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Performance evaluation of a conformal thermal monitoring sheet (TMS) sensor array for measurement of surface temperature distributions during superficial hyperthermia treatments

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Abstract

Purpose—This paper presents a novel conformal thermal monitoring sheet sensor array with differential thermal sensitivity for measuring temperature distributions over large surface areas. Performance of the sensor array is evaluated in terms of thermal accuracy, mechanical stability and conformity to contoured surfaces, probe self heating under irradiation from microwave and ultrasound hyperthermia sources, and electromagnetic field perturbation.

Materials and Methods—A prototype TMS with 4×4 array of fiberoptic sensors embedded between two flexible and thermally conducting polyimide films was developed as an alternative to the standard 1-2 mm diameter plastic catheter based probes used in clinical hyperthermia. Computed tomography images and bending tests were performed to evaluate the conformability and mechanical stability respectively. Irradiation and thermal barrier tests were conducted and thermal response of the prototype was compared with round cross-sectional clinical probes.

Results—Bending and conformity tests demonstrated higher flexibility, dimensional stability and close conformity to human torso. Minimal perturbation of microwave fields and low probe self heating was observed when irradiated with 915MHz microwave and 3.4MHz ultrasound sources. The transient and steady state thermal responses of the TMS array were superior compared to the clinical probes.

Conclusions—A conformal TMS sensor array with improved thermal sensitivity and dimensional stability was investigated for real-time skin temperature monitoring. This fixed-geometry, body-conforming array of thermal sensors allows fast and accurate characterization of two-dimensional temperature distributions over large surface areas. The prototype TMS demonstrates significant advantages over clinical probes for characterizing skin temperature distributions during hyperthermia treatments of superficial tissue disease.

Keywords

surface temperature measurement; thermal monitoring; thermometry; superficial tissue disease; hyperthermia

1. Introduction

Superficial tissue disease covers a wide range of cancerous and non-cancerous diseases and abnormal growths that afflict the skin and the underlying subcutaneous tissues. Cancerous superficial tissue diseases include the recurrent and metastatic cancers of the breast, chestwall, and skin, as well as tumor nodules that extend several cm beneath the tissue surface [1]. Numerous clinical studies have shown the efficacy of hyperthermia as an adjuvant to radiotherapy in the treatment of superficial tissue disease [2-4]. Unlike the single aperture heating device developed for small localized tumors, hyperthermia treatment of large area, irregularly shaped superficial tissue disease spread over complex anatomic contours requires

multi-element applicators with adjustable heating patterns. Commercially available multi-element array devices in the US include the Sonotherm 1000 (Labthermics Technologies, Champaign IL) 4×4 array 3.4 MHz ultrasound heating device and the Microtherm 1000 (Labthermics Technologies, Champaign IL) 4×4 planar array 915 MHz microwave heating device for treating superficial tissue regions below the skin [5-8]. Multi-element array devices in clinical use today in Europe include custom sized arrays of 433 MHz Current Sheet Applicators (CSA) [9], Lucite Cone Applicators (LCA) [10-12], and the Contact Flexible Microstrip Applicator (CFMA) [13,14]. Another approach that has been used successfully in the clinic involves computer controlled mechanical rotation of one or two Scanning Spiral Microstrip Antennas over surface disease [15]. The largest surface applicators used clinically to date are the 25 aperture 915 MHz Spiral Microstrip Array developed at Stanford University [16] and the Conformal Microwave Array (CMA) applicator [1,17,18]. Other multi-element array applicators have been developed that should be available in the hyperthermia clinic soon [19]. A detailed review of the thermal therapy devices and techniques available for the treatment of skin and superficial tissue disease is covered in [1]. Most of these applicators offer the ability to heat larger areas with more uniform heating than the previous single element applicators, given sufficient thermal dosimetry feedback. Current multi-element array applicators lack an appropriate complementary non-invasive thermometry approach to monitor temperatures under each of the “independent” heat sources. Without thermal feedback to control each source independently, the effectiveness of array applicators is reduced to closer to a single aperture heat source of equivalent size. This critical limitation has impeded the entry of recent applicator hardware to the patient clinic.

