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SURGICAL CUTTING AND ABLATION BY ENERGY BASED DEVICES: PRINCIPLES AND APPLICATIONS

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ABSTRACT. Advances in ultrasound, radiofrequency, and water jet systems are facilitating their increased use in new medical ablation or cutting applications in fields as diverse as cardiology, orthopaedics, ophthalmology, dermatology, oncology and neurosurgery. These methods involve controlled alteration or destruction of tissues via the application of thermal, electrical or kinetic energy. This market segment is characterised by advanced devices capable of heating or cooling tissue from -200°C to 400°C, or inducing vibrations of up to 60 kHz to cause tissue damage. The medical conditions targeted primarily pertain to chronic and age-related diseases, but elective and cosmetic procedures are also addressed. Medical ablation research has the potential for significant clinical and commercial gains. New capabilities in terms of tissue ablation technologies can enable new medical procedures, affording opportunities for design creativity and entrepreneurship and ultimately delivering a health dividend.

1 INTRODUCTION

The clinical conditions addressed by energy-based surgical cutting and ablation devices are some of the most urgent and severe faced by patients throughout Europe. In many cases, well established traditional methods have drawbacks that can only be avoided by alternative, mainly energy based, techniques. Such products now account for more than 10% of the total world market for medical devices [1].

For example, total blockage of an artery can prevent the advancement of a guidewire and hence preclude the possibility of deploying an angioplasty balloon or placing a stent [2]. This predicament may necessitate invasive bypass surgery to restore blood flow [3]. The use of high frequency mechanical vibrations (in the kHz range), transmitted via a flexible wire waveguide, offers the possibility of breaching or penetrating the plaque blockage [4]. Although clinical devices of this kind are in clinical use, the fundamental principles underpinning their operation remain to be understood. Ultrasound assisted cutting technologies have also been investigated and applied for many medical and surgical applications, including a recent exploratory study on joint arthroscopy.

Radiofrequency ablation involves passing electrical currents (typically of the order of 500 kHz) through biological tissue [5, 6]. This causes a local temperature elevation, which results in tissue alterations including protein denaturation and cell necrosis. This technology finds application in

the elimination of cardiac arrhythmias or the destruction of tumours in different locations of the body (liver, kidney, lung, bone, prostate, and breast) [6]. Radiofrequency ablation technology has also been applied to the ablation or debridement of fibrous soft tissues such as cartilage or the meniscus, in cases where injury or osteoarthritis cause pain or limited mobility [7, 8, 9, 10].

Water jet cutting is a non-thermal technology for cutting of tissues, including bone [11, 12]. The perceived advantage over traditional cutting methods is that precise and efficient cutting can be achieved without generating high temperatures, with consequent advantages for the biological potency, and hence healing or regeneration potential, of the residual bone surfaces. Despite its high potential for improved bone cutting, research in this area has been limited to date. Nonetheless evidence is emerging of its use for resection of the spleen and its adoption in surgery associated with splenic parenchyma [13].

The outcomes of medical ablation procedures depend directly on effecting the desired alterations to tissues, plaques or tumours with a high degree of precision and control. Thermal energy is known to have multiple effects on fibrous soft tissues, including protein denaturation, cell necrosis and the expression of heat shock proteins, but the precise effects of ultrasound, RF, or water-jet energy on physical properties have not been widely and rigorously quantified.

In this paper, the principles of these energy based surgical cutting and ablation methods will be outlined. Their applications in those aspects of healthcare that are of considerable concern in Europe will be discussed through key examples in cardiology, oncology and orthopaedics.

2 PRINCIPLES OF CUTTING AND ABLATION

2.1 ULTRASOUND

Two of the most common forms of ultrasound energy used in medical cutting and ablation are (i) high power, low frequency ultrasound, involving direct tissue contact with a vibrating device surface or edge, or (ii) high frequency focused ultrasound which is transmitted extracorporeally (as traditionally used for the disintegration of kidney stones).

