New Encapsulation Concepts for Medical Ultrasound Probes – A Heat Transfer Simulation Study

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New Encapsulation Concepts for Medical Ultrasound Probes – A Heat Transfer Simulation Study

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Abstract

Thermal management is important for medical ultrasound probes to maintain optimal performance, reliability, and lifetime of the devices, as well as to avoid heat-induced damage to the patients' tissue. This paper presents heat transfer simulations of the scan head of a trans-esophageal echocardiography (TEE) ultrasound probe, which operates temporarily inside the human esophagus for cardiac imaging. The current encapsulation design of the scan head requires manual assembly of several prefabricated parts to ensure functionalities such as heat spreading, electromagnetic interference (EMI) shielding, electrical isolation and biocompatibility. New encapsulation concepts that provide a more efficient manufacturing process while maintaining the multi-functional performance are desirable. The objective of this study is to screen encapsulation designs and materials which can simplify the encapsulation of the scan head. The main output to consider from the simulations is the maximum surface temperature of the scan head, which must be below 43 ºC to ensure thermal safety for patients. Two encapsulation concepts are analyzed: single-layer encapsulation and double-layer encapsulation. The simulation results show that a double-layer encapsulation, such as a polymer-coated metal encapsulation or a metallized polymer encapsulation, can fulfill the requirements regarding heat transfer, EMI shielding, electrical isolation and biocompatibility.

Key words: trans-esophageal echocardiography, ultrasound scan head, heat transfer simulations, encapsulation

I. Introduction

Ultrasound imaging plays an important role in the diagnosis of cardiovascular diseases. Imaging from the inside of the esophagus, known as trans-esophageal echocardiography (TEE), has the capability of giving high quality images due to the proximity of the esophagus to the heart. The TEE probe is passed down the esophagus and provides 3D images of the heart in real time [1].

The scan head of a TEE probe, referred to as 'scan head' in this paper, contains the ultrasound transducer and driving electronics. The starting point in our study is a scan head with an encapsulation which requires manual assembly of several prefabricated parts, as illustrated in Figure 1. It is therefore desirable to reduce the number of prefabricated parts and process steps to simplify the scan head assembly. Developing new encapsulation designs, as well as utilizing new functional materials, are potential approaches to reach a more efficient manufacturing. New encapsulation concepts must also maintain high image quality and medical safety for the patients.

Thermal management in a TEE scan head is important with respect to patient safety, since the transducer and the electronics in the scan head generate heat during the operation. Hence, heat distribution and heat transfer in the TEE scan head must be well-controlled to avoid hot spots on the scan head surface. According to the standard IEC 60601-2-37 of requirements for the basic safety and essential performance of ultrasonic medical diagnostic equipment, the temperature limit of medical devices in direct contact with the human body should be lower than 43 ºC to avoid thermal damage to biological tissues [2]. Thermal management is also critical to the performance, lifetime and reliability of the scan head.

Electrical isolation, electromagnetic interference (EMI) shielding, and biocompatibility are other vital concerns when it comes to patient safety and selection of a new encapsulation concept. Encapsulation materials used in the TEE scan head must ensure electrical isolation while surfaces in contact with the human body needs to be biocompatible. In addition, the encapsulation materials should provide EMI shielding to protect the device from signal interference and ensure proper operation of the device [2].

In this study, potential encapsulation designs and materials, with respect to heat dissipation, are evaluated by means of numerical simulations of heat transfer. EMI shielding, biocompatibility, and electrical isolation are also parameters to consider when selecting new designs and materials for TEE scan head encapsulation.