Unlike deep seated tumors, the target tissue in superficial diseases such as chestwall recurrence of breast cancer and plaque psoriasis generally extends only 5-15 mm beneath the tissue surface including the skin. Clinical data from our group have shown skin surface distribution as a good indicator of the underlying tissue temperature distribution within top 5-10 mm of the surface [8]. Other researchers have observed similar temperatures on the surface and at a depth of 2-3 mm [20]. Theoretical study demonstrate that peak power deposition from 915 MHz microwave hyperthermia occur at the skin surface while peak temperatures are 2-3 mm deep for practical waterbolus temperatures around 42°C [21]. Due to practical limitations on the use of interstitial probes for large area surface disease, temperature measurements from probes lying on the skin surface are the common approach used in clinical microwave hyperthermia treatments to monitor thermal dose and control/balance the power radiated by the individual heating elements to deliver a more uniform coverage of the lateral spread of target disease. Present techniques for monitoring two-dimensional temperature distributions of the skin during superficial hyperthermia treatments generally consist of either taping a number of single sensor probes at various irregularly spaced locations on the skin or pulling sensors in 5-10 mm steps through round plastic catheters laying on the skin surface. Unfortunately for the first procedure which is the most common to date, microwave hyperthermia systems generally offer only 8 fiber-optic point sensors - often less than the number of available heat sources. While the second thermal mapping technique provides many more temperature readings along the catheter tracks, the number of catheters is usually small (1-3) and it takes a long time to complete each scan. Thus, the resolution of the temperature measurements is poor both spatially and temporally. Another difficulty with the use of individual sensors involves secure placement of sensors over irregularly shaped anatomy in accurate alignment with all radiating sources in large multi-element array applicators. The round cross section probes taped on to the contoured skin surface often coated with perspiration and natural body oils or protective creams to combat skin breakdown have a tendency to loosen and pull away from the desired positions from patient movement during the 60 minute hyperthermia treatment. In addition to the probe alignment errors, uncertainty of sensor position within the probe is another potential source of error for the soft plastic sheathed probes which are susceptible to stretching.

Depending on whether heating with microwaves or ultrasound, existing techniques for monitoring surface temperature generally employ a plastic coating for the sensors to make them durable and reusable. The plastic coating provides thermal as well as electrical insulation and thus impacts the temperature measurement. For sensors inside thermal mapping catheters, the second thermal barrier formed by the plastic catheter and air trapped around the sensor add further uncertainty and time delay to the readings obtained by pulling individual sensors through the catheter. The round sensor cross-section and multiple layers of insulating plastic surrounding the sensor further increase measurement uncertainty when located at the interface between a temperature-controlled waterbolus and skin at unknown temperature. The temperature gradients across the waterbolus-probe-skin interfaces cause significant differences between measurements recorded by the insulated sensors on the skin surface and the actual temperature of tissue just beneath the skin surface [20].

While still lacking the technology for accurately characterizing surface temperature distributions, several investigators have proceeded with efforts to write automatic feedback control programs assuming they would have at least one feedback temperature for each independent heat source [22-24]. A conformal thermal monitoring sheet (TMS) with appropriately spaced array of non-perturbing stationary fiberoptic sensors is proposed in this paper as an alternative thermometry device to speed up and simplify this critically important thermal monitoring procedure and allow continuous feedback of skin temperature for use in automatic power control of the multi-element heat array applicators. The design and construction details of the prototype TMS array are presented in section 2. Section 3 presents a detailed performance evaluation of the prototype device subjected to mechanical stress, microwave and ultrasound irradiation, thermal loading, and conformity tests on a contoured surface. Results of the evaluation are discussed in section 4 along with plans to further optimize the TMS design for improved directional thermal sensing. Clinical potential of the novel conformal TMS array is summarized in the final section.

2. Conformal TMS Sensor Array

The prototype TMS array was constructed in collaboration with IPITEK Inc, manufacturer of high precision Electromagnetic (EM) field immune fiber optic thermal sensors with single sensor product lines intended for industrial use as well as high precision sensors intended primarily for medical applications.

2.1 Design

The design effort began with the search for optimum materials which included finding small diameter but rugged optical fibers that could be assembled together with soft and flexible plastic materials capable of conforming to complex surface contours of the human torso. The maximum allowable size of plastic fiber-optic sensor material that would avoid perturbation of the heating fields was studied using the 915 MHz Dual Concentric Conductor (DCC) antenna [1,18,25,26]. Plastic catheters with diameter 0.5mm, 1mm and 2mm were placed between the DCC aperture and muscle tissue equivalent liquid phantom. The SAR pattern was measured 5mm deep inside the tissue phantom using a 3mm diameter electric field probe (ALS-E020 Aprel Laboratories, Ottawa Ontario CANADA). Fig 1 shows the normalized SAR measured under a 3cm square DCC slot antenna driven at 30 Watts (maximal clinical power level) with the plastic catheter crossing the corner of the radiating slot. Comparison of the SAR measurements in Fig 1 shows large field perturbation for catheters with diameter >0.5mm and no perceptible change in the SAR pattern for catheter with diameter ≤ 0.5 mm.

