

3.25 W/kg in the muscle. Therefore, an input power of 50 W is sufficient to produce an SAR between 150 W/kg in the muscle, an SAR that is more than adequate for typical clinical use.

Fig. 18 illustrates thermographic measurements made in the tissue model after it is heated by the applicator. The patterns closely resemble the ideal patterns obtained with the radome-covered TE₁₀-waveguide source that is illustrated in Fig. 9. Thermographic results of additional testing of the applicators associated with clinical use are discussed in detail in the companion paper [8].

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Evaluation of a Therapeutic Direct-Contact 915-MHz Microwave Applicator for Effective Deep-Tissue Heating in Humans

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Abstract—A 13-cm square direct-contact microwave applicator which operates at 915 MHz was evaluated in tissue models and human volunteers to determine its therapeutic effectiveness. It was found that the applicator with radome- and forced-air cooling selectively elevates temperatures in muscles (1-2 cm) to 43-45°C. At this higher range of temperature, certain physiologic responses such as an increase in blood flow are produced. The applicator may also be used to heat malignant tumors of muscle.

I. INTRODUCTION

IT HAS BEEN demonstrated that microwave radiation at 915 MHz can produce local vigorous therapeutic

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responses when used clinically to heat deep tissue [1]. In the clinical use of diathermy, it is essential that the highest temperatures in the distribution occur at the anatomical site to be treated. Thus the heating modality to be used—which may be microwave, shortwave, or ultrasound energy—and the technique of application must be selected according to the specific site of pathology to be treated and heating pattern desired [1]. These criteria are well documented for therapeutic application in the realm of rehabilitative medicine [2]. It is also likely that these heating modalities will be useful in treating cancer.

To ensure that vigorous physiological responses are elicited, temperatures on the order of 43-45°C must be produced in the tissue. When these temperatures are pro-

duced, increased blood flow is usually triggered, causing a decline in tissue temperature despite an unchanged rate of energy absorption in the tissues. Thus the occurrence of blood-flow changes demonstrates that therapeutic temperatures have been achieved [3], [4].

It has also been demonstrated that these temperatures should be achieved when heat and stretch are used in combination to produce an increase in the extensibility of collagenous tissue in the treatment of contractures [5], [6]. Hyperthermia with temperatures of 43–45°C has also been used in conjunction with radiation and chemotherapy for treatment of cancerous tumors [7]–[9].

Microwave energy is selected as the modality of choice when its heating pattern in tissue causes the highest temperatures to be produced at the site of pathology. From assessment of the electrical properties of tissues and the selective absorption and reflection of microwave energy in tissue and at tissue interfaces, it was found that microwaves are most useful for selectively heating muscle [10]–[14]. That such selective muscle heating with microwave energy in human tissue is effective has been demonstrated by deLateur [15]. The optimal frequency range was also determined [16]; however, within this range, only one frequency (915 MHz) is presently available in this country for medical and scientific use because of FCC regulations.

The distribution of temperatures produced by microwave radiation is also modified by the preexisting distribution of temperature in human tissue, i.e., warmer at the core and cooler on the outside. This distribution is further modified by changes in blood flow produced by the therapeutic agent.

II. PURPOSE

The purpose of this study was to evaluate a new direct-contact microwave applicator to determine the temperature distributions produced in tissue models and in the anterior thigh of human volunteers. The distributions were determined from the skin surface through subcutaneous layers of fat and muscle to the bone. The applicator was tested to determine whether it could readily raise and maintain the tissue temperature in the therapeutic range (40–45°C). A determination was also made of the rate of energy absorption required to achieve these desired temperatures. The effects of physiologic factors such as the initial distribution of temperature in tissues and changes in blood flow triggered by microwave radiation were also studied.

III. METHODOLOGY

The applicator tested was a 13-cm square direct-contact 915-MHz microwave applicator with stripline feed [17]. It was designed by A. W. Guy to produce an even temperature distribution with the highest temperatures in the muscle. A lightweight dielectric matching material was used which was porous and allowed for air flow (2.5-cm thick Echo foam, HiK Flex Dielectric, 4.0). The applica-

tor housing was equipped with an air inlet so that cooled air could be passed through the applicator onto the skin surface to cool the skin and immediately underlying subcutaneous tissues.

The applicator was first tested on a plane parallel-layered model which had 2 cm of fat equivalent over 10 cm of muscle equivalent. The model, measuring 30×30×12 cm, was irradiated with the *E* field parallel to the plane of separation. Thermographic scanning of the split surface was performed 5–10 s after irradiation.

