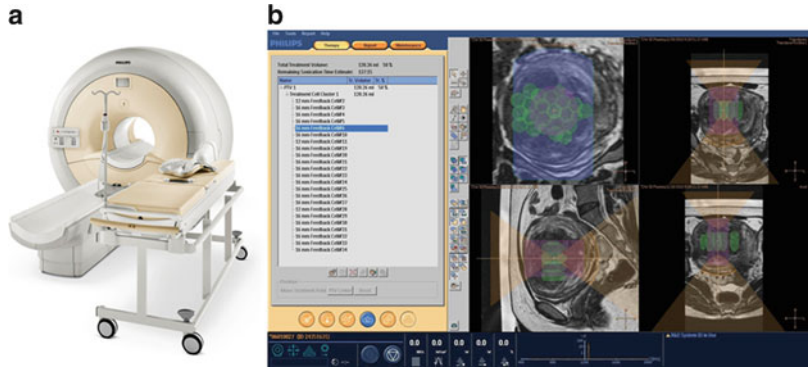

Fig. 11.15 Philips Sonalleve's high-intensity focused ultrasound ablation. (**a**) Philips HIFU tabletop adjacent to standard scanner table for MRI-guided ablation. (**b**) The user interface is computer based, providing sophisticated image-based planning, dosimetry, and monitoring. In the planning mode shown, multiple sonications are planned for throughout a volume. The ovoid sonications are seen as *green circles* in cross section in the coronal planning image (*upper left*) and as *green ovals* in the sagittal image (*lower left*) (Images courtesy Philips Medical Systems, Andover, MA)

Nonthermal Ablation

Irreversible Electroporation

AngioDynamics NanoKnife

Irreversible electroporation (IRE), as an ablative modality, is a nonthermal treatment in which the permeability of cell membranes is affected. The ablative agent is a series of high-voltage pulses delivered by a pair (or pairs) of interstitially placed electrodes. Thus, within a volume of tissue, cell membranes are exposed to a pulsed electric field above the threshold at which the cells' permeability to ions and macromolecules is increased irreversibly with a negative impact on the health of the cell. Various operating parameters impact the outcome of the effects. These include electric field strength (in volts per centimeters, V/cm), pulse duration (microseconds), frequency of pulses (Hz), and total number of pulses or duration of exposure. Of interest is that the IRE tissue ablation effect is not susceptible to heat sink or heat source effects as can be the case for thermal ablation methods, and the architecture of connective tissues is spared since the tissue is not coagulated by heat.

The NanoKnife system (AngioDynamics, Inc., Queensbury, NY) includes a generator and applicators designed for the controlled delivery of pulses of energy for the clinical implementation of IRE [22]. See Fig. 11.16. The applicators are needlelike, and the basic configuration is a pair of electrodes 15-mm apart between which the voltage is established [23]. (Notably, no grounding pads are needed as a return path to the generator). Up to six probes can be connected; system software coordinates the voltage between possible pairings. Aside from the number of electrodes, the user selects the electrode type based on the length of the non-insulated tip (ranging up to 4 cm). The NanoKnife pulse generator can deliver 10–100 high-voltage 20–100 μs long electrical pulses at a frequency of greater than 90 pulses per minute and at field strengths of 500–3,000 V/cm. Manufacturer's lookup tables provide information about optimal probe spacing and the various ablation parameters.

The system interface is a keyboard and LCD computer screen. The interface provides for an interactive probe placement process with a planning grid to determine the number of probes for a given target with click-and-drag probe adjustments. The plan can be further modified as the actual probe configuration is observed during the procedure. The Pulse Generation Screen enables settings and provides a test pulse of energy to check impedance. The system

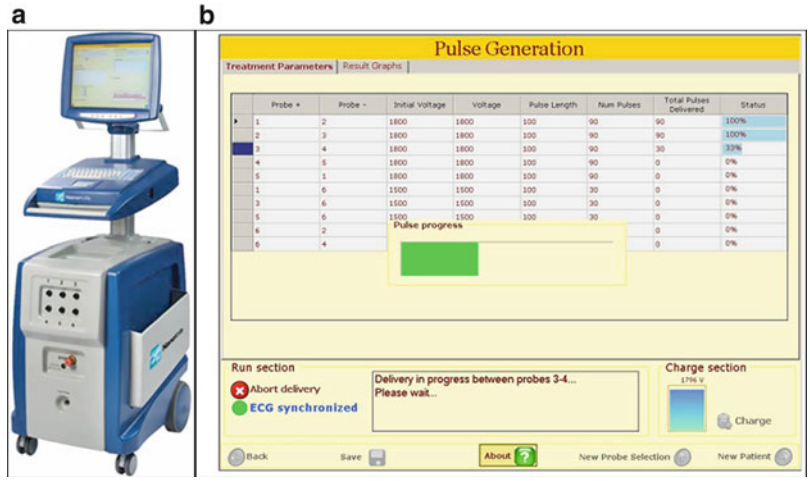

Fig. 11.16 AngioDynamics IRE. (**a**) NanoKnife system for nonthermal ablation by irreversible electroporation. Ports for as many as six electrodes are seen on the front of the main body of the system. (**b**) Progress of the ablation is monitored as the percent completion of planned high-voltage pulses between possible pairings between all electrodes placed (Images courtesy AngioDynamics, Inc., Queensbury, NY)

then tracks the overall progress of the ablation, the number of pulses for various pairs, and the percentage of the planned pulse count for the various pairs.

