MICROWAVES IN SURGERY: METHOD AND RESULTS

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Abstract: The design of new devices using 2.45 GHz radiation to produce thick eschars for coagulation in surgery of highly vascular organs is described. Twenty-two patients have been treated to date in FDA clinical trials; results in ten cases at Baystate Medical Center are detailed.

INTRODUCTION

Microwave energy can be effectively employed to control hemorrhage during surgery of large, highly vascular organs such as the spleen and liver (1) and serve as a cautery during certain other procedures in which excessive bleeding endangers the patient. The principal advantage of microwave devices, in comparison with other devices, such as the radio-frequency Bovie coagulator and laser coagulators is that microwave energy penetrates to relatively large depths (3-4 mm.) with sufficient energy to create a thick eschar which effectively seals the surface, resists seeping, and serves as an anchor for ligatures. Moreover, coagulation can be achieved even though the radiating element is submerged in flowing blood.

Other advantages of the microwave system include the relative simplicity, portability, and low cost of the microwave system required. Because 2.45 GHz is an appropriate frequency of operation for this application, microwave oven magnetrons can be employed as the power tube. The power levels available from these tubes also meet the requirement for approximately 200 Watts needed in these systems. The microwave energy is transmitted (Figure 1) from the generator through a special low-loss (1.5 db) 8-ft. flexible cable to an 1/8" semi-rigid coaxial waveguide in the haft of the device wielded by the surgeon. The surgeon turns power on and off using a foot pedal controlling a triac switch which commands the line voltage input to the magnetron high voltage transformer. The surgical devices and cable can withstand autoclave sterilization procedures; in practice the surgeon passes one end of the cable out of the sterile field for connection to the generator and connects the devices to the cable at the other end using the bayonet connectors.

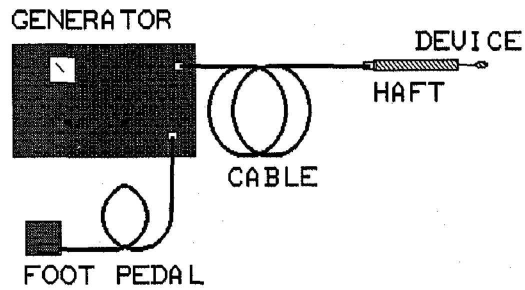

Figure 1

The microwave generator is a small (10"x12"x14") unit weighing 35 pounds. The unit largely employs standard microwave oven parts with the addition of a waveguide-to-coax transition to permit coupling to the cable, and a separate filament transformer. Because the standard oven magnetrons supply considerably more power than desired at full voltage, an expedient method of reducing the power is employed in the prototype: a variac is used to reduce the line voltage input to the high-voltage transformer. An inherent safety feature of the microwave device is that the radiators are matched to tissue. When the devices are removed from tissue, the resulting mismatch reflects about 99% of the energy back to the generator. To prevent overheating, a "watchdog" circuit in the generator monitors the reflected power and turns the generator off after three seconds of high mismatch. The surgeon may restart the generator by releasing and reclosing the foot-pedal switch (3).

DEVICES

Three devices have been designed and employed in this application. Each is a form of miniaturized loop radiator matched for 2.45 GHz microwave transmission into tissue.

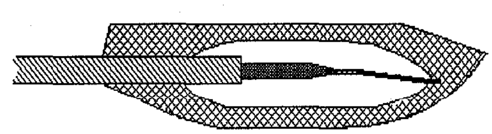

Figure 2

X

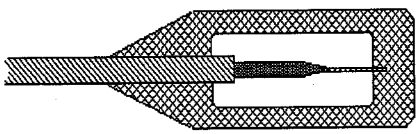

Figure 3

(In the original form, the radiator consisted of a single loop encompassed in an ordinary surgical scalpel blade.) A modified design consisting of a double-loop radiator has been found to be superior and is illustrated in Figure 2. This double loop configuration is also used as a radiator included in a dull-edge dissecting tool which is used to separate soft tissue without cutting large vessels (radii greater than 2-3 mm.) which cannot be coagulated by the fields. In using the scalpel and the dissecting tool, which is illustrated in Figure 3, as the surgeon cuts, coagulation is achieved on both sides of the blade. It has been found useful to have the devices coated with teflon to reduce adhesion of char to the blade or dissecting tool. (Only a "soft" teflon coating is possible since the hard coatings require the use of oven temperatures exceeding the melting point of even the hard solders.) This solution does not completely eliminate this problem; char is built up on the device over several minutes of use and the surgeon may either change the handle/device, or simply scrape off the char, as is often done with a Bovie. The device construction is hardy enough to withstand scraping with an ordinary scalpel, for example.

