

Applications of RF/Microwaves in Medicine

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Invited Paper

Abstract—Medical applications of RF/microwaves are highlighted in this paper. The emphasis is placed on newer emerging diagnostic and therapeutic applications, such as microwave breast cancer detection, and treatment with localized high power used in ablation of the heart, and liver, benign prostate hypertrophy, angioplasty, and others. A very brief outline of biological effects of RF/microwaves and associated issues is given as background to the applications.

Index Terms—Ablation, cancer detection, imaging, medical applications, therapy.

I. INTRODUCTION

FOR SEVERAL decades, hyperthermia and radiometry have been major subjects of interest in investigating the biological effects and applications of microwaves. More recently, other subjects have also received attention, i.e., power absorption in human subjects [1], interaction with the nervous system [2], influence of extremely low-frequency-modulated fields on membrane channels [3], and molecular effects [4]. There is evidence that RF/microwaves directly affect living systems and *in vivo* absorption experiments indicate direct effects. There are ambiguities, however, concerning the relative contributions of specific and indirect thermal effects, and the possibility of direct nonthermal interactions. Unambiguous evidence of direct effects is provided by *in vitro* studies, revealing effects at various frequencies and intensities, on a number of cellular endpoints, including calcium binding, proliferation, ligand-receptor-mediated events, and alteration in membrane channels. Interactions occurring at the microscopic level are related to the dielectric properties of biological macromolecules and molecular assemblies, in the form of functional units such as enzyme complexes, cell-membrane receptors, or ion channels. Three handbooks provide a good background in the field. Michaelson and Lin [4] review biological effects, Thuery [5] describes the industrial, scientific, and medical applications, and Polk and Postow [6] review biological effects. European research was reviewed in 1993 [7]. A detailed discussion of

some of the topics related to microwave therapeutic medicine could be found in [8].

This paper is organized as follows. Section II discusses biological effects. Section III discusses diagnostic applications. Section IV discusses RF/microwaves in therapeutic medicine.

II. BIOLOGICAL EFFECTS

A. Absorption in Human Subjects

Biological effects depend on the field in the tissues, i.e., on the specific absorption rate (SAR), defined as power deposited in a unit mass of tissue. Human tissues differ in their permittivity [9], varying with frequency. Relaxation phenomena occur at RF and microwaves. At about 100 to 500 MHz, the Maxwell–Wagner relaxation associated with biological cell membranes takes place. Various amino acids, peptides, and proteins exhibit their relaxation frequency within the same frequency range. A weak relaxation at approximately 3 GHz is associated with so-called bound water, which forms a few layers around cells, strongly coupled by physical forces to cell surfaces. Free water contributes 40%–80% of volume depending on the tissue type, and exhibits relaxation at 25 GHz at 37 °C. An evaluation of experimental data is much facilitated by graphical methods. For instance, the Cole and Cole plot is applied to dielectrics, and shows the imaginary part of the permittivity against the real part [10]. This method was successfully used for interpreting measurements on blood up to 110 GHz [11].

Cancerous tissue, except when it becomes necrotic, is highly vascular and has increased water content [9], [12]. This finding directly accounts for an increase in the permittivity of tumors compared to that of host tissue. Typically, the permittivity is approximately 10%–30% greater for high water content tissues as skin, liver, muscle, and spleen [9]. In contrast, significantly larger dielectric constant and loss factor have been reported for tumors in breast tissue (4–10 times) [12]–[14].

A number of thermal effects have been observed [4], [6]. It is estimated that a SAR of 1 W/kg produces an increase of 1 °C in human body temperature, taking thermoregulation into account. Pulsed fields may produce a detectable effect at smaller power levels than continuous wave (CW) [2], [15]. SAR above 15 W/kg produces malformations, associated with temperature increases greater than 5 °C. Ocular effects are producing cataracts at power densities larger than 100 mW/cm² and above 1 GHz.

Hyperthermia is a technique used in the medical treatments of cancer and other medical therapy. Tumors are heated to ther-

Manuscript received August 10, 2001.

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Publisher Item Identifier S 0018-9480(02)01955-5.

apeutic temperatures (43 °C–45 °C) without overheating the surrounding normal tissue. Key issues are heating, temperature measuring, and controlling the system [16]. Human exposure has led to the development of exposure standards or recommendations. Most countries have such standards for both the general population (uncontrolled conditions) and for workers (controlled conditions). Limits are based on body-averaged SAR, in 1- and/or 10-g tissue. Local SAR, of course, is not measured inside of the human body, and there is a need for reliable evaluation of risks. Investigation of human exposure is difficult because of complex geometry and heterogeneous tissues. The present controversy, about the possible hazards due to mobile communications, is due to the fact that heating and resultant biological effects are well documented with experimental data. The lack of reliable scientific data on other effects precludes their inclusion in standards. RF/microwave safety standards were established quite a time ago, following some breakthrough papers [17], [18]. There are now many applications of RF/microwaves in medicine, mostly in therapy, but also in diagnostics. The applications in medicine have been made possible to a large degree by the large amount of research devoted over many years to understanding and modeling absorption in living materials. Thus, before focusing on medical applications, a brief outline of main issues in research on biological effects follows (a more detailed review can be found in another paper in this TRANSACTIONS).

B. Interaction With the Nervous System

Effects of microwaves on the nervous system have been a subject of controversy [19], largely due to a lack of a unified and reliable methodology of investigations. A survey established in 1996 [2] illustrates the variety of exposure schemes, namely CW, amplitude modulated (AM) wave, pulsed wave (PW), and pulse modulated wave (PMW). This variety in methodology makes it very difficult to draw conclusions. If the fields are active in altering the activity and function of the central nervous system, then the changes should be reflected in the concentrations of neurotransmitters in various regions of the brain. It has been shown that 0.2–3-GHz excitation of acupuncture points can produce an analgesic effect [20]. Furthermore, respective variations in pain threshold and neurotransmitter release in the brain are proportional [21].

A number of questions remain unanswered. There is a lack of quantitative results illustrating differences between CW, PW, and extremely low frequency (ELF)-modulated wave exposure. Little information is available about the quantitative effects of millimeter waves, although these might cause resonant effects. More experiments are necessary for distinguishing between thermal, micro-thermal, and possible nonthermal effect [15]. Evaluations related to fields generated by mobile communication devices should calculate the actual temperature elevation.