The underlying principle of high power, low frequency ultrasonic cutting technology is that the vibrating distal tip of the ultrasound waveguide (e.g. wire or probe) is used to transmit energy to the surrounding fluids and tissues. Four primary mechanisms of interaction have been identified in the literature; (i) acoustic pressure fluctuations, (ii) cavitation, (iii) acoustic streaming of blood and (iv) ablation due to direct contact with the distal tip (Figure 1) [14, 15]. The principle operating parameters that affect cutting or ablation are the amplitude of ultrasonic vibration and the frequency. The typical frequency for high power, low frequency ultrasound is between 20-60 kHz. This form of ultrasound has the potential to cause cavitation in body fluids above certain power thresholds, where negative pressure is generated during the backward motion of the waveguide tip, causing the collapse of gas bubbles in the fluids or at solid-fluid interfaces.

Focused ultrasound is now being increasingly investigated for the treatment of cancerous tumours. It can be used, in combination with Magnetic Resonance Imaging, to apply focused

energy to regions of malignant tissue, for controlled heating of the tissue and destruction of tumour cells.

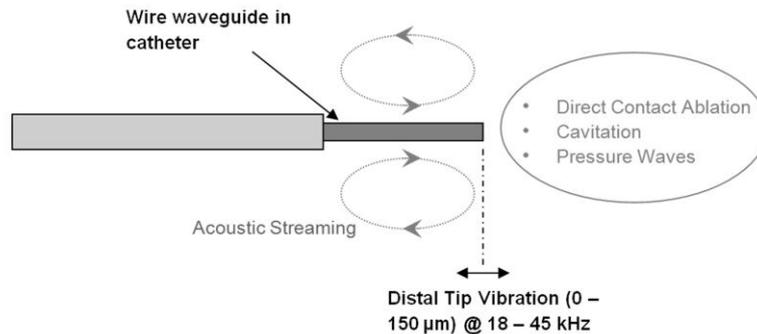


FIGURE 1 Primary methods of fluid and tissue interaction at the tip of an ultrasound wire waveguide.

2.2 RADIOFREQUENCY

Radiofrequency ablation devices operate on the basis of generating high frequency voltage (of ≈ 500 kHz), which, when brought into close proximity of tissues, causes flow of electrical currents through them. Different waveforms can be used to modulate the effect on tissues. The tissues provide the necessary impedance to produce heat as electrons overcome the resistance in the tissues, and the patient's body, therefore, becomes part of the electrical circuit. Alternating current operating at 60Hz with low voltage causes muscular contraction. At very high voltages, a 60Hz alternating current can cause electrocution. If however, the current alternates at the much higher frequency of, for example 330,000 cycles per second (330kHz), the electrical current will pass harmlessly through the patient's body without muscular contraction or electrocution. This modified current exits the electrosurgical device via the hand-held treatment electrode, enters the patient's tissues which are intended to be coagulated or cut, flows through the patient following the path of least resistance and exits via the large grounding or indifferent electrode and returns to the device. Radiofrequency devices are configured either as monopolar or as bipolar devices. Monopolar radiofrequency devices necessitate an active electrode within the surgical probe, and a passive return electrode at a site on the patient's body distant from the operative site. In comparison, a bipolar probe contains both an active and a return electrode within the surgical probe. Contemporary electrosurgery uses both cutting and coagulation, depending on the type of current used.

Electrosurgery permits the surgeon the versatility to cut and coagulate simultaneously or individually as required. A wide variety of commercial devices exploiting this technology are available [16]. For electrosurgical systems, cutting and coagulation are dependent on current density. By using a small active treatment electrode with minimal surface area, current is concentrated at the treatment electrode and cutting and/ or coagulation occurs at the tip. The amount of heat developed by high-frequency, alternating current increases by the square of the

current density. Sustained heat application causes the tissues beneath the tip of the active electrode to become hot enough to vaporize any water they contain, thereby producing a cutting or ablating effect. Circulating blood quickly dissipates heat away from the tip of the active electrode and current density becomes insufficient to heat the patient's tissues at sites distant from the tip.