The applicator was then tested on a thigh model of subcutaneous fat, muscle, and bone, which was previously described [18], [19]. Three models were used, with fat layers of 0.5, 1.0, and 2.0 cm, respectively. The models were irradiated with microwaves for 15 s at an average power input to the applicator of 520 W. Based on results obtained from the experiments on models, design modifications were made on the applicator before human subjects were used.

In the human experiments, seven volunteers who had subcutaneous fat layers < 1 cm participated along with six volunteers whose subcutaneous fat layers were ≥ 2 cm. Before each experiment was conducted, the location of the fat–muscle interface and the thickness of the subcutaneous fat layer of the anterior thigh were determined by roentgenography. The volunteers, who were given neither local nor general anesthetics, were surgically scrubbed over the area of needle insertion and were placed in a prone position on a special table constructed without metal parts. A sterilized needle guide fabricated from phenolic and Rexolite plastics was placed against the lateral aspect of the middle third of the thigh. The configuration of this needle guide is similar to that previously described [20]. Sterilized thermistor probes which had previously been tested and calibrated were used to measure tissue temperatures. To facilitate smooth insertion of the thermistor probes, a stab incision was first made with a 15-gauge cutting needle through a hole in the needle guide. The needle was withdrawn, and a sleeve was placed in the needle guide hole to reduce the gauge to 20. Then, a 20-gauge Teflon catheter, stiffened by a trochar, was inserted into the tissue. X-rays were taken to verify the positions of the probes in the tissues. The trochars were then withdrawn and the thermistor probes were inserted into the catheters. The thermistor probes were aligned vertically in the area of peak intensity of the applicator from the superficial tissues to the periosteum of the middle third of the thigh. Temperatures were recorded continuously on an oscillograph recorder before, during, and after exposure to microwave radiation. Immediately after each exposure, the thermistor probes were calibrated.

The probes, which were designed to minimize disturbances in the field, were carefully oriented parallel to the magnetic field. This was done to minimize induction of high-frequency currents. When testing the probes at 915 MHz under the conditions of the experiment [21], they were found to be accurate within ± 0.2°C.

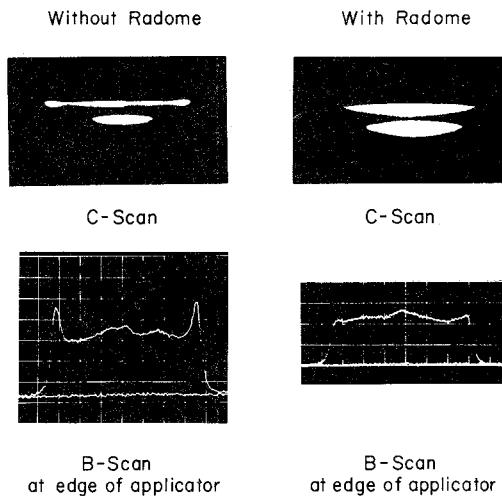


Fig. 1. Thermographs produced with a 13-cm square direct-contact microwave applicator operating at 915 MHz with and without radome on plane layered model.

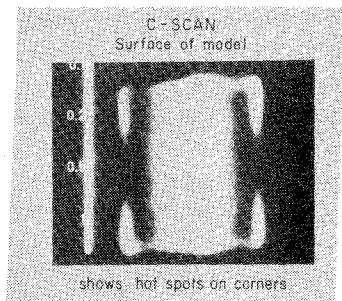


Fig. 2. C scan of the surface of a plane parallel-layered model after exposure with a 13-cm square direct-contact microwave applicator operating at 915 MHz without radome.

IV. EXPERIMENTAL RESULTS

The applicator was first tested with the plain parallel-layered tissue model. The results of the test are shown in Figs. 1, 2, and 3. The applicator was placed in direct contact with the tissue model, first with and then without the radome. The models were then placed in front of the thermographic camera for display and recording of the distribution of heat produced in the models after microwave radiation. The C scan shows the total heating pattern within the model, while the B scan shows surface heating at the edge of the applicator. (See Figs. 2 and 3.) It can be seen that the use of the radome, without forced air cooling, significantly reduced the hot spots at the corners of the applicator.

The radome consisted of 4-mm Rexolite drilled with a matrix of holes terminating in grooves that allowed cooled air to flow along the surface of the skin. To equalize surface temperatures across the skin, hole spacing was closer at the center of the radome and at the corners [17].