C. Low-Level Exposure

Exposure to low-level PW has been reported to affect brain neurochemistry in a manner broadly consistent with responses to stress. The acute exposure of rats to pulsed 2.45 GHz was found to alter cholinergic activity in various regions of the forebrain [22], [23]. Pretreatment with narcotic antagonists blocks

the effects, suggesting the involvement of endogenous opioids as a mediating role in some of the neurological effects of microwaves. This led to the speculation that microwave exposure is a “stressor.” The cerebral cortex and hippocampus are known to play significant roles in stress responses and, along with the cerebellum, contain high concentrations of benzo-diazepine receptors.

The use of low-level fields to study the sequence and energetics of events that couple humoral stimuli from surface receptor sites to the cell interior has identified cell membranes as a primary site of interaction with ELF fields in the peri-cellular fluid. Calcium ions play a key role in the stimulus amplification. Fields millions of times weaker than the membrane potential gradient of 10^7 V/m modulate cell responses to surface stimulating molecules, enhanced by weak microwave fields, also acting at cell membranes. Cell membranes are powerful amplifiers of weak electrochemical events in their vicinity [24].

Recently, microscopic effects of signals of global system mobility (GSM) and digital extended cordless telephony (DECT) mobile telephony on the calcium, potassium, and sodium channels have been simulated by computer [3]. Pulsed signals are shown to act more on the reduction of the opening probability than CWs. The low-frequency signal components induce a variation of 60% in the calcium channels. Sine waves at 8.3 and at 217 Hz, two low-frequency components of GSM, act much less on the opening probability than the composite pulsed GSM signal.

Studies of effects on *in vitro* V79 and human lymphocytes cell cultures have been followed-up, with a special emphasis on DNA synthesis. The cells were exposed to 7.7 GHz, at 0.5, 10, and 30 mW/cm², and an exposure time of 10, 20, 30, and 60 min. They exhibited a significant increase in the number of specific chromosome lesions. The micronucleus test shows evidence of changes in the genome [25]. Teratological effects of long-term low-level CW and AM *in utero* exposure on mice and rats have been investigated. The protein synthesis is measured on the level of translation in the brain and liver tissues.

When studying genetic effects, bacteria were tested for different mutations or induction of cell proliferation, with no increase in the mutation frequency and a small, but significant, increase in the cellular rate growth. Embryos of *Drosophila* were tested at 2.45 GHz. No increase in mutation frequency was obtained [7]. A resonant effect on *E.coli* cells and on rat or human leucocytes is observed at 51.7 GHz on the conformational state. The low-level millimeter-wave exposure (200 mW/cm²) of rat thymocytes resulted in genome conformational state changes, resonant at 41.65 GHz. Millimeter-wave exposure at 46.35 GHz, 100 mW/cm², and 2 h of early *Drosophila melanogaster* embryos following an ionizing treatment (1.5 Gy of X-rays) resulted in strong modification of radiation injury. The modification has only “positive” results and can protect biological objects from radiation hazards.

Some research has been led under the assumption that the effects of microwaves can be better understood while an animal is under the influence of a drug. It was found that each brain region responds differently to exposure depending on the exposure parameters. Effects on the frontal cortex are independent of the exposure system or the use of PW or CW. The hippocampus

responded to PW, but not to CW. Different brain regions have different sensitivities: the areas of the brain that show changes in cholinergic activity are not correlated with localized SAR in the brain. An important conclusion is that the long-term biological consequences of repeated exposure depend on the exposure parameters. Changes in cholinergic receptors also depend on endogenous opioids in the brain. The effects could be blocked by pretreatment, before each session of daily exposure, with the narcotic antagonist naltrexone. Endogenous opioids may play a mediating role in some of the neurological effects of microwaves [26].

D. Epidemiological Studies

Epidemiological investigations have been conducted on cancer and on genetic effects [27], [28]. Up to now, no such study establishes clearly that RF/microwave exposure leads to cancer. The dosimetry is tedious: how to measure the exposure of a human being, and how to estimate it in the past? About ten epidemiological studies on cancer are mentioned in the literature. Some exhibit an increase of the risk, although not always statistically significant. Other studies report negative results. Due to the difficulty of dosimetry, investigations *in vitro* can be very useful. Most of the results are negative, but not all of them.

Genetic studies are important for investigations on cancer, as well as for possible hereditary effects. Many of these studies can be made *in vitro*, which makes experiments easier to perform. The majority of the studies have not demonstrated the genotoxicity of RF/microwave exposure. There are, however, some positive results, with an increase of DNA alteration in brains of exposed rats and mice. This remains a controversial question.

E. Hazards

Spreading mobile telephony stations have raised concerns in Europe. The current standards are based only on thermal arguments, providing protection against known adverse health effects. Biological effects, on the other hand, may or may not result in an adverse health effect. Recommendations must, therefore, be compared with the known biological effects. More attention needs to be paid to the question: Is the protection effective?

III. DIAGNOSTIC APPLICATIONS

A. Motivation, Objectives, and Limitations

Microwave imaging of the human body for the purpose of cancer detection has been of interest to scientific community for a long time. However, the challenges posed by human anatomy and physics of electromagnetic interactions have not yet been successfully met. Nevertheless, during the last decade, progress in numerical methods and increased power of computers have made at least some niche applications finally appear feasible.

The main attractions of microwaves in the diagnosis of tumors are the innocuous nature of this type of energy at low levels, the relatively low cost of even complex microwave systems compared to the computer-assisted tomography (CAT) and

magnetic resonance imaging (MRI), and the distinctly different permittivity of tumor tissue compared to normal tissue. An additional feature is the availability of a relatively wide range of frequencies. Thus, multifrequency systems can be developed; as well, the frequency of a given system can be tailored to the application.

A general objective of microwave diagnostic applications is to use the difference between the permittivity of diseased tissue and healthy host tissue to detect abnormality and its location. The aim has been to develop a microwave method competitive with existing diagnostic techniques, such as CAT, MRI, or mammography.

Classical microwave imaging poses an inverse scattering problem, where several microwave transmitters illuminate an object, and scattered fields in numerous locations are measured. The shape of the object and spatial distribution of the permittivity are obtained from the transmitted (incident) and scattered (received) fields. Solutions to most inverse scattering problems at RF and microwave frequencies are difficult. Due to the relationship between the object dimensions, discontinuity, separation, and contrast in properties of inhomogeneities compared to the wavelength, the wave undergoes multiple scattering within the object to be reconstructed. This results in a nonlinear relationship between the measured scattered fields and object function. Also, the solution is often nonunique, as the evanescent waves are not measured, and high spatial-frequency information is lost. These problems exist in any application of microwave imaging, and various issues cited in [29]. Problems such as resolution, contrast, object size, solution speed, robustness, numerical stability, compatibility with the object geometry and accessibility, and amount of a prior information need to be successfully addressed. In medical applications, some of these problems are exacerbated by several factors. High resolution is required to detect small tumors, while high frequencies are strongly attenuated in most tissues. Similarly, the object size compared to the target scattered (tumor) is typically rather large. Total time required for data acquisition cannot be excessive, but these are no additional limitations on the post-processing time required to obtain the object function. Compatibility of the system for illumination and scattered field acquisition with clinically acceptable arrangement also poses some challenges. In practice, the object (human body) is very likely to be in the near field of the transmitting and receiving antennas.