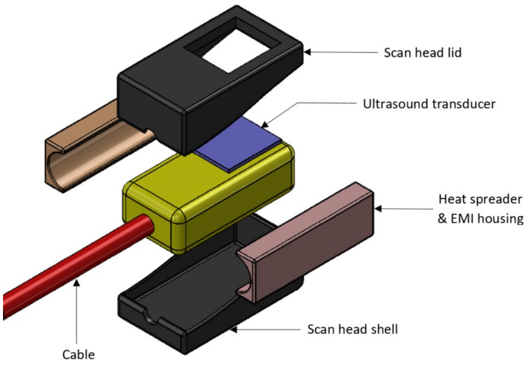
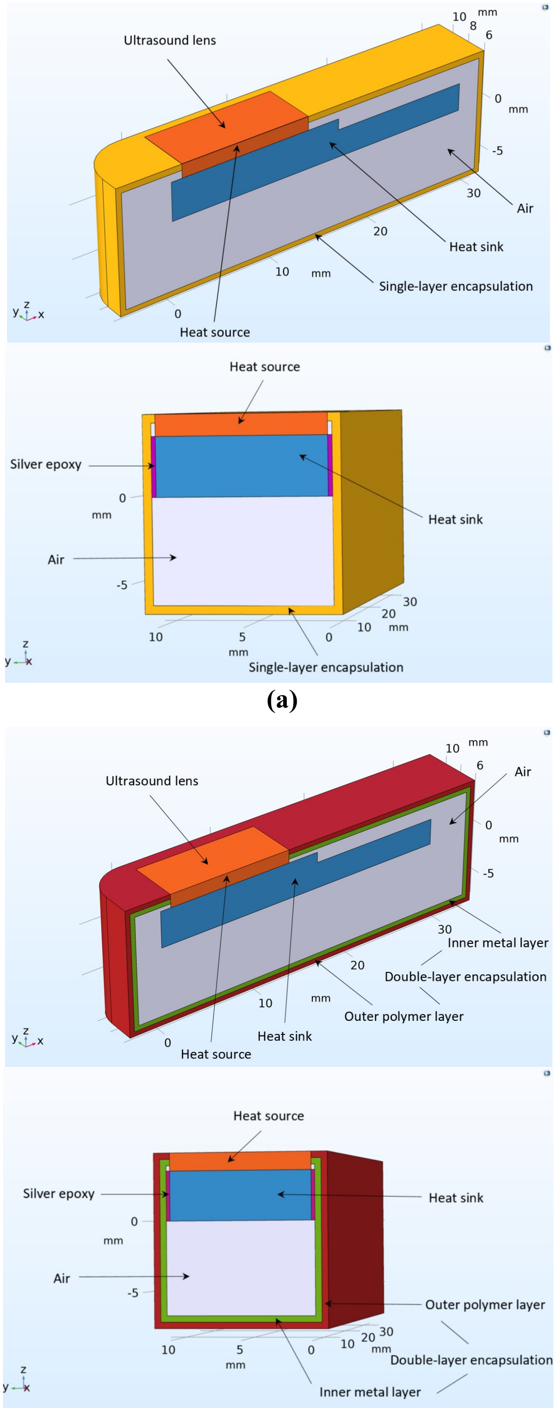


Figure 1: Simplified encapsulation design of a TEE scan head. The 'heat spreader & EMI housing' parts spread the heat from the 'ultrasound transducer' and provide EMI shielding for the scan head. The 'scan head lid' and the 'scan head shell' parts define the outer shape of the scan head, and these are in contact with biological tissue.

II. Heat Transfer Simulation Model

An idealized 3D model of the TEE scan head is simulated in COMSOL Multiphysics 5.3a. This model includes a heat source, a heat sink and an outer encapsulation. The heat source represents electronic components generating heat within the scan head, such as the ultrasound transducer and the driving electronics. The simplified heat source in this study is modelled as a silicon (Si) solid, since Si is the material of the component generating the most heat within the scan head. The heat source is in contact with an aluminum (Al) heat sink. In the model, the heat source generates a power of 1 W. This power value, being higher than the typical value for such a scan head, is selected in order to have a certain safety margin. The encapsulation covers the entire scan head, except the heat source's surface, which is the ultrasound lens, as shown in Figure 2. This encapsulation and the exterior surface of the heat source are in direct contact with the esophageal medium. The remaining volume inside the scan head, such as cables, other electronic components, organic substrates, is modelled as air for simplifying the simulations, thus representing a worst-case scenario.

