SPARING OF NEUROVASCULAR TISSUE UTILIZING HIGH THERMAL GRADIENTS

By

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ABSTRACT

Real-time, internal in-vivo tissue temperature measurement during surgical procedures is presented along with validating experimental work on ex-vivo tissue for the active cooling of tissue using high thermal gradients. This study explores the use of microthermistors to profile the internal temperature of local tissue and quantify the effects of a cooling channel in removing heat transferred to the tissue via a surgical device. Data collected during this research indicates a much lower temperature realized for tissue being actively cooled compared to tissue left thermally untreated. Results of this research support the design and development of surgical devices to actively cool tissue during surgery. These could manifest as independent cooling devices as well as devices that would incorporate pre-existing uses such as coagulation and cutting along with the ability to actively cool.

CHAPTER 1

INTRODUCTION AND MOTIVATION

1.1 INTRODUCTION

Modern laparoscopic practices, including electro- and ultrsaurgical modalities, owe their development to the historical use of therapeutic heat. Heat has been used therapeutically dating back thousands of years in Europe, Africa, and Asia. The oldest accounts of heat being used in this manner date back to Neolithic times where heat was used to stop bleeding from the head. Archaeological evidence of new bony growth around the wound site is proof that the 'patient' survived the 'surgery.' The Edwin Smith Papyrus, written in 2800 BC, describes the use of a 'fire-drill' to apply cautery. The 'drill' was a stick rotated at high enough speeds to start a fire and the end was then applied to the wound site. By 400 BC Hippocrates was referring to cautery irons not only to stop bleeding but also to excise tumors. In the 5th century India's Brahmanical texts had already described over 120 instruments, including trocars, forceps, and catheters, used for surgical procedures [1].

While civilization has advanced greatly since these historic entries into medicine, challenges remain to be overcome with even the state-of-the-art technologies in use today. Each new advancement made in controlling the use of therapeutic heat offers just as many questions as it does answers. Currently, laparoscopic practice has made possible minimally invasive surgeries in the reproductive regions of the body which two decades ago would not have been thought possible. Prostatectomy and hysterectomy procedures are currently both widely performed in a laparoscopic setting. While most of the outcomes for the patient are at levels equal to or better than for open surgeries, problems believe to be related to nerve function have not been able to be maintained. These two procedures will serve as the inspiration for this research and their histories are presented briefly below.

1.2 MOTIVATION

1.2.1 Radical Prostatectomy

The widespread implementation of prostate cancer screening over the last two decades has resulted in earlier diagnosis of prostate cancer and improved oncological results following curative therapy. Additionally, patients currently diagnosed with prostate cancer are younger and healthier than those diagnosed in the past. As a result, increasing attention is being focused on techniques and procedures that minimize treatment morbidity and preserve post-operative quality of life.

Walsh [1,2] is credited with identifying and developing a technique to spare the neurovascular bundles (NVB) around the prostate. Widespread adoption of this technique (meticulous dissections and preservation of the neurovascular bundles without use of electrosurgical devices) has resulted in improved post-operative potency rates of 68% to 86%. Within the last five years, laparoscopic and robotic techniques have also been applied to radical prostatectomy to further reduce surgical morbidity and shorten the convalescence period. Although long-term data are not yet available, results with respect to biochemical progression free survival and continence appear to be equivalent to open techniques. However, a great variability is seen with respect to postoperative potency [3]. This may be largely attributable to laparoscopic limitations that impede careful dissection of the neurovascular bundles. In many descriptions of the laparoscopic techniques, electrosurgical and ultrasonic sources are used to facilitate dissection of the neurovascular bundle affording improved hemostasis and a better view of the operative field. However, it has been demonstrated in a canine model that dissection utilizing these sources can result in neurovascular damage and poor post-operative potency outcomes [5].

It is therefore postulated that the thermal spread from electrosurgical instruments is the source of neural injury. Effective application of these concepts could greatly facilitate dissection of the neurovascular bundle alongside the prostate, thereby reducing risk of adjacent tissue injury and loss of potency.

1.2.2 Hysterectomy

Hysterectomy procedures rank second only to caesarean section as the leading surgical procedure performed on women in the United States, with over 600,000 cases reported annually [6]. These procedures carry along with them a 40% increased risk of urinary incontinence (UI) [7]. As many of the procedures are strictly cautionary and not medically urgent, the loss in quality of life to the patient is increasingly at odds with the continuing rise in cases performed.

A study performed by Brown [7] suggests the extent of uterine removal and the increased potential for NVB damage is correlated to the risk of UI. As electrosurgical and ultrasonic devices are typically used in these procedures for reasons mentioned above, actively controlling thermal diffusion from the surgical device could have a large impact on post-operative quality of life for the patient.

CHAPTER 2

REVIEW OF SURGICAL MODALITIES

A good understanding of the topic at hand requires an understanding of the history of the different modalities used to perform laparoscopic surgery. Also, as one begins to understand how to control the energy used, an understanding of temperature and thermometry is equally important. The rest of this section consists of a review of each of the three major energy modalities used in laparoscopic surgery: monopolar, bipolar, and ultrasonic.