Early microwave imaging, as described in [30], used linear (Born or Rytov) approximation and back projection algorithms similar to those of CAT. This solution is based on the assumption of waves propagating along straight lines and does not account for diffraction and multiple scattering. The limitations of this algorithm in application to human body are apparent and, thus, despite the initial enthusiasm [30], the results of reconstruction are not satisfactory. However, considerable progress has been made in development of more complex, but more realistic approaches that use numerical methods to solve nonlinear inverse problem.

Among microwave cancer-detection systems, breast cancer detection has a unique place. The small size, physical accessibility, and large contrast in the permittivity between cancerous

and healthy tissue are definite advantages. The need for alternative or complimentary diagnostic tool is unquestionable since breast cancer remains the most prevalent cancer among women, and because of limitations associated with mammography. Thus, in recent years, a clinical prototype based on imaging has been developed, and a different highly promising method of detection has been proposed.

In addition to active microwave systems to detect tumors, passive microwave radiometry has been explored for this purpose [31]. The principle of operation relies on an increased tumor temperature compared with healthy breast tissue. Microwave systems offer an advantage over infrared, as they “transmit” to the surface the higher intensity (related to temperature) from sources located deeper. Success with this technique has been limited.

B. Microwave Tomography

A few research groups in Europe [32], and the U.S. have been performing theoretical and experimental studies. In all systems, the object imaged is immersed in water or weak saline solution. Antennas are scanned over planar or cylindrical surfaces, and waves transmitted through the object and received by numerous antennas are used to reconstruct the object function, i.e., spatial distributions of the dielectric constant and/or conductivity.

A French group in collaboration with a Spanish group has been developing planar and cylindrical scanning systems [33]–[36]. Their more recent approach is based on the application of numerical methods to solve the direct problem and nonlinear optimization to solve the inverse problem. Two algorithms have been investigated: the spectral diffraction tomography (SDT) and the Newton–Kantorovich (NT) technique. The former, i.e., SDT, provides only qualitative information about the object function: the latter, i.e., NT, offers much more accurate means for reconstruction of the object function. In the NK technique, a method of moments (MoM) with pulse basis function and point matching is used for the direct problem. The difference between the computed and measured scattered fields is used to alter the object permittivity distribution. Incorporation of prior information such as the contour of the object, and the lower and upper bounds on the dielectric constant and conductivity, can improve convergence. The experimental systems operate at 2.33 or 2.45 GHz. Typically, 36 or 64 transmitting antennas, and 25 or 33 receiving antennas are used. Experiments performed thus far considered rather simple objects, e.g., cylinders that simulate a human arm. Reasonable, but not perfect, reconstruction has been obtained with signal-to-noise ratio (S/N) of 20 dB.

An Italian group developing a multiview imaging system solves the scattering problem with a pseudoinverse approach [37]–[39]. The reconstruction algorithm is done in two steps. First, the equivalent current density is obtained by relating the measured scattered fields and induced current density by means of dyadic Green’s function for the background medium. Second, this problem is solved with MoM and pseudoinverse of the Green’s function matrix. The pseudoinversion is possible since the resultant MoM matrix is invariant with respect to the view angle (at which the scattered fields are collected).

The Green’s functions to be an accurate representation of the human body permittivity require an accurate model of a specific human body under test. Such data are usually not available (unless an MRI scan is available). Various improvements to computational algorithms have been introduced, among them imaging of a limited body region and use of genetic algorithm for optimization [53]. However, no experimental results have yet been published.

The U.S. group in collaboration with Russian groups [40] has developed another imaging system. In their three-dimensional (3-D) system, there are 32 transmitters arranged along a vertical straight line and a receiver is rotated around the object. Additionally, the object is rotated around an axis. The code-division technique is used to allow for simultaneous operation of all the transmitters (at 2.36 GHz). Dielectric loaded open waveguides (1×0.5 cm) are used as antennas. Transmitters are refocused to give 32 directions of plane waves. Multiview data are generated by precise positioning of the receiving antenna on a semi-cylindrical surface (180° in azimuth) surrounding the test object. Additional data are obtained by rotating the object and repeating the receiver rotation. The total acquisition time is about 8 h. A low contrast is assumed and, thus, vector Born method is employed. Good reconstruction of the object function has been obtained for a sphere with two spherical inclusions. The contrast in dielectric constant of the object compared to the inversion liquid is approximately 5%, and in conductivity, approximately 30%. On the other hand, less than satisfactory results are reported for an object with a larger contrast (10% in dielectric constant, and approximately 50% in conductivity).

A group from Dartmouth College, Hanover, NH, has adopted a different numerical method by which to evaluate the direct problem [41]–[48]. The hybrid of the finite-element method (FEM) and boundary-element method (BEM) is used, where FEM is used for the interior of the object under reconstruction and BEM for the inversion liquid. The Newton’s iterative method is used to solve the nonlinear inverse problem. Extensive numerical evaluation of the method has been performed, and the reconstruction of the object function has been demonstrated for high contrast in permittivity (1:3). Theoretical investigations have led to the development of an experimental system initially aimed at monitoring of microwave hyperthermia treatment [43]. The system consists of four transmit–receive channels and can operate at 300–1100 MHz. Water-filled open waveguides are used as the transmit antennas and monopoles are the receive antennas. Corrections for the near-field antenna patterns are incorporated. Various sources of error, such as noise, leakage between transmitters and receivers, antenna positioning, and cables flex have been largely eliminated. Subsequent investigations showed a superior performance when waveguide transmit antennas are replaced by monopoles [44]. Compensation for nonactive antennas [47] has led to further improvements in the system performance [45]. With 32 transmit–receive antennas, in the 300–900-MHz frequency range, the dynamic range of the system is 135 dB, with low transmitter power of 5 mW.