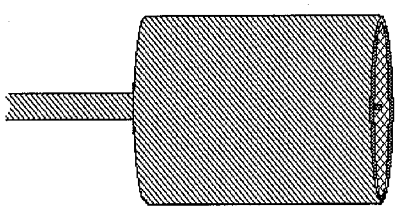

Figure 4

The third new device is a surface coagulator consisting of a loop/cavity radiator, employed for coagulation of flat surface regions which are not conveniently treated by the other devices. The configuration is illustrated in Figure 4. This applicator has been used, for example, in spot coagulating sites on organ stumps, or on the sides of wedge cuts. Its effect is to produce a coagulated area about one centimeter in diameter.

The microwave devices described in this paper have been employed successfully in twenty-one surgical procedures as an FDA-approved investigational device. Nine of these procedures were carried out Baystate Medical Center. These cases included operations on the liver and spleen and control of hemorrhage in the pelvic region. The design of these devices has been based on relatively simple principles and specifications plus considerable trial and error. The loops in the scalpel and dissecting tool are approximately a wavelength (in tissue) in circumference and are designed to produce a VSWR less than 1.5 when fully immersed. This modest requirement can be achieved without any special matching devices and is sufficient to achieve a power reflection coefficient of less than 4%. Of course, full efficiency is only sporadically attained in use, since the media surrounding the device is quickly converted to eschar. A brown "mud" is seen bubbling from the area; the color is probably the result of the denaturation of haemoglobin.

In general, the use of the microwave system and the devices requires only minimal training. Surgeons quickly grasp the essentials of its functioning. Probably the only impediment is the minor one that the uninformed user invariably tries to employ the device as usually done with the RF Bovie electrosurgical tool, which functions from outside the tissue. Also, because the Bovie RF energy is concentrated at the tip of the spark, it can cut effectively, blowing cells apart. The microwave energy is spread over a much larger volume; it is relatively ineffective in this respect and cutting (not coagulation) depends on mechanical action. For this reason, the surgeons who have used the device have found it more convenient to employ a Bovie (or an ordinary scalpel blade) to provide the initial cut through the tougher organ capsule.

The user safety aspects of the devices have been carefully investigated. Mismatch of the loops to air provides inherent protection against microwave radiation exposure of operating room personnel. In the worst case that we have been able to devise, the blade or dissecting tool is covered by about one millimeter layer of tissue which partially removes the mismatch but still permits some radiation through the layer to escape. Even in this case, however, the present radiation exposure standards are met provided that a one-inch distance is maintained from the blade. Although surgical gloves provide about a 50% safety advantage, we have advised surgeons to keep fingers at least that distance from the radiators, and to avoid bringing metallic instruments close to the loops. Video recordings of a number of procedures have shown, however, that these precepts have been occasionally ignored, so far without ill effect.

CLINICAL TRIALS

The microwave scalpel was first tested in a series of partial splenectomies in dogs. It was found that the device produced a dry coagulum measuring 4-5 mm. on the surface.

Post-operative examinations of the results showed that resorption of the eschar occurred over a seven-to-eight week period. Post-operative radionuclide scans show normal functioning of the organs. It was also found that the presence of the eschar did not adversely affect survival when microorganisms were introduced into the operative field (2). On the basis of the successful animal trials, evaluation of the device in humans has begun. Trials have been made at Baystate Medical Center, Mount Sinai Hospital (New York City), the University of Rochester Medical Center, and the University of Maryland Hospital. At Baystate Medical Center, two preliminary clinical trials of the microwave devices involved two patients, ages 71 and 73. These patients underwent partial splenectomies using the microwave system, prior to inclusion of the spleen in a resection of the pancreatic tail for malignant tumors. Hemi-splenectomy was rapidly accomplished in each case, resulting in a dry resected surface. (Long-term follow-up for bleeding was not available because the remaining spleen was removed as part of the planned pancreatic procedure. The results of seven complete later trials at Baystate Medical Center are tabulated sequentially below.

MICROWAVE SURGERY CLINICAL RESULTS; BAYSTATE MEDICAL CENTER

Patient Age	Site	Results
58	Spleen	Salvage
72	Spleen	Initial salvage, spleen lost to new tear
71	Liver	Rapid transection
78	Liver	Rapid transection
71	Liver	Rapid excision of multiple metastatic foci
95	Pelvis	Control of hemorrhage
43	Liver	Rapid excision of multiple metastatic foci

Both cases of splenic injury resulted during the course of colon resection for carcinoma. In the first patient, a 58-year old male, quick control of rapid bleeding was obtained despite cirrhosis with mild hypertension. In the second patient, a 72-year old female with a 10 cm. carcinoma attached to the abdominal wall and stomach, splenic bleeding was initially controlled by the microwave system; however, a second tear was made in the spleen during later re-positioning. Because of the prolonged character of the operation, which included partial colectomy, partial gastrectomy, and resection of a portion of the abdominal wall, splenectomy was carried out. Both patients are alive and well. Postoperative radionuclide scan of the salvaged spleen shows normal function. Splenic salvage has received increasing attention over the last decade as surgeons have become aware that removal of the entire spleen leaves the patient with a potentially fatal vulnerability to otherwise minor infections (post-splenectomy sepsis).