Fig. 4 shows thermograms of the plain parallel-layered tissue model at various depths after a 15-s exposure. The applicator was used with radome and cooling as previously described. It can be seen that the highest temperatures in the distribution occurred along the centerline of the applicator just beneath the skin and at the muscle-fascia interface.

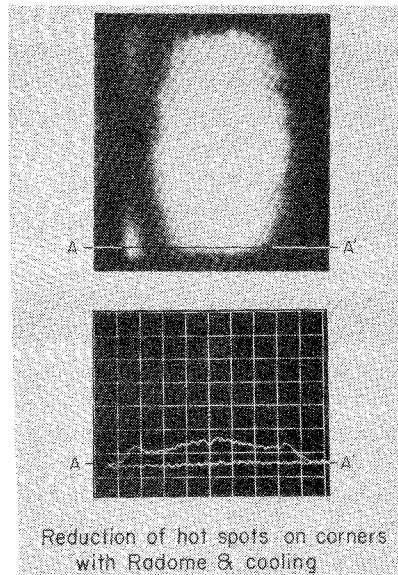


Fig. 3. C and B scans of the surface of a plane parallel-layered model after exposure with a 13-cm square direct-contact microwave applicator operating at 915 MHz with radome and cooling.

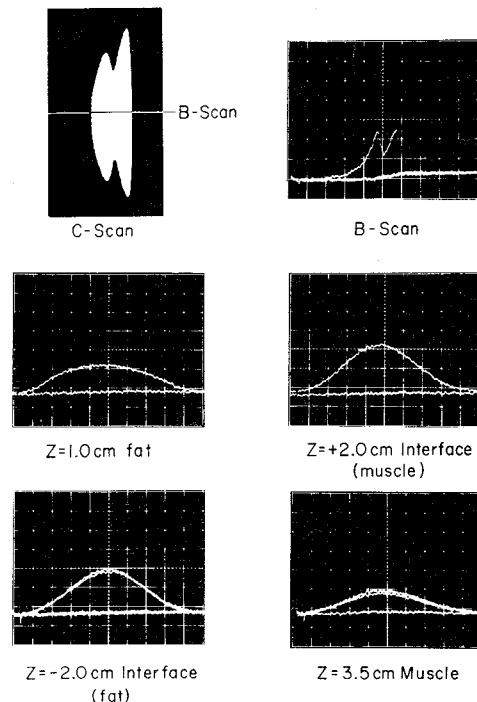


Fig. 4. X-Z plane thermograms taken of a plane parallel-layered model with a fat thickness of 2.0 cm after exposure to a 13-cm square direct-contact microwave applicator operating at 915 MHz with radome and cooling.

The applicator was next tested with the three models of the human anterior thigh as previously described. The model shown in Fig. 5 had a 2-cm fat-layer thickness, a 3-cm muscle layer, and a 3-cm bone thickness. The isotherms and B scans were calculated and plotted by an on-line computer connected to the thermograph. Fig. 6 shows the isotherms when the applicator was used with the radome without cooling. The temperature distribution shows a marked peak in the subcutaneous fat.

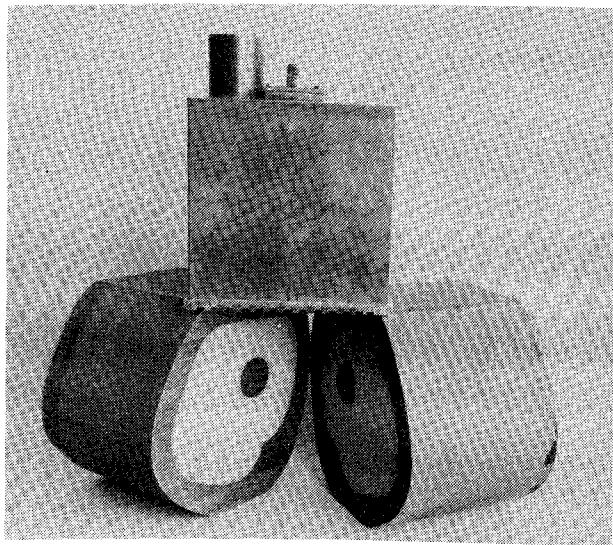


Fig. 5. Phantom thigh model with 13-cm square direct-contact microwave applicator with radome.