C. Breast Tumor Detection

Long-term research by a group from Dartmouth College has evolved into a clinical system [48]. This is an active

microwave tomography system operating in frequency domain, with frequencies in the 300–1000-MHz range. In this system, two-dimensional (2-D) images are obtained by a set of 32 transmit/receive antennas. The antenna array is scanned from near the chest wall to past the nipple. During the test, a woman is in the prone position with the breast pendant in a saline water tank. A data acquisition system consists of 32 channels connected to 32 antennas. Each antenna operates as a transmitter and as a receiver. Channel-to-channel isolation is greater than 120 dB. Monopole antennas have been selected as optimal for this application, as they can be effectively modeled and produce images of the highest quality. Scattered data are obtained for 16 antennas as transmitters for each 2-D image and seven vertical image sets at seven frequencies. Total data acquisition time is 10–15 min. Currently reported clinical results are for five volunteers [48]. Images are formed in ten iterations in about 20 min on an IBM RS 6000 model 260 workstation. Images clearly show spatial differences in the dielectric constant and conductivity. Reasonably good correlation has been observed between the dielectric constant and radiographic density, with higher dielectric constant for dense breast tissue.

In 1998, Hagness and colleagues introduced a pulsed microwave con-focal system to breast tumor detection [49]. This was the first medical application of technology that previously has been used predominantly in military radar applications. This method avoids complex and computer intensive nonlinear inverse scattering techniques. This method does not provide profiles of the permittivity, but only identifies regions of increased scattering due to a small region of different permittivity. The breast is illuminated with an ultra-wide-band pulse, and the same antenna collects the back-scattered waves. This process is repeated for multiple antenna positions. A time-shift-and-add algorithm is applied to the set of pulses recorded at the antenna output in all positions. The time delay for the round-trip to a given point in the test domain is computed for each antenna position. Next, the signals with their proper time delays are summed up. The procedure ensures that signals from a given pixel or voxel in the test domain add coherently, while the signals from scatterers in other locations form incoherent clutter. Thus, a small scatterer can be picked up if it has sufficiently large contrast compared to random inhomogeneities within the test domain. The same principle is used in several synthetic aperture ground penetrating radar systems. One of the significant advantages of this approach is that high resolution can be obtained provided that a sufficiently wide-band pulse can be used. Initial feasibility was demonstrated in 2-D [49] and extended to 3-D [50]. Antennas are placed on the flattened breast surface with the woman in a supine position. A resistively loaded bow-tie antenna of relatively large dimension (8 cm) used initially [50] has subsequently been reduced to a smaller size [51]. The antenna placement on the skin and matching to the skin impedance allow for gating out the reflection from the inner skin interface. A comprehensive numerical evaluation of performance of this system has been performed with the finite-difference time-domain (FDTD) method. Detection of tumors as small as 2 mm at a depth of 5 cm has been shown feasible [50].

Fear and Stuchly [51]–[53] have evaluated an alternative system based on the same principle numerically in 2-D and

3-D. This system is more amenable to clinical implementation, as the woman is in a prone position with the breast pendulant and immersed in a liquid medium, an arrangement similar to that in the clinical system described by Meaney *et al.* [47]. However, this arrangement poses a major challenge due to strong reflections from the skin, which cannot be gated out and have to be accounted for in the algorithms used for processing the return signals. Small resistively loaded Wu-King dipoles are used, with lengths of 2 or 1 cm, respectively, for the immersion liquid having the dielectric constant close to that of breast tissue or that of skin. The dipoles can be placed very close (2 or 1 cm) from the breast surface with satisfactory performance [69]. An array of antennas can be used in practice, but its elements have to be sufficiently spaced apart to avoid coupling; the antennas are switched sequentially to transmit and receive the test pulse. The sequential switching of the antennas ensures the incident and return pulse fidelity at the close spacing to the test object because of the small antenna size. The whole array can be rotated to the nearby position, depending on the total number of positions required. Numerical evaluation of the system has been performed with the FDTD and a pulse having bandwidth of 5.7 GHz centered at 5 GHz.

A comprehensive comparison has been made between the performance of the two systems: the planar and cylindrical [51]. Previously introduced image reconstruction algorithms are synthesized and extended to three dimensions. The results suggest that both systems for confocal microwave imaging are feasible powerful tools for detecting and localizing breast tumors in three dimensions. The image reconstruction algorithms require limited *a priori* information, are effective with both system configurations, and are a simple and rapid way to interrogate the breast for tumors in 3-D. Both the planar and cylindrical configurations have similar sensitivity of detecting tumors and their location.

IV. RF/MICROWAVES IN THERAPEUTIC MEDICINE

The use of RF (hundreds of kilohertz to a few megahertz) and microwaves (hundreds of megahertz to approximately 10 GHz) in therapeutic medicine has increased dramatically in the last few years. RF and microwave therapies for cancer in humans are well documented, and are currently used in many cancer centers, mainly outside the U.S. RF treatments for supra-ventricular arrhythmia and, more recently, for ventricular tachycardia (VT), are currently employed by major hospitals. RF/microwaves are also used in human subjects for the treatment of benign prostate hyperplasia (BPH) and endometrial ablation, and have gained international approval. In the last few years, we have witnessed an increase in thermal procedures to help patients suffering from back pain, liver cancer, loose shoulder joints, and varicose veins, and to aid hair removal. Several otolaryngological centers in the U.S. have been utilizing RF to treat upper airway obstruction and alleviate sleep apnea. Despite these advances, considerable efforts are being expended on the improvement of such medical device technology. Furthermore, new modalities such as microwave enhanced liposuction, RF/microwaves for the enhancement of drug absorption, RF/microwave for the treatment of bladder cancer, and microwave septic wound treatment are continually being researched.

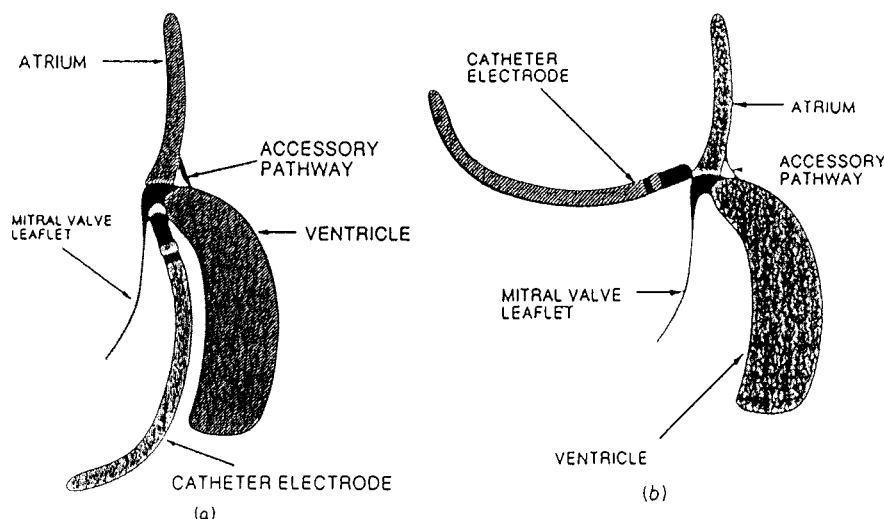


Fig. 1. Diagrams of electrode positions used in RF catheter ablation of accessory pathways. (a) For the ventricular approach, a catheter is passed retrograde across the aortic valve and positioned under the mitral leaflet. (b) For the atrial approach, a catheter is passed across the interatrial septum (transseptal catheterization) and positioned on top of the mitral valve leaflet. Electrical mapping confirms the site of the accessory pathway prior to the delivery of RF energy.