This study investigated the use of standard multi-layer Kapton® polyimide film (DuPont, Circleville, OH, USA) commonly used in flexible Printed Circuit Board (PCB) fabrication [27]. The Kapton® film possesses stable mechanical, physical and thermal properties over a

wide range of temperatures. The low dielectric constant (3.4 - 3.5) and dissipation factor (0.0018 - 0.0026) of the Kapton film makes it compatible with PCB based conformal array heating devices. The high tensile strength (165 - 231 psi) and folding endurance (285 kilo cycles) of the Kapton film provides dimensional stability to the TMS array when wrapped around a contoured human torso. The field perturbation experiments and the material properties of Kapton polyimide films led to the design of a TMS array with 250 μm diameter IPITEK fiber optic sensors embedded between two layers of Kapton film. Kapton layers with differential thickness were used to provide directional thermal sensitivity to the buried fiber optic sensors towards one side of the array. The flexible TMS assembly provides secure sensor placement with known position and spacing over highly contoured human anatomy, minimizing alignment errors so common with current single sensor placement techniques.

2.2 Construction

IPITEK fiber optic sensors were adapted to conform to a two-dimensional array format in order to achieve compatibility with the multi-element array heat applicators. Plastic fiber used in standard IPITEK sensors was cut to form array segments with appropriate lengths. A temperature-sensitive phosphor was then added at the sensing end of each segment, and the segments were arranged in a 4×4 array. For prototype 1, the spacing between sensors was chosen to match the center to center spacing of 16 heat sources in the Microtherm and Sonotherm (Labthermics Technologies Inc, Champaign IL) planar array applicators. The fiber optic sensor array with exposed plastic fibers was sandwiched between two layers of Kapton film; one layer was 100 μm thick while the other was 175 μm to provide increased thermal resistance in one direction. Fig 2 shows the rectangular shaped 4×4 prototype Kapton TMS array with sixteen 250 μm IPITEK fiber optic sensors. Each of the sensors is terminated with proprietary IPITEK fiberoptic connectors and electronics modules for real time data acquisition and calibration. The entire TMS-250 conformal array prototype investigated in this work is shown in Fig 2.

3. Prototype Testing

A series of tests were performed to evaluate the performance of the TMS-250 array in terms of thermal accuracy, conformity to contoured human anatomy, probe self heating and field perturbation during irradiation by electromagnetic and ultrasound applicators used in superficial hyperthermia treatments.

3.1 Thermal accuracy

The accuracy discussed in this paper is the deviation of the average sensor temperature measurement from the true known value ($T_{\text{avg}} - T_{\text{std}}$) established by repeatedly measuring using a temperature standard that has been calibrated against standards maintained by the National Institute of Standards and Technology (NIST). This type of measurement requires a stable temperature environment and was conducted at the manufacturer site in a stirred oil bath. The thermal monitoring sheet was placed inside an oil bath held at a constant temperature of 38.0°C. Each sensor in the TMS-250 array was calibrated separately and sensor responses were measured against a calibrated resistance temperature detector traceable to NIST. After calibration, accuracy tests were performed at 35.0°C, 38.0°C, and 45.0°C and all sensor readings were compared against the temperature standard. The accuracy of the 250 μm sensor measurements compared to the temperature standard was 0.01°C at 38°C, 0.06°C at 35°C and 0.10°C at 45°C. The TMS sensor measurements logged for duration of 2 hours after calibration were measured to be stable.

Bending tests were performed to study the fluctuation in sensor measurements for curved TMS geometry. The TMS-250 array was suspended flat inside a temperature controlled empty

chamber with the thinner Kapton layer facing upwards. The sensor was left undisturbed and temperature was logged for all 16 sensors for 60 seconds. The array was later rolled around 4 and 6 inch diameter cylindrical rings respectively and suspended inside the chamber while temperature data was again logged for all 16 sensors for 60 seconds each. This procedure was repeated twice for the 4 and 6 inch diameter curvatures. The steady state temperatures logged during flat and rolled conditions were used to quantify fluctuation in sensor measurements for curved geometry. The average steady state accuracy of the sensors at flat and rolled conditions for the 6 inch diameter roll was -0.06°C and 0.21°C respectively. The sensor measurement accuracy at flat and rolled conditions was measured to be 0.05°C and 0.23°C respectively for the 4 inch diameter curvature.