In this study, steady-state thermal conduction is considered the main mechanism of heat transport. The thermal contact between domains in the scan head is assumed to be perfect. The heat transfer can be described by the thermal diffusion equation, which is derived from the principles of conservation of energy and Fourier's law [3].



(a)

(b)

Figure 2: Cross-sections of the scan head model consisting of a Si heat source, an Al heat sink, and (a) a single-layer encapsulation, or (b) a double-layer encapsulation with an inner metal layer and an outer polymer layer. The heat sink is in contact with the inner surface of the encapsulation along its two long sides via silver-filled epoxy. The remaining volume inside the scan head contains air. The ultrasound lens on the surface of the heat source is a window for transmission and reception of ultrasound signals.

The steady-state heat equation is:

$$k\nabla^2 T + q = 0 \qquad (1)$$

where k is the thermal conductivity (W/(m·K)) of the solid material; ∇^2 is the Laplace operator; T is the scalar temperature field (K); q is the rate at which energy is generated per unit volume of the medium (W/m^3).

A convective heat flux boundary condition is applied to the outer surface of the scan head, representing the heat flux to the esophagus, maintained at human body temperature. The expression for this boundary condition [3] is:

$$q_0 = h_c(T_{ext} - T) \qquad (2)$$

where h_c is the heat transfer coefficient (W/(m^2·K)); T_{ext} is the temperature of the external medium (K), (37 ºC in our case); T is the temperature of the scan head surface (K); q_0 is the convective heat flux (W/m^2). In our simulations, the heat transfer coefficient, h_c, was set to 400 (W/(m^2·K)). This value was calculated from esophageal heat transfer measurements on a pig. The 3D model was meshed using free tetrahedral elements with a minimum element size of 5 µm in order to describe the heat flow adequately in the thinnest layers in this study.

In this study, the main constraint is to keep the maximum surface temperature of the scan head below 43 ºC to ensure thermal safety for patients. Another constraint is the outer dimensions of the scan head, which should be similar to, or smaller than, those of the existing scan head. This sets limits for the thickness of the encapsulation. Material properties of the heat source (Si), the heat sink (Al) and air were taken from COMSOL's database. Typical data for encapsulation materials were used. In further studies, encapsulation materials will be selected based on simulation results and material databases (e.g. MatWeb, NIST).

III. Results and Discussions

The objective of the heat transfer simulations in this paper is to identify appropriate encapsulation designs and materials that are able to satisfy the thermal safety requirement for the TEE ultrasound scan head as well as to simplify the assembly of the scan head. The simplification of the assembly process can be related to:

- Reducing the number of prefabricated parts to reduce the number of process steps, or
- Selecting materials and corresponding packaging techniques suitable for automatic processes.

1. Heat transfer of TEE scan head with single-layer encapsulation

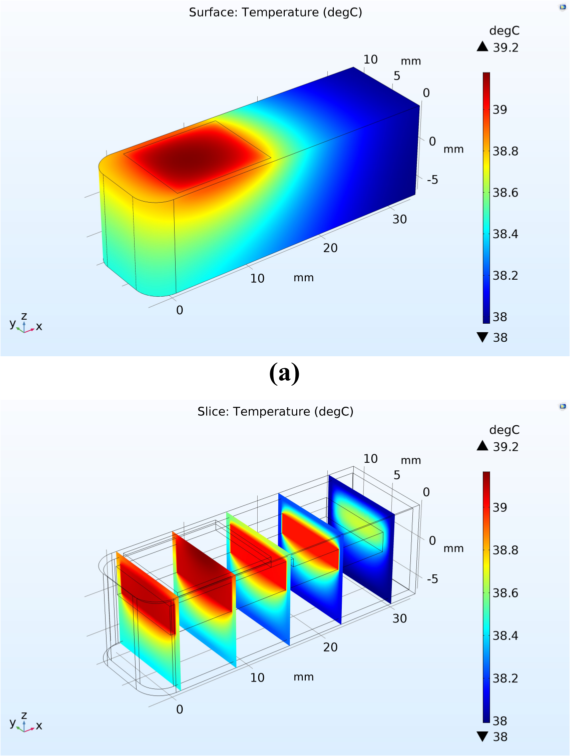
In a single-layer encapsulation design, the scan head is encapsulated by a single layer made of a single homogeneous material or a composite. This layer can be applied in an automatic process, such as a molding process with a thermoplastic or a thermosetting polymer. Such molding processes are well-developed packaging techniques suitable for automatic encapsulation of electronic components [4]. Hence, the molding processes can be employed for encapsulating the scan head in automated steps or for manufacturing prefabricated parts where any components or modules in the scan head may not endure the pressure and temperature of certain molding techniques.