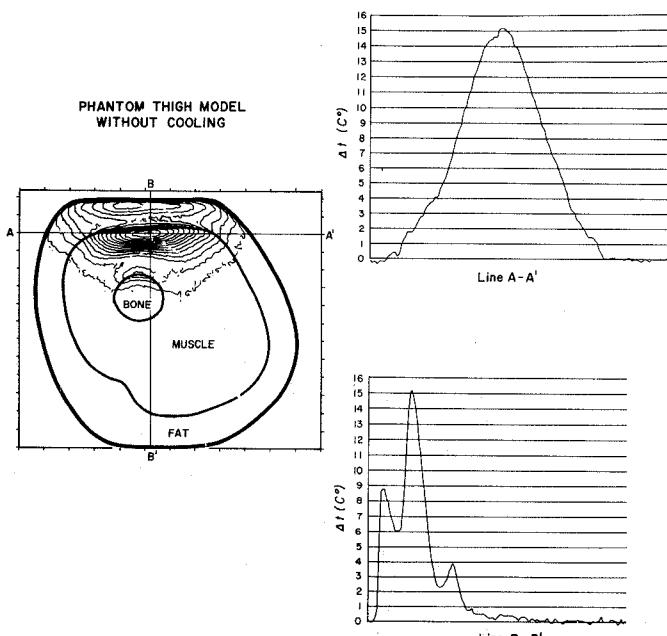


Fig. 6. Isotherms produced in the phantom thigh model after exposure to a 13-cm square direct-contact microwave applicator operating at 915 MHz with radome and without cooling.

When the run was repeated with cooling, as shown in Fig. 7, the temperatures produced in the subcutaneous fat were significantly lower. In both of these tests, a secondary peak of temperature occurred at the muscle-bone interface. This peak, which resulted from energy reflected at the interface, was not noticeable in thigh models which had more than 6 cm of simulated muscle.

From these experiments with tissue models, it was concluded that the applicator produces significant heating within the musculature, that a radome is necessary to prevent hot spots in the superficial tissues, and that air cooling is necessary to prevent excessive heating of superficial tissues.

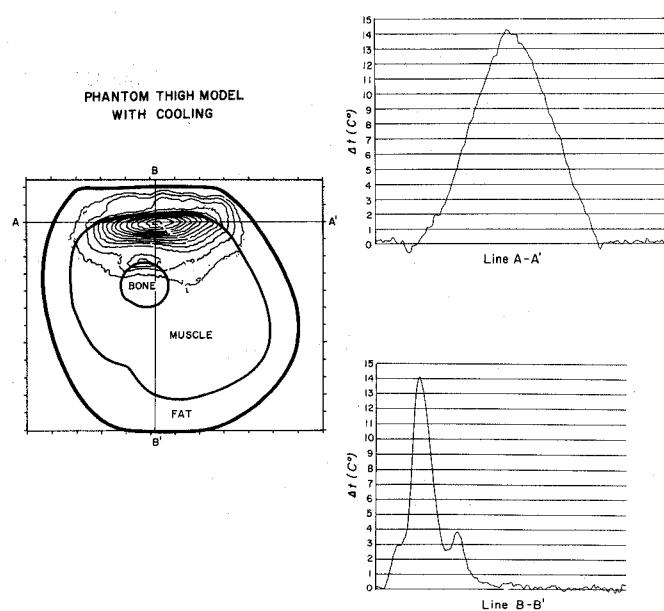


Fig. 7. Isotherms produced in phantom thigh model after exposure to a 13-cm square direct-contact microwave applicator operating at 915 MHz with radome and cooling.

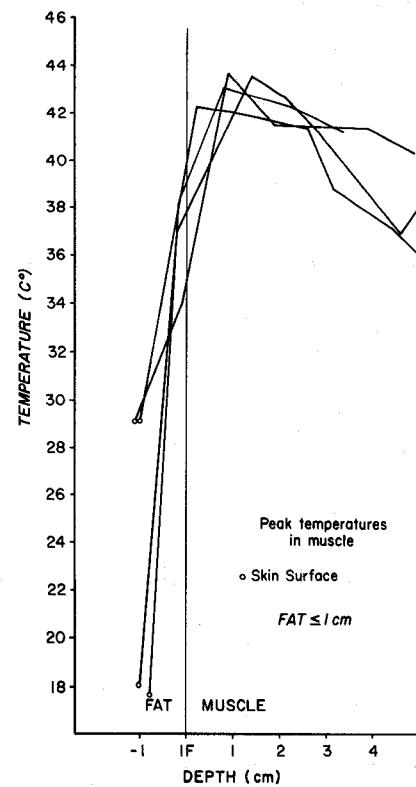


Fig. 8. Temperature distribution in all volunteers with < 1 cm of subcutaneous fat after an average of 6.5 min of microwave application with the 13-cm square direct-contact microwave air-cooled applicator operating at 915 MHz.