3.2 Conformity to Contoured Anatomy

Conformity tests were performed using a Computer Tomography (CT) scanner to quantify the contact between the prototype TMS sensor array and the surface of a human torso phantom under a CMA type water bolus [28]. Fig 3a shows the placement of the prototype TMS-250 array on the human torso phantom extending across the left chestwall and around the side under the arm. Figs 3b and 3c show the vest-shaped CMA applicator, and the 6 mm thick waterbolus layer with overlying air bladder and elastic overgarment in place over the TMS, in an appropriate clinical heating configuration. The three orthogonal CT views of the torso phantom in Fig 3(d)-(f) indicate the TMS array as a thin white line (arrows) conforming closely to the contoured phantom surface (gray). The conformity (and thermal contact) to the realistically shaped human torso model in Fig 3 is excellent with the TMS bending smoothly both around the side, under the arm, and simultaneously twisting in the axial direction to fit the complex surface contour. When integrated into the multi-layered CMA applicator [17,27], the conformal TMS array can maintain fixed sensor placement relative to the individual heating elements regardless of patient movements during a typical hour long hyperthermia treatment.

3.3 Evaluation of TMS with Clinical Hyperthermia Devices

Because these TMS arrays are intended for thermometry in microwave and ultrasound fields, perturbation of the heating patterns due to energy absorption in the TMS array was investigated in two series of tests. In the first test, the TMS was securely taped to a 16-element CMA applicator that was placed flat above a rectangular tank filled with liquid muscle tissue equivalent phantom as shown in Fig 4a. The TMS lying on the liquid tissue phantom was irradiated by a 6 element sub-array of the 16-element 915 MHz CMA applicator at 30 Watts per antenna to measure perturbation in the radiated field. The relative power density was measured with a scanning electric field probe (ALS-E020 Aprel Laboratories, Ottawa Ontario CANADA) in the XY plane 5 mm deep ($z=5\text{mm}$) inside the muscle phantom under the 6-element sub array using the procedure described previously [5]. Figs 4b-4c show the relative SAR plots measured with and without the TMS array between the applicator and the tissue phantom. As seen in Figs 4b-4c, insertion of the 0.275 mm thick TMS with 250 μm fibers had essentially no effect on the field radiated from the 915 MHz microwave array other than to reduce the peak SAR by about 5%. These measurements confirmed our expectations since both Kapton and the adhesive used in TMS construction are extremely low loss materials.

Although the TMS concept was originally intended for microwave field dosimetry, a second test setup was constructed to characterize the absorption/self-heating of the TMS exposed to an ultrasound field that is also commonly used in superficial hyperthermia treatments. The self-heating and thermal barrier characteristics of the TMS array were measured under a 3.4 MHz ultrasound (US) planar array applicator (Sonotherm 1000, Labthermics Technologies Inc, Champaign IL). In this test setup, the TMS array was placed on a solid phantom load and a 40.5°C waterbolus coupled 16-transducer US array was pressed down over the top. Temperatures were recorded in two TMS sensors near the distal edge of the TMS array and

compared to the measurements from two standard clinical thermocouple probes. Using a clinical level of ultrasound power (35W per transducer), the interface temperature was measured with two fiber-optic sensors of the TMS, two M-CC-U-0-4/7 polyethylene encased thermocouples (Ella-CS, Czech Republic) on the phantom surface just under the TMS array, and two M-CC-U-0-4/7 thermocouples in direct contact with the ultrasound bolus and muscle load just off the distal end of TMS as shown in Fig 5a. Fig 5b shows the average temperature of the thermocouple and TMS sensors. In the absence of ultrasound field, the thermocouple sensors at load-bolus interface read approximately 1°C higher than those shielded by TMS from the warm waterbolus. With the ultrasound energy on, the situation reverses and the thermocouples below the TMS array read approximately 1°C warmer than those at the bolus-load interface due to self-heating in the Kapton. Temperatures recorded by the fiberoptic sensors inside the double layer TMS were about 0.5°C lower than the true interface temperature during the transient thermal conduction heating before ultrasound power was applied, due to the time delay of phantom heating through a double Kapton layer TMS. With a clinical level of ultrasound power, the TMS sensor read 2.0°C higher than the interface due to power absorption in the Kapton.