A. RF/Microwave Ablation for the Treatment of Cardiac Arrhythmias

There are a variety of clinical conditions that can cause cardiac arrhythmia [54]. However, all arrhythmias have at their root an abnormal focus of electrical activity or an abnormal conducting pathway within the heart. The most common sources for abnormal foci lie above the AV node and are, thus, referred to as supraventricular tachy-arrhythmias (SVTs). Abnormal ventricular foci lead to ventricular tachy-arrhythmias. Reentry tachy-arrhythmias result from abnormal conducting pathways that allow for uncontrolled cycling of electrical activity as the electrical signal travels in a retrograde direction through the myocardium. Reentry can occur at the level of the AV node (AVNRT), or through accessory conduction pathways (APs).

Once the source of an arrhythmia has been identified, a cure can be achieved by destruction of the abnormal tissue. Such ablation converts electrically active cardiac tissue to electrically inactive scar tissue, thereby eliminating the abnormal focus or preventing conduction through the accessory pathway. There are several forms of energy that have been used to produce localized tissue injury, including direct current (dc), RF, and microwave, as shown in Fig. 1 [54].

There are two kinds of therapies: acute (short term) and chronic (long term). In the majority of patients, SVT is a lifelong condition, treatable for years by medications despite limitations such as their side effects. There are a significant number of patients whose arrhythmias are resistant to pharmacological therapy; some even are at risk of sudden death. Due to the risk of sudden death, pilots with Wolff–Parkinson–White (WPW) syndrome are not permitted to fly unless they undergo a curative ablative procedure. It is, therefore, clear why a minimally invasive procedure that cures an underlying arrhythmia, such as catheter ablation, becomes the treatment of choice in many types of SVT, such as atrioventricular junction (AVJ), AP, AVNRT, atrial flutter, and some single morphology type VTs.

The first supraventricular tachycardias targeted for RF ablation were those associated with the WPW syndrome. In this

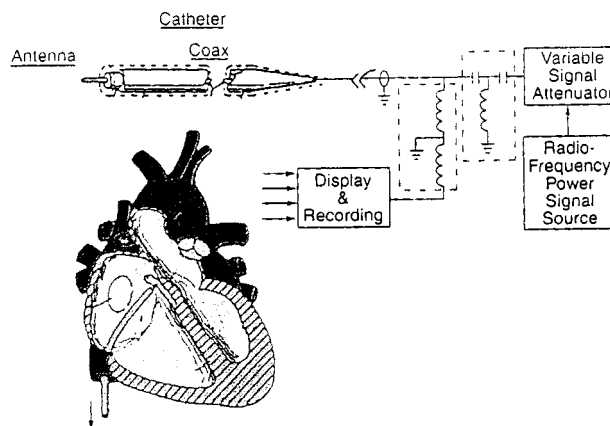


Fig. 2. Microwave system used for myocardial tissue ablation.

condition, the anatomic basis for supraventricular tachycardias is an accessory connection or pathway that connects the atrium and ventricle outside the normal AV conduction pathway. These accessory pathways cross between the atrium and ventricle at the level of the mitral and tricuspid annulus. RF energy delivered to the mitral or tricuspid annulus either from the ventricular or atrial aspect can ablate these pathways. Success rates of over 95% have been reported using either approach.

Recently, encouraging results (utilizing catheter-based procedures) in the treatment of ventricular arrhythmias occurring as a consequence of diffuse processes such as myocardial ischemia or infarction have been published. The search for ablation modalities capable of safely generating even larger lesions has spawned an interest in microwave ablation. Unlike dc and RF techniques, which generate lesions of relatively limited size and penetration, microwave energy might allow for greater tissue penetration and, thus, a greater volume of heating. Microwave ablation systems are currently being developed. Fig. 2 depicts a microwave catheter developed specifically for the treatment of VTs, requiring the creation of large lesions [55].

Microwave power using either 915 or 2450 MHz has been studied in an attempt to enlarge myocardial lesions in catheter ablation [56], [57]. Microwave energy is delivered down the length of a coaxial cable that terminates in an antenna capable of radiating the energy into tissue.

Helical and whip antenna designs were evaluated in a tissue equivalent phantom at 915 and 2450 MHz utilizing a coaxial cable (0.06-in outer diameter) [58]. All catheters were measured utilizing a network analyzer while placing them in an active phantom model.

In vivo ablation using microwaves was performed on a canine left ventricular myocardium. A power of 80 W was delivered for a total of 5 min. Mean lesion size measured $435 \pm 236 \text{ mm}^3$, which was similar in size to lesions created with small-tipped RF catheters. In our experience, the microwave ablation catheters were not capable of producing lesions larger than those produced by RF catheters [58].

Practical problems remain to be solved before microwaves can become a useful clinical energy source. These problems include: 1) power loss in the coaxial cable; 2) resultant heating of the coaxial cable during power delivery that has led to a breakdown in the dielectric and catheter material; and 3) lack of a unidirectional antenna that can radiate energy into tissue and not the circulating blood pool. At the present time, microwave catheter systems are poorly efficient radiators of energy into cardiac tissue. These obstacles will have to be overcome before microwaves supplant RF as the preferred energy source for cardiac ablation.

B. Treatment of Benign Prostatic Hypertrophy (BPH)

BPH represents an enlargement of the prostate gland, which can lead to compression of the urethra and, thus, cause urinary tract obstruction. Although drug therapy may be effective for patients with early stages of BPH, many men will need invasive intervention for relief of symptoms. Surgical excision of prostatic tissue has been the standard care for more advanced forms of BPH. Transurethral RF and microwave procedures are becoming promising alternatives to surgical intervention. The goal of therapy is to decrease the volume of prostatic tissue.