Photo-Activated Drugs

Light Sciences Oncology Aptocine

Aptocine (Light Sciences Oncology, Bellevue, WA) is a drug (talaporfin sodium) that is currently under investigation for ablation of solid tumors in various organ systems [24]. When activated by its disposable light source, the energized drug generates singlet oxygen within a volume of tissue – this presents direct cytotoxic effects as well as secondary vascular damage and a possible antitumor immunologic response. The photoactivation of the drug is nonthermal – the drug provides no treatment unless activated, and the light itself is not therapeutic in the absence of the drug.

The applicator for the treatment, the drug activator, is a 1.2-mm-diameter linear array of tiny 664-nm red light-emitting diodes (LED) tethered by a microwire to a very small on/off control unit. See Fig. 11.17. The LED array can fit within a catheter and can thus be placed interstitially. Multiple activators can be used simultaneously to treat larger volumes. Once the activators are in place, Aptocine at ~1 mg/kg is injected into the patient intravenously and the LEDs are powered on (at ~20 mW/cm) for a preset time (targeting a total energy of ~200 J/cm). A small liquid crystal display on the power supply keeps time as the endpoint for the exposure.

Injectables

Rex Medical Quadra-Fuse

Quadra-Fuse (Rex Medical, Conshohocken, PA) is a mechanical device. It is an injection needle in an array-type configuration engineered to provide a more even distribution of injected liquid agents such as ETOH over that of a simple straight needle [25]. See Fig. 11.18. After placement of the 18-G cannula in tissue, the three tines of the array are deployed by manipulating the handle. The tines are not in fact solid but are fine 27-G stainless steel tubes with four machined micro-holes at each tip through which fluid can be injected. While the symmetry of the three tines about the axis of the cannula helps the distribution of the liquid, a more homogeneous distribution can

Fig. 11.17 Life Science Oncology. A small power/supply with clock is shown wired to the 1.2-mm-diameter array of LEDs (*red light*). The latter is placed interstitially, and treatment is effected by activation of intravenously injected Aptocine (vial) by the light (Image courtesy Light Sciences Oncology, Bellevue, WA)

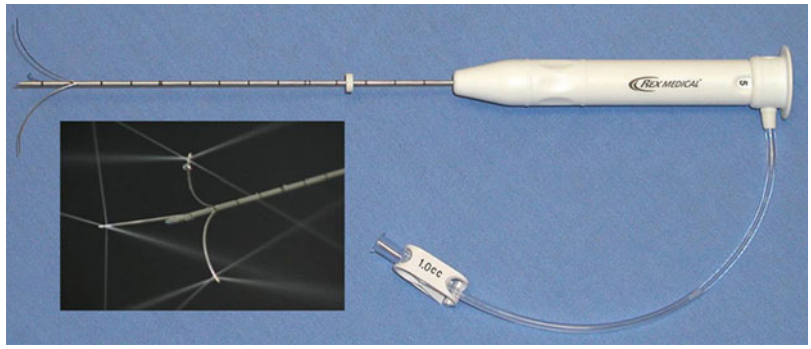

Fig. 11.18 Rex Medical Quadra-Fuse. The array-type configuration of the hollow tines of the device allows for a more even delivery of liquids (such as ETOH) in tissue, *inset*. Micro-holes in each of the tines assist in the distribution. Further, tine deployment can be done incrementally for staged deposition over a volume (Images courtesy Light Sciences Oncology, Bellevue, WA)

be achieved by a staged deployment of the array. As an example, the standard Quadra-Fuse needle deploys fully to 5 cm, but it is designed to open stepwise as 1, 2, 3, 4, and 5 cm – thus providing for partial injections throughout the volume. To withdraw the tines and to redeploy after a rotation of the cannula can also assist in the distribution. Overall shaft lengths available for the cannulae are 10, 15, and 20 cm. The alternative short tip model deploys to a maximum of 2 cm.

Closing

This chapter attempts to sweep the full spectrum of today's technical approaches to ablation. While the reader may thus appreciate the breadth and diversity of this topic, it is difficult to have a definitive and exhaustive list of companies, products, and device features in any snapshot of a field. Also, there are always advances coming to market and new ideas being implemented.

Examples include ablation devices specialized for certain disease states such as the versatile M1004 (RF Medical Co., Ltd., Seoul, Korea) for myolysis and, separately, the Halt Fibroid RFA System (Brentwood, CA); novel new designs such as the spiral elements of the bipolar RFA Encage System (Trod Medical, Bradenton, FL); and also devices based in eastern markets such as the 2.45-GHz Forsea MTC-3 (Forsea Microwave & Electronic Research Institute, Nanjing, CH). Readers are encouraged to investigate the device marketplace beyond this chapter to pursue details, to recognize their own preferences, and to assess the suitability of an approach for one's given clinical environment (e.g., OR vs. IR). Lastly, beyond the devices and their operation, readers are also encouraged to study the physical principles behind a chosen modality to be certain of the full scope of a given device's utility (or limitations).

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