3.4 Comparison with Standard Clinical Hyperthermia Monitoring Techniques

Finally, the performance of the prototype TMS array was compared with other temperature probes that are commonly used for clinical microwave hyperthermia treatments. Fig 6a shows the experimental setup with various thermometry sensors including the TMS-250 array, bare Teflon encased fluoro-optic probe (Luxtron Corp, Santa Clara CA) underneath the TMS array, Teflon encased fluoro-optic probe both bare and inside #19 ga (0.91 mm dia) PVC and Teflon thermal mapping catheters was securely taped in close proximity on a PVC bolus bag. During the experiment, all temperature sensors were sandwiched between the PVC bolus bag and a high density polystyrene sheet of 1 cm thickness. The polystyrene sheet insulated the sensors from fluctuations in room temperature and enabled characterization of the thermal response of individual sensors. To demonstrate differences in the transient as well as steady state response of the various probes, the probes were placed close together on a large uniform temperature waterbolus that was subjected to a step change in temperature of 18.0°C while recording thermal response of all sensors. To accomplish this step change, 23.0°C water was uniformly and rapidly circulated at 2 L/min flow rate through a large 6 mm thick waterbolus till steady state was reached. After recording temperatures from all sensors for approximately 4 minutes, the heat exchanger in the water circuit was moved from the 23.0°C bath and plunged into a heated bath to circulate 41.5°C water through the bolus.

Fig 6b shows the thermal response curves of the TMS-250 sensor array and standard clinical probes in contact with the PVC waterbolus bag during this 18.0°C step change. Note that all TMS sensors respond more rapidly to the steep transition and read closer to the actual bolus temperature than the current clinical monitoring techniques. The spread in readings of temperature among the multiple sensors of each type is due to minor temperature differences across the large water bolus surface. The average temperature of water flowing in and out of the entire water bolus compartment is seen to vary rapidly from about 23.0°C to 41.0°C, with a time delay of approximately 25 seconds for the transit of water across the large bolus surface. Twenty seconds after the step change, the TMS and Luxtron sensors read 2.0°C and 4-5.0°C respectively cooler than the average water outflow temperature. By 180 seconds, all TMS sensors reached steady state and remained within 0.5°C of the bolus outflow temperature while the standard fiberoptic sensors were still lagging by 2.5-3.0°C. At steady state, the average of the temperatures read by the TMS sensor array was 41.08°C compared to the waterbolus outflow temperature of 41.1°C while the round cross section probes read approximately 1°C below the waterbolus outflow temperature.

4.0 Discussion

This effort describes a detailed investigation carried out during the early testing phase of a novel prototype device for monitoring temperature distributions over the skin surface. The mechanical stability, microwave and ultrasound absorption loss, and field perturbation properties of the materials were studied carefully before determining optimum construction of the TMS array. SAR measurements in liquid muscle phantom established that use of sensors with ≤ 0.5 mm diameter should avoid significant microwave field perturbation. The design effort enabled fabrication of a thin and flexible thermal monitoring sheet using readily available Kapton polyimide film and 250 μ m diameter IPITEK plastic fibers with overall thickness smaller than the standard Teflon encased Luxtron fluoroptic probes. Additional plastic coating typically used with existing single or multi-sensor plastic fiberoptic probes serve as an insulating layer that introduces further time delay and impacts temperature measurement. The standard Teflon or PVC encased round fiberoptic sensors are useful for interstitial tissue temperature monitoring during deep hyperthermia or thermal ablation procedures, where the depth profile of tissue temperature can be obtained by pulling the sensor to various positions inside the catheter. However, for the skin surface, temperature measured by the round plastic sensors with omni-directional thermal sensitivity is significantly influenced by the bolus pressure and toughness of the skin which affect how deeply the round probe sinks into either the skin or waterbolus surface, and by limitations in spatial sampling of large surface areas. On the other hand, a conformal TMS probe configuration with stationary regularly spaced grid array of fiber-optic temperature sensors embedded between differential thickness Kapton layers can gather sufficient measurements to characterize entire surface temperature distribution of the skin over large contoured anatomy without uncertainties in sensor position.

