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Short communication

Effects of an implant on temperature distribution in tissue during ultrasound diathermy

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ABSTRACT

The effects of an implant on temperature distribution in a tissue-mimicking hydrogel phantom during the application of therapeutic ultrasound were investigated. *In vitro* experiments were conducted to compare the influences of plastic and metal implants on ultrasound diathermy and to calibrate parameters in finite element simulation models. The temperature histories and characteristics of the opaque (denatured) areas in the hydrogel phantoms predicted by the numerical simulations show good correlation with those observed in the *in vitro* experiments. This study provides an insight into the temperature profile in the vicinity of an implant by therapeutic ultrasound heating typically used for physiotherapy. A parametric study was conducted through numerical simulations to investigate the effects of several factors, such as implant material type, ultrasound operation frequency, implant thickness and tissue thickness on the temperature distribution in the hydrogel phantom. The results indicate that the implant material type and implant thickness are the main parameters influencing the temperature distribution. In addition, once the implant material and ultrasound operation frequency are chosen, an optimal implant thickness can be obtained so as to avoid overheating injuries in tissue.

1. Introduction

Ultrasound diathermy has been widely used to treat various soft tissue disorders for decades. The ultrasound that propagates through human tissue causes pressure waves, which in turn lead to molecular vibration and subsequent tissue heating. Though controversy still exists, ultrasound is believed to be beneficial for various soft tissue disorders, such as chronic tendinopathy or ligament injury. A random controlled trial showed significant benefits of ultrasound in the treatment of calcified tendinitis at the end of an intensive 6-week treatment program [1]. During ultrasound treatment, ultrasound wave propagating in tissue produces heat as a result of energy absorption, especially at or near the surfaces of bone. This localized heating near bony surfaces preferably produces hyperemia and enhances extensibility of tissue such as ligaments, tendons and joint capsules. Mechanical effects of ultrasound on tissue, such as cavitation, streaming and standing waves, may also induce therapeutic bioeffects. For example, high focal pressure and shear stress produced by cavitation have been shown to induce sonoporation, thrombolysis, platelet aggregation, or opening of the blood–brain barrier [2–5]. However, if uncontrolled, the intense heat produced by therapeutic ultrasound might induce detrimental bioeffects. Heat can exacerbate acute inflammation and thus ultrasound is usually avoided in the management of acute tendinitis, arthritis, or ligament sprain. Applying ultrasound near structures vulnerable to thermal injury, such as nerve, brain, eyes and reproductive organs, is avoided.

The use of therapeutic ultrasound near implants is controversial. Application of ultrasound on a patient equipped with a

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pacemaker is generally contraindicated since ultrasound may cause its malfunction [6]. Plastics such as methyl methacrylate or polyethylene have high acoustic attenuation coefficients and will be overheated under ultrasound exposure. Therefore, ultrasound is usually avoided near implants containing plastic materials, such as artificial hip joints with polyethylene liner or breast implants. Metal has a lower acoustic attenuation coefficient and higher thermal conductivity than bone and soft tissue. No focal temperature increase has been observed when metal implants are exposed to ultrasound [7–11]. However, the studies of therapeutic ultrasound on areas with implants and bones are usually qualitative and poorly controlled. The effects of implant thickness and distance to the ultrasound probe are also unknown.

Thorough understanding of the characteristics of thermal therapies using ultrasound is important for the development of standards to ensure the safety and efficacy of treatments. To enrich *in vivo* or *ex vivo* experiments, numerical modeling of thermal therapies using ultrasound is a viable tool to investigate the influence of implants in tissue. In this study, the influences of plastic and metal implants on ultrasound diathermy have been systematically studied by both experimental and simulation methods. *In vitro* experiments on transparent temperature-sensitive tissue-mimicking hydrogel phantoms with implants were conducted to calibrate parameters in the numerical models and verify the simulation results. Furthermore, a parametric study was carried out to investigate the effects of ultrasound operation frequency, implant material type, implant thickness and buried depth of the implant on temperature distributions in the hydrogel phantoms during ultrasound diathermy.