The applicator was then tested on human volunteers who were divided into two groups, the first having an anterior thigh fat layer ≤ 1 cm, and the second having a fat layer ≥ 2 cm. The thermistor probes were inserted as previously described. The subjects were then irradiated

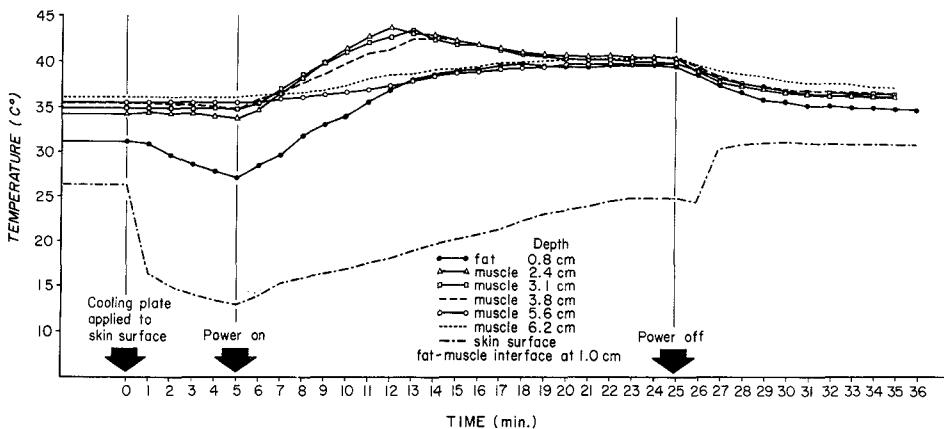


Fig. 9. Temperatures at various tissue depths in one individual before, during, and after exposure to microwave application with a 13-cm square direct-contact air-cooled microwave applicator operating at 915 MHz.

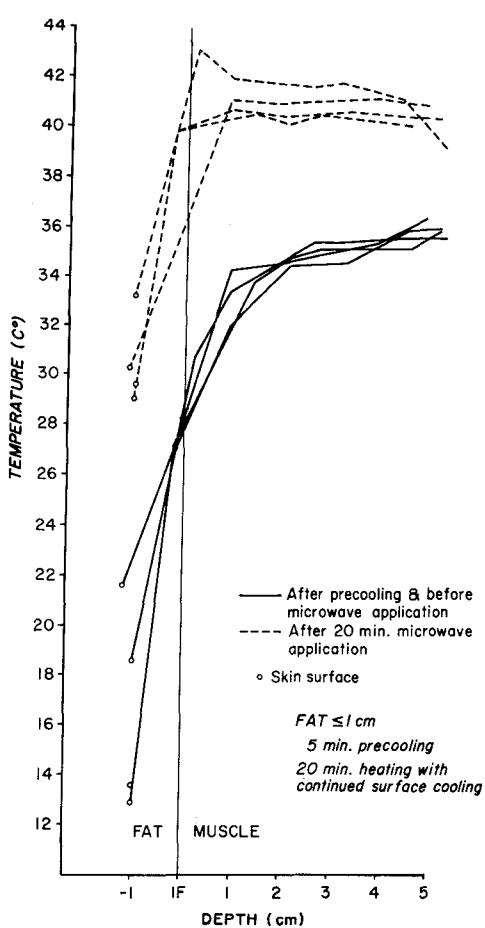


Fig. 10. Temperature distribution in all volunteers with < 1 cm of subcutaneous fat before (—) and 20 min after (----) microwave application with 13-cm square direct-contact air-cooled microwave applicator operating at 915 MHz.

with the radome in place, with and without cooling. It was found that when cooling was not used, none of the three volunteers in the first group could tolerate more than 5 min of the planned 20-min exposure; concurrently, temperatures reached or exceeded the upper limit of the therapeutic range (45°C). The highest temperatures occurred in the muscle, 0.5–0.6 cm from the fat–muscle