Transurethral needle ablation (TUNA) is an endoscopic treatment using RF energy to produce thermal lesions inside the prostate tissue [59]. This procedure can be performed in an outpatient office setting under local anesthesia. The benefits of TUNA have been demonstrated in long-term follow-up studies. This technology uses RF (460 kHz) with excellent control of the RF thermal energy applied to the tissue. Two modalities are being tested using the TUNA procedure. The monopolar system uses one needle electrode inserted into the prostatic tissue with the dispersive electrode situated at the back of the patient. In the monopole catheter, two needles (electrodes) activated one at a time and oriented 40° apart, can be deployed. The high RF current density near the needle electrode imbedded in the prostate generates resistive heating in the order of 75°C – 95°C . Under the bipolar system, up to four needles are introduced into the prostate tissue, allowing current flow between the multiple needles, creating resistive heating, thus avoiding the dispersive electrode. The bipolar system provides better consistency and uniformity of procedure and better impedance control.

Target temperatures are achieved in 4 min with the monopolar system versus 15 s with the bipolar system. Treatment time was reduced by 50% when compared to the monopolar TUNA system. Histological sections demonstrated macroscopically and microscopically similar lesions for the monopolar and bipolar system, but the bipolar device created a larger treated area per single lesion.

Transurethral microwave thermotherapy (TUMT) has also shown promise as a therapeutic modality for the treatment of BPH. This technique uses a microwave delivery system housed within a transurethral catheter. Its goal is to selectively destroy prostatic tissue without damaging the urethral mucus or structures surrounding the treatment area. At microwave frequencies, temperatures in the target tissue can be raised to as high as 45°C – 70°C without damaging periprostatic tissue. TUMT is used routinely worldwide.

Microwave balloon catheters for the treatment of BPH are currently being tested. With balloon catheters, it is possible to produce high therapeutic temperatures throughout the prostate gland without causing burning of tissues, and to produce biological stents in the urethra in a single treatment session. Compared to conventional microwave catheters, the distances microwaves have to travel through the prostate to reach the outer surface of the gland are reduced by the use of balloon catheters, as is the radial spreading of the microwave energy. Furthermore, compression of the gland tissues reduces blood flow in the gland and the local cooling caused by it. Also, since balloons make excellent contact with the urethra, much better than do conventional catheters, the urethra is well cooled by the cooling liquid and, therefore, well protected from thermal damage [71].

C. Microwave Balloon Angioplasty (MBA)

MBA, the first microwave application in cardiology, was developed with the ultimate goal of decreasing both acute and long-term restenosis risks [60], [61]. MBA, like percutaneous transluminal balloon angioplasty (PTCA), employs a balloon catheter that is advanced to the site of arterial stenosis. While PTCA uses only the pressure generated by balloon inflation to dilate the affected artery, MBA takes advantage of the volume heating properties of microwave irradiation. In MBA, a microwave cable-antenna assembly is threaded through the catheter, with the antenna centered in the balloon portion of the catheter. By heating the tissue as the balloon is inflated, it was hoped that a patent vessel would be created that would be resistant to both acute and chronic reocclusion. Early *in vivo* studies, at 2.45 GHz, were conducted to assess the effects of various energy levels upon normal and atherosclerotic rabbit iliac arteries. Research on the therapeutic potential was subsequently conducted on atherosclerotic rabbit iliac arteries using microwave energy to raise the balloon surface temperature to 70°C – 85°C . When compared to simultaneously performed conventional angioplasty, MBA at 70°C produced no significant results, as shown in Fig. 3(a). However, MBA at 85°C produced significantly wider luminal diameters both immediately after angioplasty and four weeks after the procedure [see Fig. 3(b)]. Further work, utilizing mongrel dogs with thrombin-induced coronary occlusion, has demonstrated the feasibility of MBA as a treatment modality for coronary

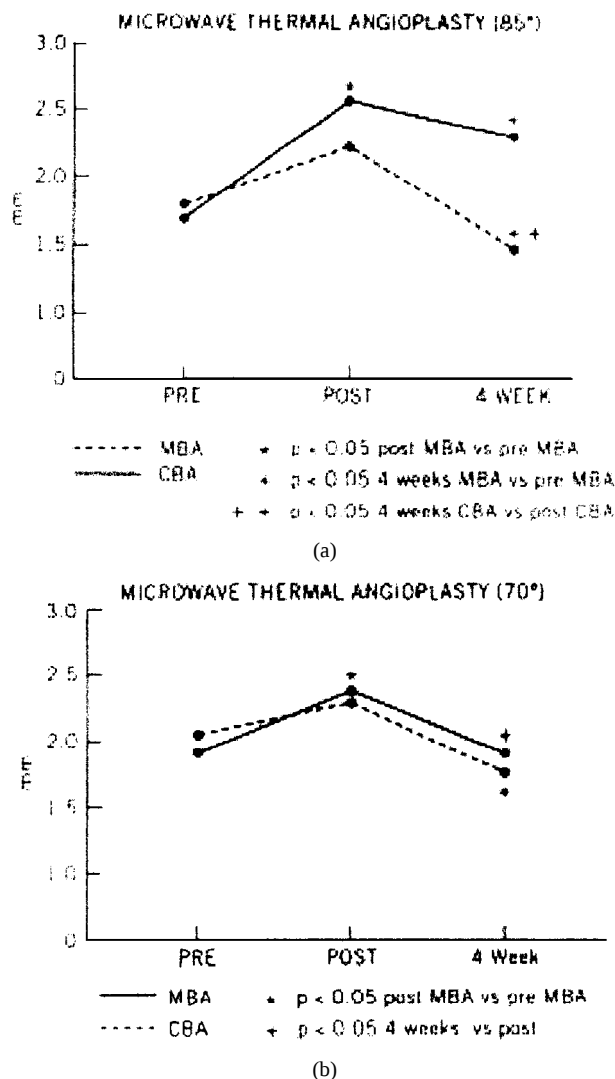


Fig. 3. (a) Microwave thermal angioplasty (85°). (b) Microwave thermal angioplasty (70°).

thrombosis. MBA of such coronary thrombi in dogs resulted in patent vasculature with the added benefit of an organized and stabilized thrombus. Although the technique described was successful in animal studies, it has not yet found its way into clinical use. However, the MBA is now being researched around the world for the treatment of carotid stenosis and occlusions in peripheral circulation and, lately again, as a procedure to reduce the rate of re-stenosis.

D. RF in the Treatment of Obstructive Sleep Apnea (OSA)

OSA is a disorder in which the sufferer's upper airway becomes intermittently blocked during sleep, creating an interruption in normal breathing. The therapeutic approach to OSA depends upon the frequency and severity of the symptoms. Weight loss may be sufficient to treat mild OSA cases, but further intervention is often needed. Dental appliances and ventilators [to provide continuous positive airway pressure (CPAP)] have both been effective at maintaining airway patency. However, these therapies are uncomfortable and suffer from low patient compliance rates (40%–70%). Surgical interventions attempt to provide an anatomical cure by excision of excessive tissues (uvu-

lopalatopharyngoplasty) or by maxillofacial surgery. Unfortunately, cure rates using these techniques have been between 30%–75% [8], [62].