The thermal accuracy of the prototype 16 sensor TMS array was measured to be at least 0.10° C at three clinically relevant test temperatures. The calibration bath used in thermal accuracy tests was marginal in size to accommodate the TMS. Warping the sheet to fit inside the bath produced small temperature gradients that degraded the thermal accuracy of the array during calibration. The calibrated TMS sensor measurements logged for a duration of 2 hours inside a temperature controlled waterbath were stable and matched the temperature standard with 0.1° C accuracy. The stability and accuracy of the prototype TMS sensor array are reproducible even after more than a year since the prototype fabrication. The thermal accuracy and readout stability of the TMS array in flat and tightly curved conditions tested over the range of 35 – 45.0° C indicated a larger but still acceptable 0.23° C temperature deviation for a 2 inch radius of curvature. But a 4 inch diameter curvature is tighter than most surfaces encountered in clinical measurements of the human torso. The thermal gradient established by convection air currents around the curved TMS array adversely degraded the sensor accuracy in the bend tests. Performing the bend tests inside a well stirred oil bath would minimize the thermal gradients across the TMS surface and enable a better characterization of the device. The close conformity of the TMS array both under the arm and around the body seen in Fig 3 indicates that excellent body contact can be maintained over the highly contoured human torso.

As shown in Fig 4, irradiation of the TMS array exposed to 915 MHz microwave fields at power levels in excess of the clinical requirements produced no perceptible perturbation of the radiated field pattern and no perceptible self-heating of the Kapton TMS array. A uniform approximately 5% decrease in SAR observed across the entire pattern could easily be accommodated in clinical treatments by increasing the applied power as necessary to achieve the desired skin surface temperature which is accurately characterized by the TMS sensor array. The 1 – 2° C error in temperature measurement seen in Fig 5 for the 4×4 array of 3.4 MHz ultrasound applicator with 38 Watts per transducer clearly indicates probe self-heating due to absorption of ultrasound energy within the soft plastic probe and Kapton layers. As with other

probes used to monitor ultrasound therapy, this probe self heating must be accommodated with appropriate temperature correction procedures [29,30].

Comparison of the thermal response curves in Fig 6 clearly demonstrates the superior ability of the TMS array to respond rapidly to a steep rise in temperature (18°C). Even though the 4 Luxtron sensors (current gold standard for clinical microwave hyperthermia treatments) were taped directly to the water bolus (heat source) surface, the Luxtron sensors were slower to respond and by 35 seconds read temperatures 2-3 °C cooler than the TMS array measurements and 3-4 °C cooler than the bolus outflow temperature. The thin Kapton layer overlying the IPITEK 250 µm sensor on the bolus side introduced less insulation and time delay in reading the bolus temperature than the bare Luxtron probe and especially the catheter encased Luxtron sensors which have a polyurethane insulated round cross section that is less suited for accurate temperature measurement at an interface between two planar surfaces. This is a significant finding that supports TMS sensor array thermometry as superior to the current best clinical approaches used for thermal characterization of large surface tissue regions [1].

The primary motivation to develop the TMS array is thermal dosimetry of temperature distributions across large surfaces of skin, a thermometry application that is currently unmet with current systems [8]. It should be noted that this paper does not address the ability of hyperthermia applicators to treat to any specific depth, but rather this thermometry approach will provide the critical information necessary to change power levels of multi-element applicators to deliver most uniform lateral distribution of heating across large superficial tissue disease [35]. Efforts thus far have been aimed at evaluating the prototype TMS for use in monitoring and control of surface temperature distributions under multi-element array microwave hyperthermia applicators like the 16 element Microtherm and 32 element CMA applicator developed for treatments of chest wall recurrence of breast cancer [1,5,31,32]. This thermometry approach should be equally useful for superficial hyperthermia induced with numerous other multi-element array microwave applicators [9,13,14,16,33,34]. Clinical evaluations of these multi-element applicators have demonstrated the ability to deliver adjustable heating patterns to large surface areas over highly contoured portions of the anatomy if sufficient feedback information is available to guide power adjustments [1,5]. Unfortunately, existing thermometry techniques rely on a small number of sensors taped to the skin or thermal mapping of a single fiberoptic sensor through long plastic catheters on the skin which requires long times up to half the available treatment time before adjustments can be made to the applicator power settings to improve heating distribution for the second half of therapy. In contrast, the TMS array investigated in this work can provide continuous readings of 16 surface measurements in a regular grid that matches the center to center spacing of the heat sources. The multilayered conformal design with stationary arrangement of embedded fiberoptic sensors eliminates uncertainties in sensor position over the contoured human anatomy. The differential thickness TMS with the thinner Kapton film on the tissue side lowered the thermal barrier between buried fiberoptic sensors and skin while at the same time increased the thermal isolation of the waterbolus. As seen in Fig 6b, the differential thickness enabled the prototype TMS sensor array to read surface temperatures on the thinner Kapton film side with an accuracy of 0.1°C compared to the standard round cross section clinical probes that exhibited steady state temperature differences of >1°C from the true surface temperature. The thin (<0.3 mm) TMS sensor array with thermal resistance equal to 0.0023 m²K/W results in an incremental change in the thermal impedance of the coupling waterbolus towards the tissue surface. A number of new TMS probe configurations with improved directional thermal sensitivity and low overall thermal barrier characteristics for good regulation of spatial inhomogeneities in skin temperature are investigated in a related study [36].

