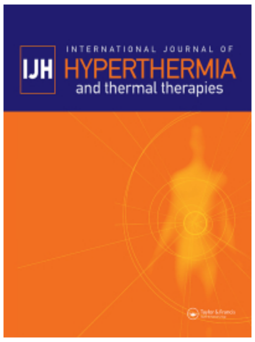

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Thermal ablation and high-temperature thermal therapy: Overview of technology and clinical implementation

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Thermal ablation and high-temperature thermal therapy: Overview of technology and clinical implementation

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Abstract
High-temperature hyperthermia or thermal therapy is being applied for destruction of cancerous tissue, eradication or reduction of benign tumours and targeted tissue modification and remodelling. Many of these high-temperature technologies provide a minimally-invasive alternative with lower morbidities compared to the traditional surgical procedures. The effects of high-temperature thermal exposure on tissues, examples of heating technology and procedures of clinical practice related to high-temperature thermal therapy are reviewed. This brief review encompasses interstitial, endocavity, intraluminal and external applications of RF, microwave, ultrasound, laser and thermal conduction energy sources. The technology is prevalent and in various levels of advancement, with the move toward more spatially-accurate and controllable heating systems combined with image-guidance and treatment verification warranted, especially for the treatment of cancer.

Keywords: *Thermal ablation, thermal coagulation, minimally-invasive surgery, hyperthermia, image guidance, cancer, prostate, breast, liver, bone, spine*

Introduction

High-temperature thermal therapy is currently being implemented as a minimally-invasive alternative to traditional surgery in the treatment of benign disease and cancer, as well as repair of sports injuries and tissue re-shaping or modification. Thermal ablation, thermal coagulation, high-temperature hyperthermia, coagulative therapy and thermotherapy are other terms often used to describe this use of heat to directly modify or destroy tissue. Many different types of energy sources are applied, including laser, radiofrequency (RF) current, microwave, ultrasound and thermal conduction based devices. Heating energy can be applied by external means or internally via interstitial, intraluminal or intracavitary approaches. The use of high-temperature thermal therapy is prevalent, with increasing

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commercial interest and clinical implementation. New heating technologies with improved precision or control of the heating patterns, combined with non-invasive MR thermal monitoring or other image-based approaches, have potential to improve accuracy and verification of therapy delivery which is most critical for the treatment of cancer. This paper provides a brief review of the following: thermal effects and dosimetry of high-temperature therapy on tissues; and selected examples of clinical heating technology, strategies of use and clinical efficacy.

Thermal mediated effects of high-temperature exposure

In delivering high-temperature thermal therapy, most devices are used to generate target temperatures typically in excess of 48–50°C up to ~95–100°C. The outer boundary of tissue destruction is often defined by the 50–54°C contour and a lethal thermal dose exposure (as defined below) of $t_{43} > 240$–540 min. The duration of thermal exposure varies, depending upon the type of heating modality, target location and dimensions, temperature distributions and treatment strategy. For example, the thermal exposures may range from 10–20 s for high-intensity focused ultrasound (HIFU) to produce single-shot 2 mm diameter × 10 mm long lesions [1], a few minutes for laser ablation of ~1.5 cm diameter volumes in prostate [2], ~10–15 min for RF ablation of 2–3 cm diameter liver tumours [3], 30–60 min for transurethral microwave ablation of ~3 cm diameter × 2 cm volumes of prostate for treatment of Benign Prostatic Hyperplasia (BPH) [4] and longer duration (~1.5–2+ h) for treating appreciable volumes using sequential summation of single shots with the very precise HIFU techniques [5, 6]. The higher thermal exposures irreversibly damage and coagulate critical cellular proteins, tissue structural components and the vasculature leading to immediate tissue destruction [7]. In the areas of lower but still lethal thermal exposure, typically at the borders of the thermal coagulated lesion, the tissue will die within 2–3 days [8]. Beyond the effective border of tissue destruction, non-lethal hyperthermic temperatures mediate physiological changes such as increases in blood flow, permeability and tissue oxygenation [8]. It is within these regions outside the direct lethal zone that adjunct therapies to thermal ablation are being proposed (e.g. radiation therapy [9] or chemotherapy [10]) to accentuate the penetration and thoroughness of tissue destruction. An example of a thermal coagulative lesion produced in a canine prostate gland *in vivo* [11] is shown in Figure 1(a), demonstrating the gross appearance of the different regions of thermal damage [12]. Contrary to the use of heat for outright tissue destruction, high temperatures for thermal shrinkage of structural collagen alone (e.g. skin, ligaments) require exposures greater than 60–75°C for effect [13].