Electrosurgical currents can be altered into different waveforms that perform different functions. For the majority of applications, surgeons can modify the effect of the alternating current by switching from a cutting to a coagulating mode by varying the current waveform and power. At relatively low voltage, currents that are constantly on (rectified and filtered) cut and ablate tissue. At relatively high voltage and intermittent (e.g. 6% on) (damped), currents heat tissues to the point of protein denaturation, effective in sealing small blood vessels or shrinking and coagulating tissue. However, during arthroscopic meniscectomy, coagulation of the avascular cut edge is considered unnecessary. Consequently, such devices are pre-configured for each tissue application for optimal cutting. Pollack identified four factors that affect tissue damage in electrosurgery. These are the surface area of the treatment electrode, the duration of electrode-tissue contact, power setting and type of current (e.g. damped, rectified or filtered) [17].

2.3 WATER JET

That tissue can be cut with water jets is well known [18]. The key element is water jet travelling at high velocity. When the water stream strikes the tissue or bone, material can be rapidly removed by the erosive force of the water. The water jet method offers the advantages of no mechanical contact between tool and bone or tissue, with minimal mechanical force applied, minimal localised heat-affected zone, and accuracy of control. It should be noted that in established applications such as in cutting of steel and titanium by water-jet small diameter particles usually ground garnet are injected into the water jet by means of a special nozzle. The water jet accelerates the particles which gather a large kinetic energy. Material removal is achieved by the combined effects of the particles and water jet. When softer biomaterials such as tissue are to be cut no such abrasive particles can be introduced, and cutting has to be effected solely by water. In the latter case pure water is replaced by saline.

3 APPLICATIONS

3.1 ULTRASOUND – APPLICATION IN CARDIOVASCULAR DISEASE

Cardiovascular disease (CVD) is the main cause of death in the European Union (EU) accounting for over 2.0 million deaths each year [16]. Of the two main forms of CVD, coronary heart disease (CHD) alone is responsible for 1.92 million deaths in Europe each year (over 741 000 in the EU) [19].

Balloon angioplasty and stenting are widely used interventions for restoration of blood flow through arteries with total or partial blockages. The ability to position a guidewire so that it forms a path through the stenosis (or blockage) is essential for balloon or stent placement and has been reported to be the key indicator of success for such procedures in 80% of cases [2]. Chronic total occlusions (CTOs) which cannot be bridged lead to significant numbers of referrals for coronary artery bypass graft surgery. The limitations of by conventional guidewire technology have prompted consideration of the possibility of transmitting mechanical vibrations in the low

ultrasonic range (~20kHz) to the plaque locations by means of wire waveguides. This approach has long been identified as having the potential to disrupt calcified lesions through directly applied mechanical vibrations transmitted via long, low profile, flexible superelastic wire waveguides. In early 2005, approval to market such a device in the European Union was granted for the treatment of chronic total occlusions [20], and the device was granted FDA approval in 2007. Clinical trials results have also now been published.

3.2 ULTRASOUND – APPLICATIONS IN ORTHOPAEDICS

Tearing and fraying of the menisci are associated with severe pain, effusion, catching, locking and joint tenderness, leading to reduced mobility and potentially post-traumatic osteoarthritis. The menisci are predominantly non-vascularised, limiting their ability to heal naturally. Surgery is often the only treatment option. Several million arthroscopic knee procedures are performed worldwide annually. Current commonly used keyhole surgical devices involve shaving frayed tissue as well as radiofrequency based processes that dissolve the tissue. Major limitations yet to be fully overcome include poorly controlled removal of meniscus and cartilage, high temperatures, debris or particles and roughened residual tissue surfaces. Recent pre-clinical work has investigated the prospects for ultrasound assisted cutting technologies for tougher tissues such as frayed meniscus, with promising results [21]. However, the unquantified risk of thermal necrosis in adjacent cartilage and bone, as well as vascular damage remains a concern for surgeons. Further studies are needed to fully evaluate these issues, and optimise designs accordingly.