All types of materials, such as polymers, metals, ceramics, composites, are considered to find a material appropriate for single-layer encapsulation design. Thermal conductivity k is the only parameter of the material needed for steady-state heat conduction. Therefore, the value of k was varied in a wide range (0.1 – 500) W/(m·K) to simulate heat transfer for different material categories. Thermal conductivity of polymers and their composites are often in the range of (0.1 – 3) W/(m·K), while common ceramics, metals, and alloys have higher thermal conductivity [3], [4].

In heat transfer simulations for single-layer encapsulation, the thickness of encapsulation layer was kept at 0.5 mm or 1 mm, while the thermal conductivity was varied from 0.1 to 500 W/(m·K). A thickness value of 1 mm was chosen as the upper value since this is the encapsulation thickness of the current scan head. The thickness of 0.5 mm was based on the typical lower limits for some of the relevant encapsulation processes, such as injection molding of polymers and die casting of metals, to facilitate the manufacturing of the encapsulation layer [5], [6].

An example of a heat transfer simulation of the scan head encapsulated by a single-layer encapsulation is shown in Figure 3. The encapsulation layer is Cu with a thickness of 0.5 mm, and a thermal conductivity of 400 W/(m·K). The surface temperature of the scan head in Figure 3 varies from 38 ºC to 39.2 ºC. The maximum surface temperature occurs at the opening surface of the heat source, which is not encapsulated (see Figure 2).

Figure 4 shows the effect of the thermal conductivity on the maximum surface temperature for two encapsulation thicknesses of 0.5 mm and 1 mm. For both thickness values, the maximum surface temperature decreases with increasing thermal conductivity. Increasing the thermal conductivity from 0.1 to 50 W/(m·K) leads to a large drop in the maximum surface temperature. When increasing thermal conductivity to values higher than 50 W/(m·K), the reduction in maximum surface temperature is relatively small. Figure 4 also indicates that when the thermal conductivity of the encapsulation material is higher than 20 W/(m·K) for 0.5 mm thickness, or higher than 10 W/(m·K) for 1 mm thickness, the maximum surface temperature of the scan head will satisfy the requirement that no hot spots on the surface are hotter than 43 ºC.



(a)

(b)

Figure 3: (a) Surface temperature, and (b) bulk temperature of the scan head having a 0.5 mm single-layer encapsulation with *k* = 400 W/(m·K)

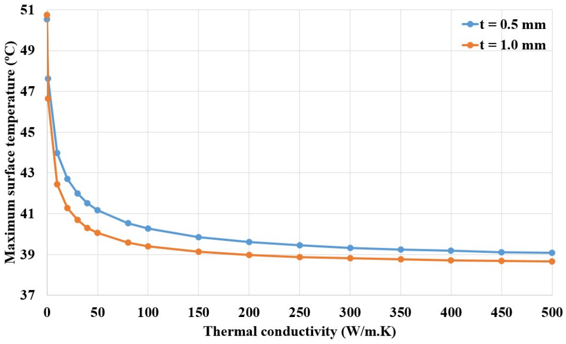


Figure 4: Effect of the thermal conductivity of the encapsulation material on the maximum surface temperature of the scan head. Simulation results for single-layer encapsulation with a thickness of 0.5 mm and 1 mm.