2. Materials and methods

2.1. Experimental setup

For real-time observation of the heating process during therapy using an ultrasound probe (US-700, Ito Co, Japan) commonly used by physical therapists, a model system that mimics a patient's metal plate fixation for a bone fracture was constructed. The system consists of a 15-mm-thick transparent temperature-sensitive hydrogel layer overlying a flat bovine bone with a metal implant (a 316 stainless steel plate of 7 mm long and 2 mm thick) on it (see Fig. 1). In other words, a composite system with three layers of materials – hydrogel layer, implant plate and bone plate from top to bottom, was built. This type of sample design is called the "metal implant group" in this study. In contrast, similar designs but with a plastic implant (a polyethylene plate of 7 mm long and 2 mm thick) or without an implant were also constructed for comparison purposes. These are called the "PE implant group" and "bone-only group", respectively. Fig. 2 shows the top-view images of the three sample groups: the bone (Fig. 2a), stainless steel plate/bone (Fig. 2b) and polyethylene plate/bone (Fig. 2c) can be seen through the 15-mm-thick, transparent hydrogel layer. The composite samples developed were heated by an ultrasound probe at a power of 12 W for 900 s. To challenge extreme conditions, the ultrasound probe was kept stationary and the exposure time was longer than that used in clinical settings (5–10 min.) To measure the temperature histories during heating, thermocouples were inserted into the hydrogel layer and placed in contact with the surface of the implant or bone (if no implant) at positions 1 mm and 30 mm away from the central axis of the ultrasound probe (i.e., the blue dashed line in Fig. 1). The ultrasound probe covered with ultrasonic gel was positioned above but in contact with the hydrogel layer with the output ultrasound beam projected in the normal direction to the hydrogel layer, implant plate and bone plate.

2.2. Preparation of NIPAM-based hydrogel phantoms

Transparent reusable N-isopropyl acrylamide (NIPAM)-based hydrogel phantoms were adopted to mimic human tissue and to enclose the implant plate and bone to achieve the sample designs described in the previous section. The hydrogel phantoms were formed by crosslinking copolymerization of NIPAM and N,N′-methyl-enebisacrylamide with the addition of acrylic acid (AAc) to adjust the cloud point so that it fell in the temperature range of biological significance [12]. The reusable hydrogel phantoms with a cloud point temperature of 52 °C were fabricated for the heating experiments. The 52 °C was chosen since it represents the threshold temperature above which an irreversible tissue damage are likely to occur. Heating the transparent NIPAM-based hydrogel phantom past the cloud point would lead to the segregation of NIPAM, resulting in an increase of the phantom's opacity.

The fabrication process of the phantoms consisted of the following steps: 1.32 ml or volume ratio 0.274% of AAc (99.5%, Acros Organics, USA) was first dissolved in 450 ml degassed, distilled water before adding 27 g of NIPAM (Acros Organics, USA) to the aqueous solution. The solution was gently stirred at room temperature until complete dissolution of NIPAM. 1.125 g of MBAm (97%, Alfa Aesar, UK) and 0.585 g of ammonium persulfate (APS; Sigma Chemicals, USA), which acted as the initiator for crosslinking, were then added consecutively into the aqueous solution. The mixture was gently stirred at room temperature until homogenized. Finally, 1.2 ml of polymerization agent N,N,N′,N′-tetramethylethylenediamine (TEMED; 99%, Sigma Chemicals, USA) was added to the mixture.

The final aqueous mixture was immediately poured into molding containers in which a flat bovine bone with an overlying implant plate (for the metal and PE implant group samples) had been placed beforehand. The mixture was allowed to polymerize completely at room temperature to form the composite samples as shown in Fig. 2. The samples were either tested in the heating experiments within 24 h after complete polymerization of the hydrogel, or stored in an airtight container to avoid dehydration (if left in air) or swelling (if placed in water) of the hydrogel for later experimental usage. As shown in Fig. 2, the NIPAM-based hydrogel phantoms were optically transparent, gelatinous materials. Our previous studies indicated that the material properties of the phantoms are similar to those of human soft tissues [12,13].

2.3. Comparison of heating behaviors

The changes of transparency (opaqueness) of the hydrogel phantoms while heating by the therapeutic ultrasound system were compared among the three groups of samples. The samples were heated by 3 MHz ultrasound at a power of 12 W (or an intensity level of 2 W/cm^2) for 900 s. The shape and location of the opaque area formed within the hydrogel phantoms after heating were recorded. The heating experiment was repeated at least three times for each sample group for verification. The power and duration of the heating experiments were chosen according to our previous study [12] on the NIPAM-based hydrogel phantoms; the opaque (denatured) areas formed in the phantoms and real tissues are comparable in terms of shape and size.

2.4. Simulation of pressure field

For a three-layer composite sample, assume that a layer medium of uniform thickness L is sandwiched between two dissimilar layer media and that a plane wave is normally incident at the boundaries between the media, as shown schematically in Fig. 3. Let the characteristic impedances of these media be R_1, R_2 and R_3, respectively. When an incident wave in medium 1 arrives at