Tissue thermal damage at high-temperature exposures can be predicted by using an Arrhenius analysis or the Sapareto-Dewey iso-effect thermal dose relationship [8, 14–16]. These relationships have been applied to different cell lines and *in vivo* systems and demonstrate that within defined temperature ranges tissue thermal damage is approximately linearly dependent upon exposure time and exponentially dependent upon the temperature elevation (Figure 1(b)). Based upon this relationship, the thermal exposure can be quantified as a thermal dose which can be expressed in equivalent minutes at 43°C (EM43°C or t_{43}). Thermal doses of 120–240 min at 43°C generate considerable tissue necrosis, but the sensitivity between tissue types is variable [8, 15]. The application of thermal dose and thermal damage values have been validated for high temperature (>48°C)

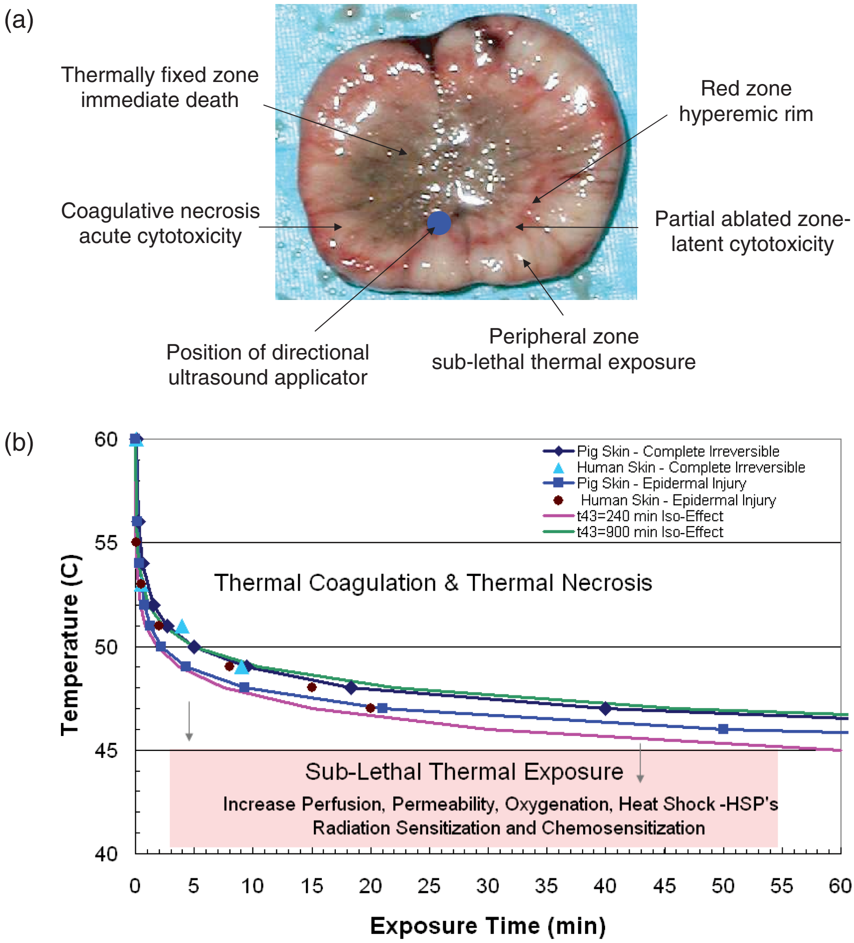

Figure 1. Thermal mediated effects of high-temperature thermal exposures: (a) Example of a thermal coagulative lesion in canine prostate produced from a rotated directional interstitial ultrasound applicator [11], with distinct regions of the thermal damage labelled [12]; (b) Plot of temperature-time thresholds of acute thermal damage measured by Henriques and Moritz [16, 83] in pig and human skin *in vivo* bracketed by iso-effect thermal dose thresholds of 240 EM43°C and 900 EM43°C.

thermal therapy *in vivo* including humans in such tissues as brain [17, 18], prostate [19–22], breast [23], muscle [24], skin [16] and liver [25].

Examples of technology and clinical implementation

Thermal ablative therapy is being applied to treat localized cancerous tumours in sites such as liver [26–28], kidney [29], brain [30, 31], lung [32], breast [23, 33], prostate [5, 34, 35] and bone [36]. Furthermore, non-oncological uses of high-temperature thermal therapy include treatment of prostatic hyperplasia [4, 37], cardiac arrythmias [38, 39], uterine fibroids [33, 40] and mennorhagia [41], vision correction [42], varicose veins [43], low back pain [44], reduction of upper palate and turbinates to reduce snoring [45, 46], stabilization of skeletal joints [47, 48] and cosmesis such as dermal tightening [49, 50].

Minimally-invasive devices and procedures

One of the most prolific areas of development of thermal therapy technology is for treating disease of the prostate. There are numerous examples of clinical thermal therapy techniques that provide a minimally-invasive alternative to surgical transurethral resection (TURP) for treating BPH [4], including transurethral microwave delivery [51, 52], transurethral RF energy [53] and transrectal high-intensity focused ultrasound (HIFU) [54]. These approaches have demonstrated durability and efficacy close to TURP but with lower morbidity. The HIFU techniques are integrated with transrectal ultrasound imaging for guidance and treatment planning to accurately ablate target regions in the prostate and have been applied for treating localized prostate cancer [5, 55, 56]. Recent efforts have coupled ultrasound elastography with the transrectal ultrasound imaging to visualize the HIFU thermal lesions and provide a means of treatment verification [57].