3.3 ULTRASOUND – APPLICATIONS IN DENTISTRY AND GENERAL SURGERY

Ultrasonic devices are also used for the removal of plaque from teeth, while preserving dentin and enamel. The technology has also been employed in phaco-emulsification, soft tissue cutting, bone cutting, lipoplasty and bone cement removal. In some of these applications, a critical factor is the ability of the technology to exhibit tissue-selectivity, where certain tissues are destroyed while other tissue types are left undamaged. For example, in bone cement removal commercial devices changes in acoustic emissions can be detected when coming into contact with bone rather than bone cement. A relatively recent comprehensive review of the use of high power, low frequency ultrasound devices in medicine and surgery is available [15].

3.4 RADIOFREQUENCY – MENISCUS AND CARTILAGE CUTTING AND ABLATION

Much attention has focused on research into the effects of energy sources for meniscal ablation, addressing in particular mechanical and thermal damage in meniscus and cartilage, and osteonecrosis [7,8,9,10]. RF devices are known to injure both cartilage and meniscal tissue to varying depths, ranging from undetectable to 1,980µm in depth. More recently, other investigators have compared non-sharp cutting technologies with well-established technologies for given clinical interventions, to establish benchmarks for efficacy and damage in arthroscopy.

Cutting with radio-frequency (RF) current can be achieved through ohmic heating of tissue, whereby its resistance to the passing of an electrical current causes an intra cellular rise in temperature, or also through arc discharge; which causes vaporisation of tissue cells. These effects can be controlled and effectively applied to soft tissue masses. The advantages of radio-

frequency cutting include (i) Reduced mechanical force during incision, (ii) Reduced infection due to electro-cauterisation of capillaries during incision, (iii) No mechanical contact under certain conditions, (iv) Minimally invasive keyhole surgical possibilities, (v) Incision free tumour removal possibilities.

Literature describing modeling principles for the physics of ultrasound and radiofrequency devices is available. The finite element method is suitable for the solution of the appropriate partial differential equations for arbitrary geometries (in this case, representing the physical tissue structures around the ablation or cutting site). Key obstacles to accurate simulation include the lack of appropriate tissue property measurements (acoustic, electrical, thermal), and the fact that suitable, validated tissue alteration models (describing the altered physical and mechanical properties of tissues (or tumours) in response to injury of this type) are not available in the literature.

3.5 RADIOFREQUENCY – LIVER, KIDNEY AND PANCREATIC TUMOURS

Radiofrequency (RF) ablation technologies are well established for some applications (e.g. liver resection) and gaining acceptance for others. Key issues for liver surgery include limiting blood loss, and facilitating faster operating procedures. Higher morbidity and mortality rates are linked with long surgical times. One approach is to pre-coagulate tissue prior to resection [22], and this can be achieved through application of RF energy through ablation of perfusion electrodes. RF has also found application in RF assisted kidney resection and pancreatic surgery.

3.6 WATER JET – WOUND DEBRIDEMENT, NEUROSURGERY, LIVER RESECTION, THROMBUS DISSOLUTION, SPLEEN

Water jet (or saline jet) technology has been clinically applied for applications as diverse as debridement of burn wounds, the destruction of smooth brain tumours and brain metastases, liver resection and extraction/disintegration of thrombus in the neurovascular system. While pressures up to 20,000 bar are common for industrial applications, it has been found that pressures in the region of 30-40 bar have been found to be suitable for experimental liver dissection applications, in combination with nozzle diameters of 0.1mm. Pressures in the region of 5-20 bar with a 0.12 cm nozzle have been found suitable for the dissection of brain tissue, achieving cuts of several cm in depth at higher pressures, while preserving small intracerebral vessels [11]. As noted earlier advances in spleen- preserving or – conserving surgery are now being made in which high pressure water jets are used in order to treat tumours [13].

3.7 WATER JET – CARTILAGE AND BONE

Water jet techniques have also been applied in orthopaedic surgery, notably to the cutting or debridement of bone and cartilage [12]. Water jet techniques have been found to produce smoother chondral surfaces, allowing more precise cutting, than competing technologies. The technology has also been considered for bone cutting in revision prosthetic surgery or osteotomy, but surface roughness improvement will be required by comparison with conventional tools.