Four patients underwent resection of liver tumors. The first of these patients underwent left lateral segmentectomy for a primary hematoma; hemostasis was excellent despite the presence of cirrhosis. The patient made an uneventful recovery but developed a new tumor eight months later. This tumor was identified as a new primary, rather than a recurrence of the disease; the patient subsequently committed suicide. The second patient underwent a subsegmental resection of an 8 cm. hemangioma on the right lobe of the liver; excellent hemostasis was obtained using the microwave dissecting tool although it was necessary to ligate two large vessels within the base of the liver wound. Because of the use of the blunt microwave instrument, these vessels were easily identified and ligated before they were injured. The patient made an uneventful recovery.

The third and fourth liver patients underwent resection of seven and six separate hepatic metastases, respectively. (Metastatic tumors of the colon appear most frequently in the liver and their surgical removal is a difficult procedure made dangerous by the possibility of uncontrollable bleeding.) Use of the microwave dissecting tool allowed rapid removal of the multiple lesions with minimal blood loss in these cases. The first patient made an uneventful recovery without evidence of fever or other postoperative complications. The second patient also recovered successfully after experiencing a mild postoperative fever.

One patient was treated for massive pelvic hemorrhage which followed abdominalperineal resection. This patient was a 95-year old male who had undergone the resection after failing radiation therapy to control a large rectal cancer; early in the post-operative period, he was noted to have brisk pelvic hemorrhage and was returned to the operating room. It was not possible to control the bleeding with packing or ligation. At this point the microwave system was used, with ultimate control of the hemorrhage. The patient recovered and showed no recurrence of the disease two years later.

In addition to the two preliminary trials and the seven complete trials listed above, another trial of the microwave system was discontinued as a result of a microwave equipment problem, later identified as due to a faulty power switch. This trial involved a 59-year old patient who underwent resection of four hepatic metastases. The operation was concluded using standard techniques and the patient remains disease free seven months later.

DISCUSSION

Tabuse (4) originated the idea for microwave transection of liver tissue, working originally with rabbits. His technique consisted of the production of a series of charred holes across the intended transection plane, using a needle antenna. The latter consisted of a simple open-ended coaxial line with the inner conductor extended a short distance. Transection was then accomplished by division through the sequence of charred punctures. He has more recently reported (5) on the successful extension of this technique in more than fifty major hepatic resections. Although the procedure is cumbersome, it has proven effective in keeping blood loss in the range of 1000 ml. and replacement in the range of 500 ml. during a major resection. Prolonged postoperative fever was observed in 21% of the patients and bile leaks developed in 13%.

The idea of linking a microwave radiator to a scalpel blade developed as an attempt to streamline Tabuse's instrument to provide continuous charred transections. It provides good control of bleeding, without clamping of major veins and arteries. The loop radiator provides a more uniform coagulating field and a well-matched configuration. Because of the equation of current/charge continuity, there is no current and effectively no radiation from the needle tip, the coagulation is heaviest at the base of the needle and light at the bottom of the puncture. This situation is greatly alleviated in the loop design where current persists over the entire loop. The devices described in this paper represent variations on this basic idea.

To a large extent the microwave scalpel system uses conventional microwave oven technology. However, in a few respects the system does stretch available technology to its limits. These are in the low-loss high-power capability of the light-weight flexible cable that is required for clinical application and in the power-handling capability of the small-diameter semi-rigid coaxial waveguide and connectors. In general, the surgeon desires the highest power setting available in order to increase the speed of coagulation. The available components do provide sufficient coagulation power, but improvements in the performance of these components will permit more rapid performance.

Medically, the particular advantage offered by the microwave system described in this paper is that it provides coagulation in depth. This advantage also implies that the system cannot be employed in situations in which the surgeon cannot permit the destruction of a relatively thick (3-4 mm.) layer of tissue, even though it provides rapid, secure coagulation. Conversely, it does offer significant advantages in the surgery of large, highly vascular organs and other regions in which dangerous hemorrhage can occur, or in trauma situations in which the coagulating power of the microwave devices is required.

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