From a heat transfer point of view, a single-layer encapsulation can provide good thermal management for the scan head when the encapsulation material has a thermal conductivity higher than 20 W/(m·K) and a thickness in the range of (0.5 – 1.0) mm. However, other factors, such as EMI shielding, electrical isolation, biocompatibility, processing, have to be considered when selecting the encapsulation material for the TEE scan head.

To the best of our knowledge, there is no single material which can satisfy all the requirements. Polymers are good candidates for electrical isolation and biocompatibility, as well as being suitable for automatic encapsulation processes. However, they have low thermal conductivity and they are transparent to EM waves. Ceramics can provide good thermal dissipation and electrical isolation, but the EMI shielding performance of ceramics is poor. Metals is perfect for thermal dissipation and EMI shielding, but they do not provide electrical isolation.

On the other hand, there may be composite materials (e.g. polymer-based composites) with thermal conductivity higher than 20 W/(m·K) which also can satisfy the contradictory requirements, such as electrical isolation and EMI shielding. Potential composite suitable for the single-layer encapsulation designs will be investigated further.

2. Heat transfer of TEE scan head with double-layer encapsulation

Metals can satisfy most of the requirements, such as heat transfer, EMI shielding, and biocompatibility. Since the scan head is in direct contact with the patient's esophagus, the outer encapsulation layer must provide electrical isolation. This can be achieved by covering the outer surface of a metal layer with a polymer layer. In this paper, two double-layer encapsulation designs are considered.

- Polymer-coated metal encapsulation: a double-layer design in which a thin coating of a biocompatible polymer covers the outer surface of prefabricated metal parts
- Metallized polymer encapsulation: a double-layer design in which a thin metal layer is deposited on the inner surface of prefabricated parts made of a biocompatible polymer.

2.1. Selection of materials for double-layer encapsulation designs

For double-layer encapsulation designs, many metals can be used, since electrical isolation and biocompatibility are handled by the polymer layer. Some common metals used for electronics packaging are Ag (*k* = 428 W/(m·K)), Cu (*k* = 400 W/(m·K)), Au (*k* = 318 W/(m·K)), Al (*k* = 236 W/(m·K)) [3], [4]. Cu is the metal chosen in this paper since it has high thermal conductivity and low price. In addition, there are many well-developed methods for processing Cu [4]–[6].

Polymer materials for polymer-coated metal encapsulations must be able to provide thin and durable layers. There are several techniques for applying smooth, uniform, thin coatings of a polymer on the outer surface of a metal part. Spraying or dip coating of polytetrafluoroethylene (PTFE), a biocompatible polymer, on Cu parts prefabricated by die casting [7]–[9] is an example.

Regarding the metallized polymer encapsulations (i.e. a metal layer being thinner than the polymer layer), the polymer part(s) can be prefabricated by injection molding, and then a thin metal coating can be applied to the inner surface of the polymer parts. Electroless plating followed by electroplating can be used for applying the metal coating, providing metal layer with thickness from nm to mm [8]. The thickness of the metal coating must satisfy the EMI shielding requirement (see Sect. 2.3). Such a double-layer encapsulation could be a Cu-metallized part made by injection molding in an appropriate polymer material such as polyethersulfone (PES) [6], [7].

In fact, the thermal conductivity of most (unfilled, biocompatible) polymers are in the range of 0.1 – 0.3 W/(m·K). Hence PTFE and PES can be used as representative polymers.

2.2. Heat transfer of TEE scan head with polymer-coated metal encapsulation

An encapsulation consisting of Cu parts coated with PTFE is considered. The latter will be in direct contact with the human esophagus. The Cu part may be fabricated by die casting, and the PTFE coating can be applied with an established coating method.