4 MODELS OF TISSUE BEHAVIOUR, DAMAGE AND ALTERATION

4.1 BACKGROUND

The literature on tissue cutting and ablation is characterised by experimental and clinical studies which report primary evidence such as material removal rate, temperature changes and, in some cases, histological studies for a given technology, device, set of operating parameters and tissue type.

4.2 MODELING OF ULTRASOUND ABLATION

The use of computational modeling is well reported for focused ultrasound applications, predicting the pressure amplitudes, focused field effects and thermal effects in fluid and surrounding biological tissues. Frequencies modeled, however, are generally in the Megahertz range and with acoustic pressures predictions up to 6 MPa. For high acoustic pressure fluctuations, non-linear effects may become significant [23]. Gavin *et al* present an acoustic fluid-structure model of a therapeutic angioplasty device that can predict the pressure amplitudes in the fluid field surrounding a vibrating waveguide tip [24, 25]. The model is capable of predicting the effect of waveguide geometry changes, such as wire length, on the instruments resonant response, and on the transmission of acoustic energy to the surrounding fluids. Predicted acoustic pressure distributions compare favourably with analytical solutions for simpler geometries [25] and those reported from experimental pressure measurements by Makin and Everbach [26] (see Figure 2). Results also correlate well with the experimentally observed onset of cavitation (Figure 3).

Under elevated temperatures, proteins in tissue and blood undergo a physical change, known as denaturation, which is accompanied by changes in the tissue's physical consistency. Changes in protein folding arrangements occur when tissue is heated and can be irreversible if the heating is severe (known as denaturation), causing gross shrinkage, changed hydration levels and other property changes. A single function may be used to approximate this form of tissue damage, despite the fact that it is associated with many different reactions, each with its own rate coefficient. It is proposed that this process is related to protein denaturation and can be characterized by a single rate constant of the Arrhenius form. However, this function does not directly predict the physical or mechanical changes brought about, such as shrinkage, or changes to modulus and thermal conductivity which are certainly relevant to simulations. A useful framework for modeling the constitutive response of thermally damaged biological soft tissues is presented by Tao *et al*, based on mixture theory [27]. This work was motivated by the need to understand the mechanisms associated with advances in laser, microwave, radiofrequency and similar medical technologies. The model encompasses a flowing fluid, water, loosely bonded with the tissue, and a porous solid tissue with associated tightly bonded water molecules. The tissue is considered to have two elements, native and damaged, which may inter-convert due to damage or healing.

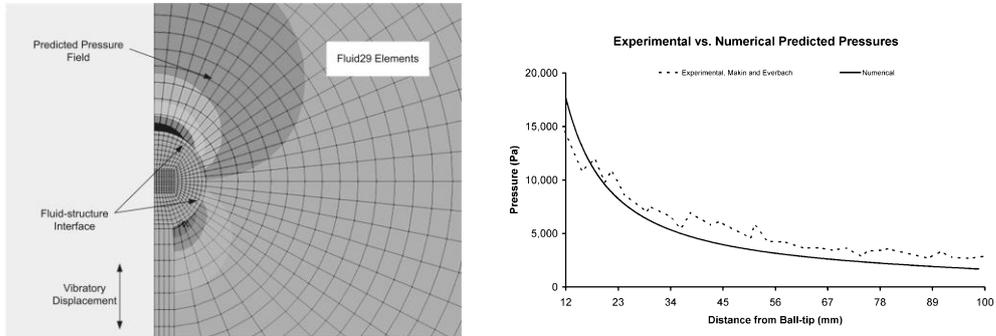


FIGURE 2 (a) Predicted pressure amplitude field around the distal tip of the wire waveguide with 1.0 mm spherical tip. (b) Comparison of predicted pressure amplitudes and experimental results published by Makin *et al.* (Originally published in the Journal of Medical Devices [25] and reproduced with kind permission of the ASME)