Recent clinical studies have demonstrated the feasibility of using implants with multiple interstitial microwave antennae to produce a contiguous high-temperature thermal exposure for thermal ablation of recurrent prostate cancer [58]. This approach, when combined with an hydrodissection technique to separate the rectum from the prostate, appears to effectively treat the peripheral zone of the prostate gland while preserving the rectum. Another interstitial technique utilizes an implant of ferromagnetic seeds which thermoregulate at 70+°C. These seeds are surgically placed throughout the prostate gland, similar to procedures followed for permanent brachytherapy implants, and exposed to an oscillating magnetic field to induce an ablative temperature distribution for treatment [59, 60]. Catheter-based ultrasound devices for interstitial or transurethral prostate ablation are currently being developed to be combined with MR temperature imaging and have demonstrated enhanced dynamic spatial control and ability to conform the ablation to the periphery or targeted regions of the gland [11, 61–63].

Other interstitial or intraluminal technologies would include miniature ultrasound arrays, with rotating planar transducer segments, developed and applied for precise thermal ablation of digestive tumours [64], such as biliary carcinomas [65]. Implantable laser fibres [66, 67] and RF devices [68] are being used for ablating uterine fibroids, significantly reducing fibroid volume and offering symptomatic improvement. Water-cooled laser applicators can be used for treating liver metastases [69] and have been investigated for combining laser ablation with high-dose rate brachytherapy [70]. Cooled laser applicators with a small cross-section, combined with MR thermal imaging for temperature and thermal dose feedback control, are under development for precise applications in brain [71]. The treatment of discogenic back pain with high-temperature therapy is being performed using small diameter heating catheters (thermal conduction or RF sources) placed under fluoroscopic guidance directly into the intervertebral disc [72, 73]. Possible mechanisms of action include thermal destruction of nociceptive nerve fibres infiltrating the damaged disc and sealing of annular fissures.

Interstitial or percutaneous RF ablation techniques are more commonly being used under image guidance to treat inoperable tumours in sites such as liver, kidney, adrenal gland and lung [74, 75]. Devices with deployable electrodes can cover spherical tumour volumes ranging from 1–3 cm, possibly up to 5 cm diameter with newer configurations. Some of these devices have multiple temperature sensing on electrodes. Alternatively, single needle devices with internal water-cooling can reduce surface charring and allow for greater amounts of RF energy to be applied to produce large thermal lesions. These RF devices can also be used to treat painful bone metastases, providing pain reduction and quality of life improvement [32, 76].

Non-invasive and external devices and procedures

Local high-temperature thermal therapy can also be applied using external heating techniques. A microwave adaptive phased array system, consisting of dual-opposed 915 MHz apertures positioned to compress the target tissue, has been used to 'focus' the energy and deliver 48–50°C for 60 min to breast tumours. Thermal dose $t_{43} > 210$ min and peak temperature >49.7°C have been shown predictive of 100% tumour necrosis for treating early stage breast cancer [23].

Extra-corporeal high-intensity focused ultrasound (HIFU) can be applied for ablation of deep-local tumour sites. In one approach, positioning of the HIFU treatment zone is based upon pre-treatment planning with CT/MR images and during therapy using integrated real-time diagnostic ultrasound. Instead of sequential discrete shots to produce a series of small ablation zones, the focal zone is scanned continuously to ablate large regions. This approach has been used to treat over 1000 tumours, including bone, breast, liver, kidney, lung, sarcomas and benign tumours [77, 78]. The most precise thermal ablation technology uses high-intensity focused ultrasound in combination with magnetic resonance (MR) imaging and MR thermal monitoring; this platform provides image based treatment planning combined with real-time control and assessment of the treatment and has been applied for sites such as breast [79, 80] and uterine fibroids [6, 81]. Non-invasive thermometry using MRI is now being utilized to guide many forms of thermal therapy where accuracy of treatment is required [82].

Current status and future directions

Thermal ablation and high-temperature thermal therapy techniques are becoming more acceptable as a minimally-invasive alternative to surgery for the treatment of some cancers and many forms of benign disease. Currently, many of these procedures are applied with limited or no temperature sensing and with limited image guidance, making control and verification of treatment delivery difficult. The more precise heating technologies are integrated with MR thermal imaging or ultrasound imaging to provide a means of treatment monitoring, making them more acceptable for thermal ablation of cancer. Ongoing advances in real-time image guidance, treatment monitoring and treatment planning for thermal therapy, coupled with improved heating devices with more precise localization and spatial control of thermal exposure, can be integrated together to dramatically improve clinical efficacy and acceptability of this form of therapy. Arguments could be made that such platforms are too complex, not practical nor commercially viable; however, as demonstrated with the MRI-guided HIFU systems, these sophisticated platforms are accurate and practical, especially for the treatment of cancer with a curative intent. In addition, the combination of thermal ablation with complementary therapies appears to provide a viable therapeutic enhancement.

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