In our simulations, the Cu thickness was 0.5 mm and 0.9 mm, while the PTFE thickness was varied from 10 µm to 100 µm. The Cu thickness of 0.5 mm was chosen based on a typical lower limit for thicknesses achieved by die casting and the required mechanical integrity of the metal part [5]. The Cu thickness of 0.9 mm Cu was chosen as an upper value, so that the total thickness of the double-layer encapsulation does not exceed the encapsulation thickness of 1 mm of the current scan head. The PTFE thickness range was based on capabilities of available coating methods [8], [10].

An example of a heat transfer simulation of a scan head having polymer-coated metal encapsulation is presented in Figure 5. In this case, the Cu inner layer is 0.5 mm thick, while the PTFE outer layer is 100 µm thick. Figure 5 shows that the surface temperature of the scan head varies from 37.6 ºC to 39.4 ºC. The maximum surface temperature occurs on the outer surface of the heat source.

Figure 6 shows the effect of the thickness of the PTFE coating on the maximum surface temperature for two Cu thickness values 0.5 mm and 0.9 mm. For both Cu thicknesses, the effect of PTFE thickness ranging from 10 µm to 100 µm is negligible. Furthermore, maximum temperatures obtained with 0.5 mm and 0.9 mm Cu are quite close. Any combination of Cu having thickness in the range of (0.5 – 0.9) mm with PTFE having thickness in the range of (10 – 100) µm will give a maximum surface temperature of about 39 ºC, which satisfies the thermal safety requirement (max. 43 ºC).

From a heat transfer point of view, a polymer-coated metal encapsulation can provide good thermal management for the scan head. However, the thickness of the polymer coating should be considered carefully. First, the coating must be uniform, so that there are no areas with coating significantly thinner than the nominal value. Secondly, the thinnest coatings in the range simulated may be prone to damage when the scan head is used, such as scratches exposing the metal. This may be detrimental for the electrical isolation or the biocompatibility. The electrical surface resistance of such polymer-coated metal encapsulations should be measured in order to identify the most appropriate polymer coating thickness and coating process. In addition, measurements of EMI shielding effectiveness and biocompatibility should also be conducted.

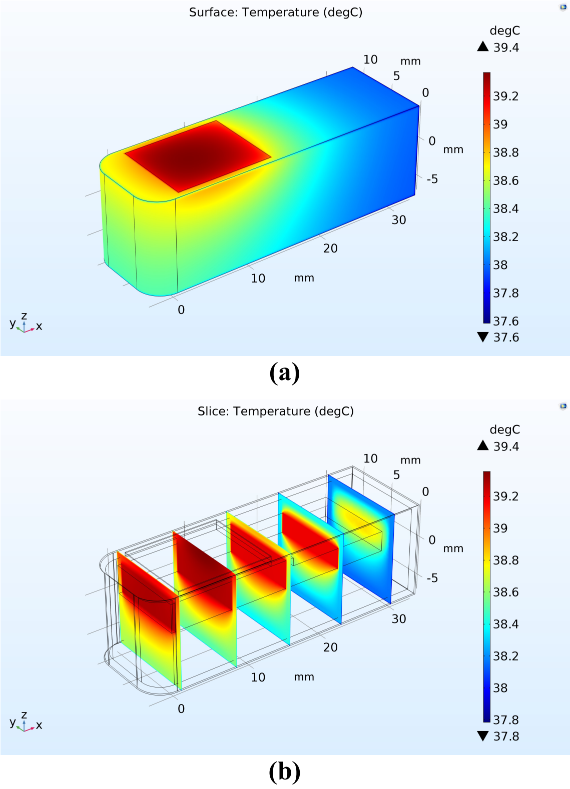


Figure 5: (a) Surface temperature, and (b) bulk temperature of a scan head with polymer-coated metal encapsulation. The Cu inner layer is 0.5 mm thick, the PTFE outer layer is 100 µm thick.