Recently, Somnus Medical Technologies, Sunnyvale, CA, has developed an RF system (Somnoplasty), which uses needle electrodes to create precise regions of submucosal tissue coagulation. Thus, both the tissue volume and its resulting airway obstruction are reduced. Applicator probes have been developed to target specific tissues, including the base of the tongue. Somnoplasty is performed on an outpatient basis, under local anesthesia, and is expected to boast such benefits as immediate results, little postoperative edema or discomfort, and no permanent scarring.

E. Microwave Assisted Lipoplasty (MAL)

Lipoplasty is the most popular technique for body contouring in aesthetic surgery today. Suction lipectomy, or liposuction, is the term used by plastic surgeons to describe the surgical disruption and removal of subcutaneous adipose tissue by means of a cannula. A cannula is selected by its maximum diameter, ability to dissect through tissue and ease of fat removal. The deep fat layer offers minimal resistance to dissection and removal. However, since the superficial layer is fibrous and more vascularized, it is more difficult to penetrate and often bleeds. It was anticipated that using microwave volume heating would further enhance and benefit of the tumescent technique because the absorption of microwave energy by the wetting solution and the adipose tissue would result in fat liquefaction, thus easing its extraction. This should assist in the removal of more fibrous tissue from certain anatomic areas such as the back, flanks, and breasts [61].

Microwave liposuction (see Fig. 4) research involves two distinct areas, i.e., the development of the apparatus, including a new cannula system, which allows for the insertion of the microwave heating element (a coaxial cable terminated by an antenna), and the investigation of the microwave-aided liposuction technique, including variations in power delivery, temperatures reached, and length of time for RF/microwave energy delivery [63]. The microwave-enhanced liposuction system employed an approach used previously in our MBA. It is similar to the system now in use in human trials for treatment of BPH. Thus, the microwave-enhanced liposuction system used similar components. A standard Byron Accelerator Type III cannula (Tucson, AZ) was modified to hold the thin coaxial cable. The whip-type antenna delivers power at 2.45 GHz. The tip of the cannula, distal to the suction port, was replaced with a plastic dome to facilitate microwave transmission. In addition, a thermistor was secured near the tip of the antenna to provide temperature-measurement feedback during the procedure.

The histology analysis of the suctioned fat architecture revealed that the microwave-treated fat aspirate showed evidence of both thermal fat necrosis and viable adipocytes. Most important, the remaining adjacent fat revealed normal adipose tissue and there was no histologic evidence of dermal injury. The specimens treated with the highest power showed the most thermal damage. These findings suggest a direct correlation between increased power and thermal destruction, confirming a thermal mechanism for tissue destruction. In addition, we have shown

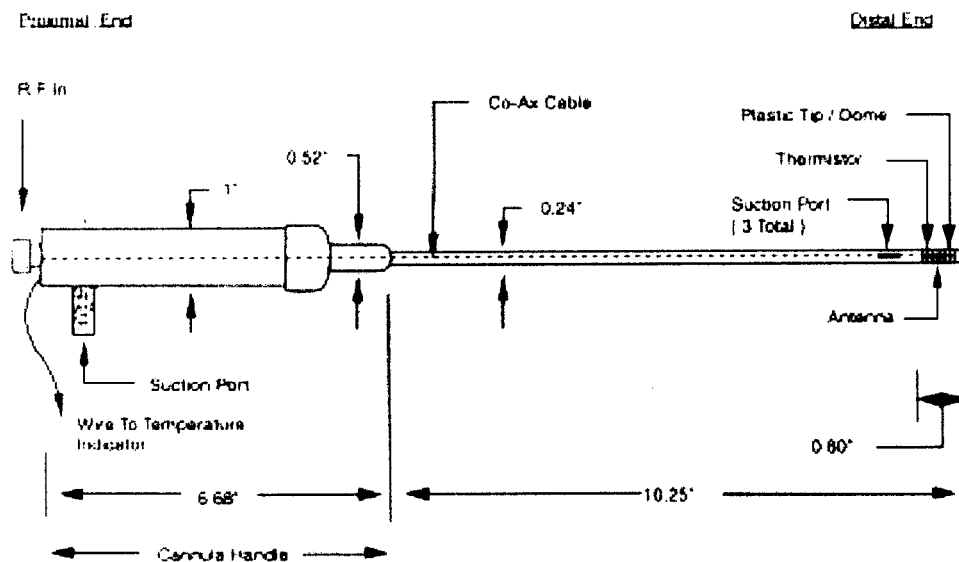


Fig. 4. Microwave-aided liposuction cannula.

that this is a very localized phenomenon, assisting in efficient removal of fat, and that it does not affect peripheral structures. These early histological findings show that no adjacent tissue is damaged and, therefore, selective removal of fat may be possible with MAL. Both the *in vivo* animal studies and the *ex vivo* human studies showed that MAL improves the ease of tissue removal by the cannula and decreases trauma to surrounding tissue, which minimizes blood loss. Comparative human studies will ultimately determine the relative efficacy of this promising new technology.

F. Nerve Ablation for the Treatment of Gastro-Esophageal Reflux Disease (GERD)

GERD is the result of retrograde flow of stomach contents into the esophagus. Heartburn, chest pain, regurgitation, voice disorders, and swallowing dysfunction can all occur as a result of stomach acid, bile, and digestive enzymes chronically refluxing into the esophagus and causing irritation. The lower esophageal sphincter (LES) is a muscular valve at the junction of the esophagus and the stomach, which normally prevents the reflux of stomach contents. However, the LES can weaken over time, or its effectiveness can become impaired when a hiatal hernia develops. If the LES and diaphragm are unable to provide sufficient force to adequately compress the gastro-esophageal junction, the patient experiences gastro-esophageal reflux. Such reflux may be present most of the day. In most patients with GERD, the LES may have a normal baseline tone, but relaxes inappropriately, thus causing the typical symptoms. Such transient lower esophageal relaxation (tLESR) accounts for 80% of reflux patients. In these patients, the stretching of the stomach, which is typical after a meal, triggers reflux. Distension of the stomach triggers stretch receptors, which transmit signals via the myenteric plexus of nerves located between the muscle layers of the stomach and esophagus. When the brain receives signals from these receptors, a signal is sent to the motor neurons around the LES, causing its relaxation. If this signaling system is working inappropriately, reflux is the result.