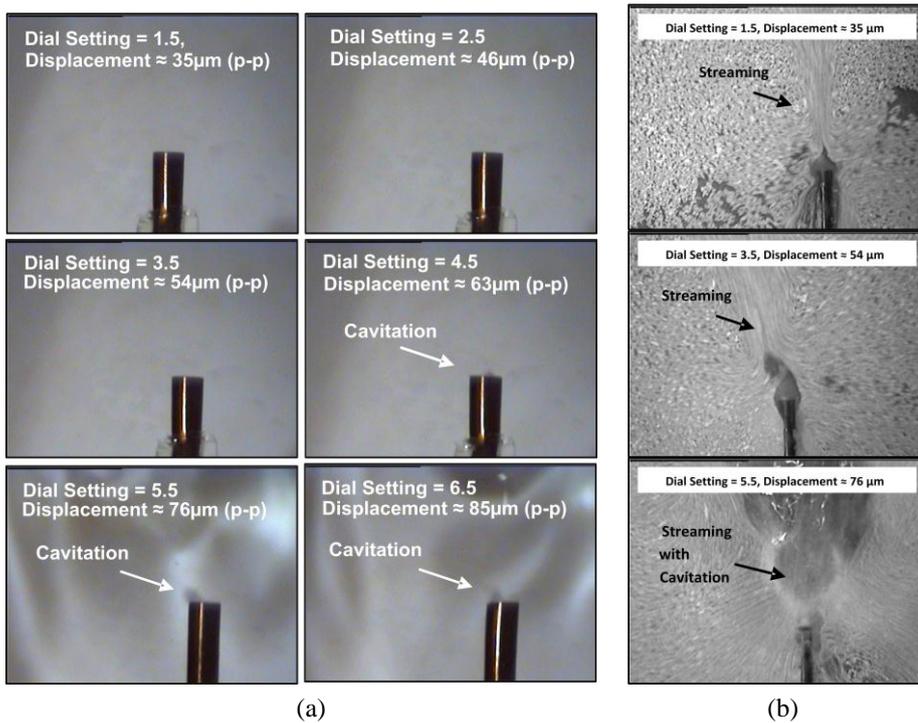


FIGURE 3 (a) Images of the distal tip of the 1.0 mm diameter wire waveguide for various p-p displacements. (b) Acoustic streaming at distal tip of 1mm diameter wire waveguide. (Originally published in the Journal of Medical Devices [25] and reproduced with kind permission of the ASME)

4.3 MODELLING OF RADIOFREQUENCY ABLATION

The modeling and the simulation of the RF ablation of liver tumors has been investigated by several authors. A recent overview on the state-of-the-art and future challenges is given by Berjano in [6]. Many of the existing approaches neglect the dependence of the tissue parameters on the temperature. The energy balance involved in phase changes of water and reduced electric conductivity by a rapid drop of the conductivity close to the boiling temperature receives little attention.

4.4 MODELLING OF WATER JET CUTTING

Few models are available for the interaction of water jets with materials, and these do not seem to have been extended to describe tissue interactions [28, 29, 30]. Existing models deal with the interaction of the water jets with non-biological materials such as steel or rock, and most studies involve the presence of abrasive particles which would not be suitable for medical purposes. Nonetheless, these models could provide a useful starting point for the development of models which reflect the complexity of natural tissues. Some useful examples include the work by Hashish [31], and that by Momber and Kovacevic [32]; in the latter a method of evaluating energy balance in water jet cutting could be a foundation for comparable studies in the interaction of water jet with tissue. Kovacevic with others has also monitored thermal energy distribution in water jet cutting [33]. Studies of energy balance have been undertaken by Dumitru *et al* [34]. Interest in the use of water jet for cutting meat stimulated Alitavoli and McGeough [35] to apply expert process planning methods to evaluate the benefits of the technique.

5 CONCLUSIONS

The further development and increased understanding of these new and developing technologies for cutting and ablating tissues, plaques and tumours will be an important research field for some time to come. The optimisation of future medical devices and development of new treatments depends on (i) the development of preclinical experiments with precision instrumentation, capable of quantifying the physical effects associated with each technology, (ii) the detailed characterisation of tissue properties relevant to each treatment modality, such as low frequency ultrasound attenuation coefficients, or non-linear thermal and electrical conductivities, (iii) the development of numerical models (validated and calibrated) for device-tissue interactions, and (iv) the further development of appropriate tissue damage models, to closely reflect the true tissue or tumour alterations induced.

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