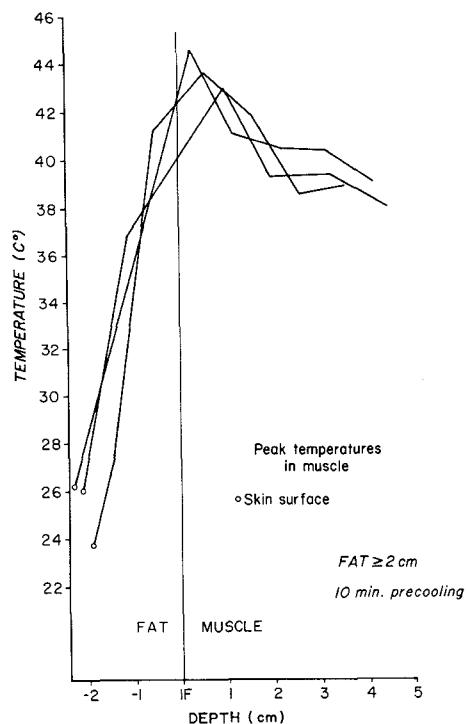


Fig. 11. Temperature distribution in all volunteers with ≥ 2 cm of subcutaneous fat after an average of 10 min of microwave application with the 13-cm square direct-contact air-cooled microwave applicator operating at 915 MHz.

interface, and a sharp temperature drop was observed in deeper muscle. All of these subjects complained of surface and deep-muscle pain which was referred to the region of the knee. When cooling was used, with identical net power levels, a 20-min exposure was tolerated by all four volunteers. No pain necessitating discontinuation of treatment was reported. Peak temperatures produced in the muscle are shown in Fig. 8. These temperatures occurred at an average time of 6.5 min after onset of radiation. Fig. 9 gives a complete thermal distribution for one subject, showing all temperatures recorded and the timing of the experimental procedure. In this case, the peak temperatures occurred 7 min after onset of radiation. After this time, the increased flow of blood caused temperatures in

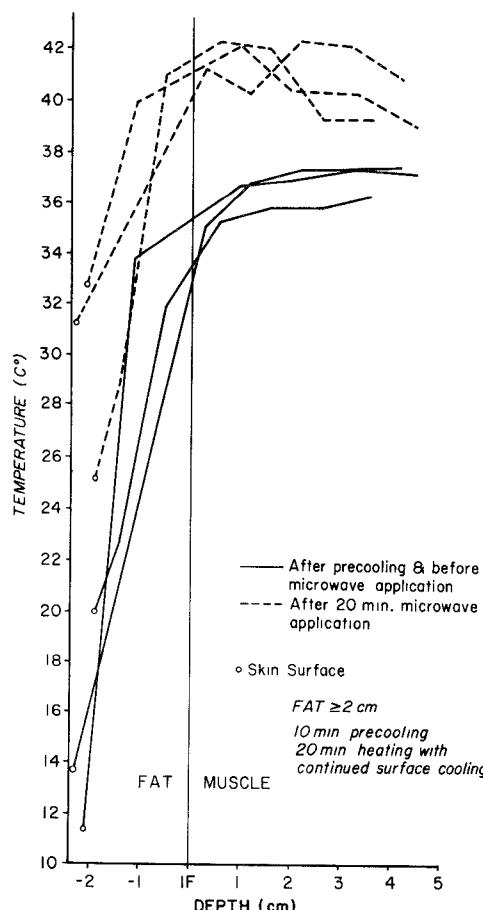


Fig. 12. Temperature distribution in all volunteers with ≥ 2 cm of subcutaneous fat before (—) and 20 min after (----) microwave application with the 13-cm square direct-contact air-cooled microwave applicator operating at 915 MHz.

the tissue to decline despite unchanged power input. At the end of the 20-min treatment, the temperatures throughout the muscle tissue had stabilized at a therapeutic level. The final temperatures after 20 min of treatment for the ≤ 1 -cm fat subjects are shown in Fig. 10. The temperature curves in muscle are more uniform when cooling is used because of the cooling produced by blood flow.

The three volunteers with a thicker layer of fatty tissue were then tested in the same manner. Again, when cooling was not used, the subjects were unable to tolerate a 20-min treatment because of the higher temperatures produced at the skin surface. Again, the upper limit of therapeutic temperatures was reached or exceeded (45°C). Peak temperatures occurred on the skin surface, causing pain at this site. When cooling was used, the peak temperatures occurred at an average time of 10 min from onset of radiation (Fig. 11). The final distributions of temperature in the three volunteers that were cooled are shown in Fig. 12. Thus with cooling, excessive heating of the skin was prevented and effective heating of muscle was achieved. Once again the distribution of temperature was more uniform.