2.1 ELECTROSURGERY ENERGY

2.1.1 Introduction and History

Electrosurgery is the use of alternating current to cut and coagulate tissues. It has proven itself to be a major advance in surgery by minimizing blood loss and reducing operative times. It became a mainstream procedure in its monopolar form through the use and promotion of Harvey Cushing and William T. Bovie in 1928 [8].

The efforts were followed in 1940 by the introduction of bipolar surgery by Greenwood [9]. Greenwood's technique was later refined in 1960 [10] giving us the basic form of bipolar energy in use today. The evolution of laparoscopic gastrointestinal surgery brought with it interest in bipolar electrosurgery, however, less than 15% of general surgeons today use bipolar electrosurgery [11]. In contrast, 45% of gynecologists use bipolar electrosurgery as their primary energy to cut and coagulate tissue [11].

2.1.2 Process

Electrolytes within body cells can be essentially viewed as electrical conductors and the tissues and cells between the two electrodes therefore serve as the pathway for electrical current to traverse through the body. The procedures most commonly performed with electrical energy are cutting and coagulation and the ability to perform these procedures without incidence to the patient is directly dependent on the current's frequency. The frequency of alternating current is measured in Hertz (Hz) and is equal to how many times the current changes direction per second. For most modern electrosurgical procedures this frequency is in the range of 500 to 2,000 kHz. At frequencies this high, electrolytes serving as the conductors for the current exhibit very little lateral movement and their concentrations across cell membranes do not change. Thus, cardiac defibrillation, or the depolarization of neuromuscular membranes, does not occur. As is well known, normal household current's relatively low frequency of 60 Hz can induce cardiac defibrillation. The frequency at which human tissue no longer reacts in this way to alternating current has been experimentally determined as roughly 100 kHz.

Electrosurgery uses the electrical current itself to heat tissues. Current flowing through tissues produces heat through the excitation of the cellular electrolytes (ions). Excited ions colliding with each other release energy in the form of heat.

The basic principle of electricity is current flows following the path of least resistance. In human tissue, the resistance is inversely proportional to the electrolyte concentration, and thus water content. Therefore, current flow is greatest in tissues such as blood, and least in those such as bone. In general, current flows preferentially through blood, then nerve, then muscle, then adipose tissue, and finally bone [12].

As heat is generated in tissue the tissue dries out and the loss of water produces an increased electrical resistance. As a result, surrounding tissue becomes relatively less resistive to electrical current and the current's pathway will switch course. This makes predicting the route current will take very difficult and unintuitive.

Alternating current is a sinusoidal bi-directional flow of electrons resulting is no net gain of electrons at either pole of the circuit. Through Ohm's law current (I) is related with resistance (R) to voltage (V) as:

$$V = I * R$$

Current (I) is the flow of electrons and is measured in amperes (A). Voltage (V) is the pressure force driving the electrons and is measured in volts (V). The higher the voltage the further an electron can move. Resistance (R) is the impedance the medium gives to the current and is measured in ohms (Ω).

Electric power is the energy produced over time and is measured in joules/sec (J/s), or watts (W). It is equivalent to the current times voltage and therefore can take the following forms:

$$P = I * V \quad \text{or} \quad P = V^2 / R \quad \text{or} \quad P = I^2 R$$

The challenge for electrosurgical devices and thus electrosurgical generators is to deliver the appropriate current at voltages matched to the tissue's resistance. Otherwise, current will be too low to produce the desired effect or too great and harm the patient. Since the overall effect on tissue is dependent on the current flowing through it, the current density (CD) is of importance and is equal to the current divided by the area of contact:

$$CD = I / A^2 = A / cm^2$$

Since the area of contact for a pinpoint tip is less than that for a spatula-shaped device, the CD is greater for the pinpoint device and it produces the desired surgical effect with less effort but conversely has the ability to harm the patient quicker than a device of greater contact area.

Ultimately, it is the heat produced from electrosurgery that allows the cutting and coagulating of tissues. The amount of heat released is proportional to the tissue's resistance and is inversely proportional to the cross sectional area of the tissue through which the current flows [1].

For current to flow a completed circuit must be present and is represented in electrosurgery as the return of current to the generator (which is grounded). In electrosurgical two basic types of circuits are used: monopolar and bipolar.

In a monopolar circuit, current flows between two electrodes held widely apart. These two electrodes are the active electrode which is small, thereby providing a high power and current density, and the return or passive electrode which is large, thereby providing a low current density. The passive electrode is just as capable of producing injury as the active electrode if the surface area it covers is small enough (and therefore the CD is large). Consequently, the passive electrode must be placed over an area that will allow uniform contact with the body. If contact is only partial, current density at the indifferent electrode will be greater and injury can result. Since the path of least resistance is always taken to reach the indifferent, consideration must also be given to where the indifferent electrode is placed on the patient. In general, the indifferent electrode should be as close to the operative site as possible to minimize the volume the current will need to travel through.