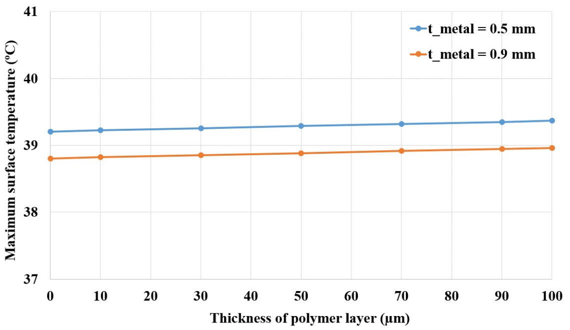
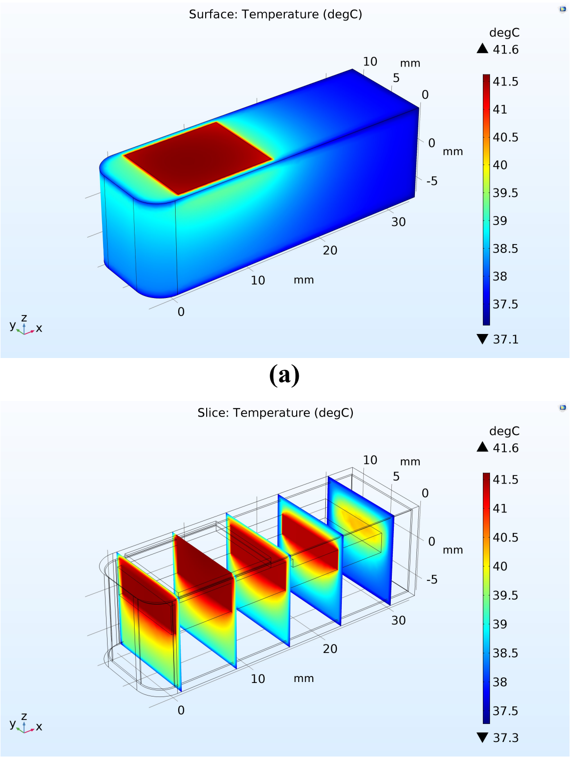


Figure 6: Effect of polymer layer thickness on the maximum surface temperature of the scan head encapsulated by polymer-coated metal structure having metal thickness of 0.5 mm or 0.9 mm.

2.3. Heat transfer of TEE scan head with metallized polymer encapsulation

In this type of double-layer encapsulation, we have considered a PES part with the inside metallized with a thin layer of Cu. The polymer part(s) could be prefabricated by injection molding, and the Cu layer could be deposited by conventional metal plating techniques, such as electroplating or electroless plating.

The simulations were applied for two PES thickness values (0.5 mm and 0.9 mm), and the Cu thickness vas varied from 10 µm to 100 µm. The PES thickness of 0.5 mm was chosen due to the lower limit of injection molding [6], [8], and the consideration of the mechanical integrity of the polymer part. The PES thickness of 0.9 mm was chosen as an upper value, so that the total thickness of the double-layer encapsulation does not exceed the encapsulation thickness of 1 mm of the current scan head. The Cu thickness range was selected based on the capabilities of plating techniques, and the requirements for EMI shielding [8], [11].



(a)

(b)

Figure 7: (a) Surface temperature, and (b) bulk temperature of a TEE scan head with metallized polymer encapsulation. The outer PTFE thickness is 0.5 mm while the inner Cu thickness is 100 µm.

An example of a heat transfer simulation of a scan head encapsulated as mentioned above is shown in Figure 7. This double-layer encapsulation design has a 100 µm Cu inner layer and a 0.5 mm PES outer layer. The surface temperature of the scan head in this case varies from 37.1 ºC to 41.6 ºC. The maximum surface temperature occurs at the outer surface of the heat source. Note that the maximum surface temperature (41.6 ºC) is higher than that of the polymer-coated metal encapsulation (around 39.4 ºC, Sect. 2.2). In the latter case, the heat spreading metal layer was thicker while the thermally insulating polymer layer was thinner.