A schematic heating curve for human tissue is shown in Fig. 13. The rate of energy absorption can be calculated

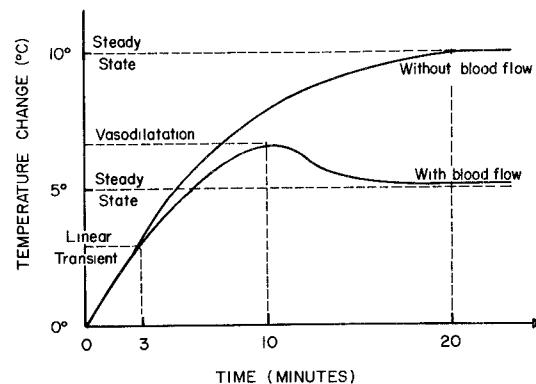


Fig. 13. Schematic representation of transient and steady-state temperature for a typical tissue under diathermy exposure.

TABLE I
FORMULA FOR CALCULATION OF ABSORBED POWER

MASS-NORMALIZED RATE OF ENERGY ABSORPTION = SPECIFIC ABSORPTION RATE (SAR)	
$W_a = \frac{k \cdot c \cdot \Delta T}{t}$	
W_a	Watts/kg
k	4.186×10^3 (Joules/Calorie)
c	specific heat - kcal/kg $^\circ\text{C}$
ΔT	$^\circ\text{C}$
t	time (sec.)

TABLE II
CALCULATED VALUES OF ABSORBED POWER IN HUMAN MUSCLE

SPECIFIC ABSORPTION RATE (SAR) in W/kg ¹ in MUSCULATURE (1-2cm)	
RUN	SAR
1	121.60
2	78.17
3	118.70
4	75.27
5	167.93

¹ at 555.55 mW/cm² maximum power density of incident radiation.

from the slope of the initial transient according to the formula taken from Table I ($W_a = k \cdot c \cdot \Delta T / t$) [22]. Typical specific heats for human muscle and fat tissue are 0.86 and 0.30 kcal/kg $^\circ\text{C}$, respectively [23]. By using this formula, the rate of absorption was calculated for five subjects who participated in the experiment. These data are shown in Table II. The power levels were calculated at one of the thermistor locations 1-2 cm from the fat-muscle interface in the musculature. The total power input to the applicator was 40 W, thus the averaged specific absorption rate (SAR) was 2.81 W/kg per watt.

In a similar manner, it is possible to estimate the flow rate of blood in the musculature from the maximum slope

TABLE III
FORMULA FOR CALCULATION OF BLOOD FLOW

BLOOD-FLOW RATE IN MUSCLE	
$m =$	$\frac{W_b}{k_2 \cdot c \cdot \Delta T' \cdot \rho_b}$
$m =$	blood flow millimeters per 100 g/min
$W_b =$	power dissipated by blood flow W/kg
$\rho_b =$	g/cm^3
$k_2 =$	constant 0.698
$c =$	specific heat of blood kcal/kg°C
$\Delta T' =$	$T - T_a$
$T_a =$	arterial temperature
$T =$	tissue temperature

TABLE IV
CALCULATED VALUES FOR BLOOD FLOW IN HUMAN MUSCLE

CALCULATED BLOOD-FLOW RATE IN MUSCLE		
RUN	<u>m1/100 g/min</u>	
1	-	28.90
2	-	28.91
3	-	25.00
4	-	23.64
5	-	29.69

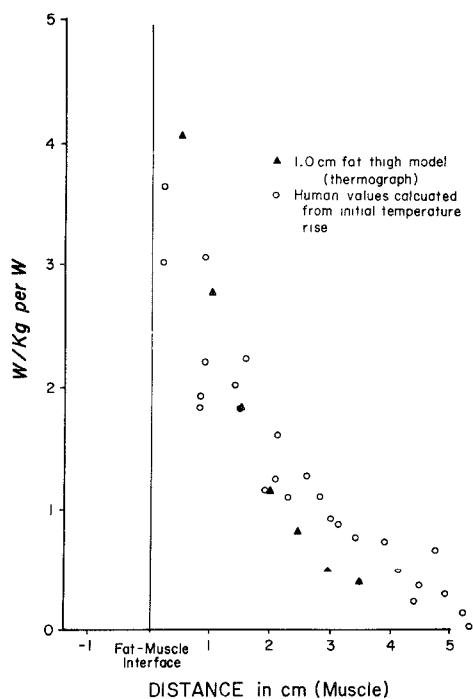


Fig. 14. Comparison of the calculations of the specific absorption rate (SAR) in thighs of human beings and models.