5. Conclusions

This effort describes the design and performance of a prototype thermal monitoring sheet (TMS) conformal array of miniature fiber optic sensors intended for characterization of surface temperature distributions across large areas of skin during superficial clinical hyperthermia treatments. TMS sensor arrays fabricated from fiberoptic sensors embedded in <0.3 mm thick Kapton sheets exhibit very small temperature offset and time delay in reading true skin surface temperatures. Compared to the current clinical probes with omni-directional thermal sensitivity, TMS sensor arrays with differential thickness lowered the thermal resistance and capacitance to the side with thinner Kapton, and significantly improved the speed and accuracy of surface temperature measurements. The fast thermal response time, low probe self heating under EM field and low EM field perturbation of the TMS sensor array, dimensional stability of sensor locations over contoured anatomy, and measurement accuracy of 0.1°C even when adjacent to another (waterbolus) surface at different temperature appears very promising for use in surface thermometry of the skin. The TMS array investigated in this paper provides a novel thermometry approach capable of yielding high density and/or large area 2D thermal distributions with improved sensitivity and accuracy. Successful completion of this fixed geometry, body conforming array of thermal sensors should produce a non-invasive thermal dosimetry device that can significantly improve monitoring and real time control of superficial hyperthermia treatments with multi-element array heat applicators.

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Fig 1. Measured SAR patterns 5 mm deep inside liquid muscle phantom under 3cm square DCC antenna driven with a clinically relevant power of 30 W at 915 MHz, with 0, 0.5, 1, and 2 mm diameter plastic catheters across one corner of the radiating slot.

Fig 2.
A view of the prototype TMS 4×4 sensor array with fiber-optic cabling for the 250 μm diameter IPITEK fiber-optic sensors to the readout electronics module.

Fig 3.

Conformity test showing (a) TMS position on torso phantom with (b) overlying waterbolus, (c) air bladder vest and elastic overgarment as in typical CMA clinical setup; (d)-(e) Orthogonal views of the CT scans demonstrate excellent conformity and thermal contact to realistic curving and twisting body contour.

Fig 4.

(a) Schematic diagram of the experimental setup for measuring SAR pattern at 5 mm depth inside muscle tissue equivalent liquid phantom irradiated with 915 MHz from a 6 element sub array of a CMA applicator; b) SAR pattern with intervening 0.275mm thick TMS-250 sheet, superimposed above the outline of the 6 DCC antennas; (c) SAR pattern without TMS sheet.

Fig 5.

TMS probe self heating from irradiation by Sonotherm 3.4 MHz ultrasound array hyperthermia applicator. (a) Experimental setup; (b) comparison of standard thermocouple (TC) probes with TMS sensors reading tissue phantom temperature before and after application of maximal clinical power level. Note close correspondence of all probe temperatures at the interface after contact with the water bolus at 30 seconds, and consistent 1-2°C self-heating of the Kapton sheet fiber-optic sensors during application of a high clinical power level of ultrasound at time 10- 20 min.

Fig 6.

(a) Experimental setup showing the placement of the TMS array and standard clinical temperature probes close together on a large equi-temperature waterbolus sheet with rapidly circulating water (4×4 array of black dots indicate sensor location); (b) Comparison of the thermal response of TMS sensor array with standard clinical probes for a rapid change in circulating water temperature.