Triadafilopoulos *et al.*, [64] performed RF ablation on the stomachs of Yucatan mini-pigs, with the goal of disrupting the nerve pathways associated with tLESR, which run through the upper portion of the stomach (cardia) and the LES. Filling the stomach with carbon-dioxide gas creates distending pressure. By measuring the amount of pressure needed to cause LES relaxation (yield pressure), comparisons could be made before and after RF ablation. In all animals, yield pressures were found to be significantly higher after ablation, demonstrating that there was either a higher threshold for triggering the LES relaxation nerve reflex, or that transmission of the reflex to the brain was impaired.

G. RF Ablation of the Liver (Hepatic RF Ablation)

RF ablation continues to find minimally invasive applications to treat patients and save lives. In hepatic RF ablation, for example, tumors are thermally destroyed *in situ*, creating coagulation necrosis and protein denaturation. In many cases, RF ablation techniques are being utilized where radiation treatments and chemotherapy offer no curative options because the liver is not amenable to tumor resection due to tumor cells number and distribution are due to liver dysfunction. The RF ablation technique, in comparison to true resection, is focal in nature and, therefore, spares the normal liver, which results in lower patient morbidity.

The RITA Corporation, Mountain View, CA, has developed a controlled tissue ablation system to treat solid organ tumors using minimally invasive RF ablation [65]. The ablation equipment includes an RF generator and a family of electrodes. The controlled application of RF energy through an electrode placed directly in the tumor heats tissue to the required target temperature. Each electrode consists of a thin hollow stainless-steel shaft, which itself acts as a primary electrode and also allows the introduction into the tumor of a curved array of secondary electrodes. The secondary electrodes have temperature sensors mounted on the tips to provide temperature feedback. The RF generator delivers up to 50 W to destroy or ablate the tumor.

The operator sets the desired temperature. The ablative protocol consisted of heating each tumor to around 100 °C for at least 6 min; the generator automatically adjusts the power to attain the proper temperature and displays delivered power, impedance, and temperature.

Some of the unique features in treating solid tumors are as follows.

- *Minimally invasive*—many procedures can be performed through a laparoscopic or even a percutaneous approach, frequently on an outpatient basis.
- *Creates large volume of ablated tissue*—the current device can ablate a spherical area of approximately 3 cm, approximating the size and shape of many cancerous lesions.
- *Temperature feedback leads to predictability and controllability*—the system provides temperature feedback at the periphery of the ablation volume to confirm tissue destruction. It also provides impedance feedback, which can be used to guide the application of RF power in order to ablate the tumor.

It is worth mentioning that the technique described above is currently being tested for treatment of breast cancer.

H. Electrothermal Arthroscopic Surgery

The use of RF energy as an adjunct to arthroscopic surgery has recently been described for the treatment of shoulder, knee, and vertebral disk injuries. ORATEC Inc., Menlo Park, CA, has developed an electrothermal arthroscopy system, and has published widely on its applications [66]. The success of this electrothermal modality is based upon the ability of heat to either alter the properties of, or destroy, type-I collagen. Collagen is the principle component of ligaments and tendons. Type-I collagen is composed of a triple helix of molecules, held together by heat-sensitive hydrogen bonds. When these hydrogen bonds are broken, the helical structure is disturbed, and the molecules contract. The amount of contraction is proportional to the temperature and the duration of heating. Contraction of type-I collagen begins at approximately 60 °C. Up to 50% contraction has been reported at between 80 °C–90 °C. Furthermore, above 80 °C, collagen fibers melt and fuse, allowing for ablation, cutting, and contouring of collagen-based tissues [67]. Monopolar RF devices can provide both precise temperature control and predictable depth of penetration.

The ability of RF electrothermal energy to cause shrinkage of collagen tissues led to the first clinical application, i.e., the treatment of shoulder joint instability. Glenohumeral instability is one of the most common causes of shoulder pain in patients under 35 years of age. The ligaments, which anchor the upper arm to the shoulder joint (glenoid cavity), can tear as the result of traumatic subluxation or dislocation. Tearing or even stretching of these glenohumeral ligaments (the labrum) can result in recurrent dislocation. Recurrent instability of the shoulder joint significantly affects a patient's daily life, and precludes participation in sports [68]. Open surgical procedures, which had once been the traditional therapy, involve reattachment of the torn labrum, and restoration of tension to stretched ligaments. While this procedure has a high success rate at stabilizing the joint,

it is associated with significant loss of overhead range of motion. Thus, a return to aggressive sport activity is still impaired. Laparoscopic techniques, which only repair the capsulolabral detachment, result in high rates of continued subluxation. For an arthroscopic procedure to be successful, it must address the loss of tension in the joint capsule as well. As reported by several investigators, RF electrothermal energy has been successful at shrinking the tissues of the ligamentous joint capsule and, thus, increasing the tension on these ligaments and stabilizing the shoulder joint [69], [70].

Malleable RF probes are also finding uses in the treatment of knee disorders, anterior cruciate ligament instability, and chronic low back pain, to mention just a few.

V. CONCLUSIONS

In this paper, we have reviewed a few of the existing applications of RF/microwaves in medicine. In medical diagnosis, significant progress has been made in imaging. It has been facilitated by progress in numerical methods applied to electromagnetics and modern computers. Nevertheless, at this time, these techniques are not competitive with more established imaging methods. Detection of breast tumors appears highly promising, particularly the methods that use pulsed confocal systems. Several therapeutic applications have been highlighted. A more detailed discussion of some of the topics can be found in [8].

ACKNOWLEDGMENT

The author, A. Rosen, wishes to recognize the assistance and advice of many who, since the early 1980s, have participated in research in the areas of RF/microwaves in medicine, some of whose research was covered in this paper. These individuals are: from Jefferson Medical College, Dr. P. Walinsky and Dr. A. J. Greenspon; from MMTC, Dr. F. Sterzer and D. Mawhinney; from Temple University, Dr. W. Santamore; from the University of Pennsylvania, Dr. L. P. Bucky. The authors also extend their gratitude to J. Hendrick, formerly of VidaMed Inc., H. Sharkey of ORATEC Interventions Inc., and B. Cheskin of RITA Medical Systems Inc., who were so kind to furnish some of the material; and to W. Janton for his technical skills and invaluable support. Finally, recognition is due to D. Rosen for her contribution to the research on microwave assisted liposuction, and for revising this paper's manuscript. The author, M. A. Stuchly, thanks Dr. E. Fear for providing some of the information on diagnostic applications and D. Shannon for help with the editing of this paper's manuscript.

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