Figure 8 shows the effect of Cu thickness on the maximum surface temperature, for PES thicknesses of 0.5 mm and 0.9 mm. For both PES thicknesses, the maximum surface temperature decreases when increasing the thickness of Cu layer from 10 µm to 100 µm. Figure 8 also indicates that the thermal safety limit of 43 ºC is reached when the Cu layer thickness is above a certain value, e.g. above 50 µm when the PES thickness is 0.5 mm.

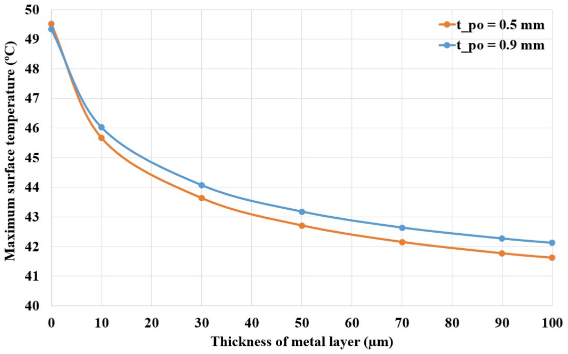


Figure 8: Effect of the metal layer thickness on the maximum surface temperature of a scan head with metallized polymer encapsulation. Results for Cu metal layers and two PES polymer thicknesses: 0.5 mm and 0.9 mm.

From a heat transfer point of view, a metallized polymer encapsulation can provide adequate thermal dissipation when the Cu layer thickness is above a certain value. The Cu thickness must also provide sufficient EMI shielding.

The EMI shielding effectiveness (EMISE) of PES–Cu encapsulations with different thickness combinations (i.e. 0.5 – 0.9 mm PES and 10 – 100 µm Cu) was calculated based on ref. [11]. The results show that the proposed metallized polymer encapsulations can provide adequate EMISE. In all cases considered, the EMISE is higher than 100 dB in the frequency range of (0.03 – 3) GHz, which is a common frequency range for testing EMISE of medical devices used in professional healthcare facility environment [12], [13]. These values are above the shielding requirements for medical devices classified in the same group as the TEE scan head (group 1, class B). For example, the peak limit for radiated disturbance of these devices, at a measurement distance of 3 m, in the frequency range (1 – 3) GHz is 70 dB [13]. Nevertheless, EMISE measurements of such encapsulations must be conducted to verify the theoretical results and to select the most suitable metal layer thickness.

IV. Conclusions

The heat transfer of a TEE scan head was simulated. The target of the simulations was to identify promising encapsulation concepts which can ensure the safety for patients (maximum scan head surface temperature below 43 ºC), and simplify the assembly process of the scan head. Two encapsulation concepts were analyzed, single-layer encapsulation and double-layer encapsulation.

Our simulation results show that a single-layer encapsulation, with appropriate thermal conductivity and thickness, can provide sufficient heat transfer for the scan head. However, further analysis is required to figure out specific material(s) which can comply with other functional requirements. The materials should have thermal conductivity higher than 20 W/(m·K), while satisfying requirements such as EMI shielding and electrical isolation.

On the other hand, a double-layer encapsulation, such as a polymer-coated metal encapsulation or a metallized polymer encapsulation is able to provide the multi-functional performance required for this scan head. For a polymer-coated metal encapsulation, any combination of inner metal layer thickness in the range of (0.5 – 0.9) mm and outer polymer layer thickness in the range of (10 – 100) μm will satisfy the thermal requirement. For a metallized polymer encapsulation, the inner metal layer must have a certain thickness in order to satisfy the thermal requirement. As an example, a Cu layer must be thicker than 50 μm when the thickness of a typical polymer material is 0.5 mm.

In further work, prototypes will be fabricated, and experimental measurements will be performed in order to verify the proposed encapsulation concepts. Both manufacturability and thermal management will be considered.

Acknowledgements

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