of temperature decline as produced by blood-flow cooling. This formula $m = W_b / k_2 \cdot c \cdot \Delta T' \cdot \rho_b$ is given in Table III [22]. The blood flow was calculated from the tissue-heating curves of the same five subjects and is given in Table IV. Since the maximum blood-flow rate in musculature during exercise is 30–33 ml per 100 g of tissue per minute [24], these values show that maximal blood-flow levels can

be reached during treatment with this microwave applicator.

If it is therapeutically desirable to override this blood-flow cooling effect to maintain maximum temperatures in the tissue, the output of the applicator must be increased during treatment. For our sample of volunteers, because of physiological variability, 30-percent additional power would be required to ensure a therapeutically effective applicator with an adequate margin of power.

Finally, since testing the diathermy applicators for compliance with performance standards and determinations of the efficacy of such applicators will be mainly performed on models rather than on human subjects, it is important that the data obtained from the models represent that which would be obtained from humans. Fig. 14 shows a plot of the calculations of SAR from human experimentation as compared with those from thermograms of a comparable model. The average for models with 1–2-cm muscle thickness is 2.74 W/kg per watt while for human beings it is 2.81 W/kg per watt; the agreement is excellent.

V. CONCLUSIONS

It became apparent that for effective treatment using this applicator to selectively heat muscle to therapeutic levels, a thin radome should be used to minimize edge heating. The radome should be drilled and grooved and the applicator should be fitted with an air inlet so that cooled air can be blown through the applicator and dispersed by the radome for precooling and for continued cooling of the skin surface and subcutaneous tissues. This arrangement ensures that the highest temperatures in the distribution will be reached in muscle tissue.

It is evident from the experiments carried out on human volunteers that the 13-cm square direct-contact microwave applicator with radome and cooling selectively heats musculature, that temperature can be brought to a level between 43 and 45°C at 1–2 cm in muscle, and that by increasing power levels after blood flow has cooled this tissue, it may be feasible to push these temperatures back to 43–45°C and hold them at these levels for longer periods of treatment. Thus the possibility exists for using this applicator to heat cancerous tumors in muscle. Indeed, some physicians are presently using microwave applicators for this purpose.

From comparisons of calculations of SAR in human thighs with those in models it was found that the models are highly reliable predictors of temperature distributions produced in human tissues.

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The Performance of a New Direct Contact Applicator for Microwave Diathermy

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Abstract—A direct contact applicator, specifically designed for microwave diathermy at the Industrial, Scientific, Medical (ISM) frequency of 2.45 GHz was evaluated by studying near-field patterns in free space, thermographic heating patterns in phantoms of simulated fat and muscle tissue, and associated leakage radiation. The main features are a circular waveguide with a short conical flare horn output section surrounded by an annular choke and two sets of dual posts to generate far-field circular polarization. The significant near field components of the therapeutic beam are in a transverse plane, parallel to the aperture. Heating patterns on the exposed surface of muscle phantoms and inside fat-muscle phantoms are spatially similar and relatively uniform. The leakage level is 0.8 mW/cm² per 100 W of forward power for direct contact and 4 mW/cm² per 100 W of forward power for a 1-cm air gap between aperture and planar phantoms. The uncertainty of these leakage measurements is ± 2 dB. This investigation demonstrates the technical feasibility of a safe and effective direct contact microwave diathermy applicator operating at 2.45 GHz. The applicator is a viable candidate for hyperthermia applications.

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I. INTRODUCTION

PRESENT clinical practice in microwave diathermy uses spaced applicators for high power therapy [1]. Since the product performance standard, proposed by the Bureau of Radiological Health (BRH), requires minimum exposure of operator as well as unprescribed tissue of patient, direct contact applicators are desirable. They are inherently safer as they can readily reduce unwanted radiation. To demonstrate the technical feasibility for a safe and effective design, Transco, in accordance with BRH specifications [2], developed a prototype direct contact applicator operating at the ISM (Industrial, Scientific, Medical) frequency band of 2450 ± 50 MHz. This applicator became part of a BRH microwave diathermy system prototype, constructed to demonstrate the feasibility of the provisions of a draft microwave diathermy product performance standard.

Three important considerations guided the design of the applicators.