The active and passive electrodes in a bipolar circuit are intentionally adjacent to each other, minimizing the distance current must flow through tissue. As current passes through the tissue from one electrode to the other, the tissue is desiccated and the resistance increases. As discussed above, the current will then seek alternate routes making it easier for it to reach the passive electrode and possibly unintentionally damaging nearby tissue.

2.1.3 Electrosurgical Effects

The three effects of electrosurgery are cutting, fulguration, and desiccation. Cutting and fulguration are similar non-contact processes defined by the electrical waveform used. Dessication is the action that occurs whenever the electrosurgical device comes into contact with the tissue.

Electrosurgical cutting is the process by which electrons cut grooves in tissue. True electrosurgical cutting is a non-contact activity using the principle of EDM in which the device must be a short distance from the tissue to be cut. It requires the generation of brief sparks between the electrode and the tissue. The heat from these sparks is transferred to the tissue and as the electrons bombard cells, the energy transferred to them increases the cell’s temperature. Due to relationships within the Ideal Gas Law a temperature is eventually reached where the pressure and volume are too much for the cell membrane and the cell explodes. Cutting uses a non-modulated sine wave to maximize the current delivered to the tissue while the device is activated.

Fulguration also requires non-contact between the electrosurgical device and the tissue. However, since fulguration is used to coagulate instead of cut tissue, a lower power is used. This is achieved by intermittent short bursts of high voltage to ensure the coagulation is deep enough but that the effect is not so strong as to cut the tissue. The active electrical wave is used only about 5-10% of the time the electrosurgical device is activated, or the duty cycle is only 10 %. This allows the cellular temperature to heat up but also cool back down. This constant switching of temperature is what produces the fulguration effect.

Desiccation is the process by which tissue is heated and the cell's water evaporates, thus drying out the cell. Desiccation is achieved with either the cutting or the fulguration waveform by contact of the electrosurgical device with the tissue. It is the electrosurgical effect used most by surgeons.

Electrosurgical generators today are microprocessor controlled electrical generators that deliver power in the form of the necessary waveforms. An important distinction among electrosurgical generators is the mechanism by which current is delivered to tissue. Household current in the U.S. is delivered at a constant voltage of 110 volts. If the resistance increases, the current flow decreases. Standard electrosurgical generators, however, deliver the power set by the surgeon on the generator. With increasing tissue resistance, voltage is increased in an attempt to maintain the power output. As a result, higher voltages are needed to send the same power to tissues of higher resistance.

2.1.4 Monopolar Electrosurgery

Monopolar energy using electrical current at high enough pressure/voltage to heat tissue in order to perform surgical procedures. The exit pathway for the electrical energy is in the form of a grounding pad usually placed on the patients thigh.

Numerous potential dangers have been identified since electrosurgery's introduction because the effect is not necessarily confined to the surgical site. Refinements in the delivery of energy and various monitoring systems have reduced these risks. Nonetheless, it is important to realize the potential dangers of electrosurgery.

The use of electrosurgery in the laparoscopic surgery is complicated by the unique environment that exists during these procedures. The laparoscopic environment is different from that present in open surgery because of the presence of an insufflating gas having a low heat capacity. As a result, instruments may not cool as rapidly as in the open environment and the high water content of the gas increases the conductive capacity of the medium. The gas itself may support combustion such as is the case for nitrous oxide. Limited access to the tissues requires the use of cannulas to pass instruments into the abdomen. These cannulas are the source for direct coupling. Finally, the limited field of view and narrow focus on a small area allows events to occur unnoticed outside these fields of view. Fortunately, most if not almost all injuries can be eliminated by the use of modern generators and electrode monitoring systems.

Monopolar technology is manufactured by a wide range of companies but the primary manufacturer of generators used for this technology is Valleylab (Boulder, CO). Two examples of their generators are shown in Figure 1 below.

QuickTime™ and a
TIFF (LZW) decompressor
are needed to see this picture.

(a) (b)

Figure 1. The Surgistat (a) and Force FX (b) generators by Valleylab.

The following are the most common faults encountered with monopolar electrosurgical devices:

Ground Pad Failures

The return or passive electrode needs to be in uniform contact with the patient over a large surface area. The reason it does not produce injury is that the large surface area disperses the current creating a low current density over the whole electrode and thus minimizing any thermal effect. Lack of uniform contact can result in significant current concentration and damage. Return electrode monitoring electrodes are used to monitor the area of contact ensureing it is adequate enough to prevent injury. They monitor the resistance to current flow across the electrode and when surface contact is not adequate (the resistance at the site is low) the generator stops all current to the electrode and the system alerts the surgeon with an audible sound.

Alternate Site Injuries

If the patient is in contact with any metal that is itself grounded, current will flow from the patient through the metal to the floor. If the site of contact is small, a burn may result. This was often seen at the site of electrocardiographic leads when these generators were used.

Modern generators basically eliminate the alternate site burns by requiring the current to return to the generator. If the current leaves the patient by a site other than the return electrode, not enough current returns to the generator and it can not deliver more current to the electrode.

Demodulated Currents

Demodulated currents are currents of low enough frequency (<100 kHz) to cause muscle and nerve depolarization [13]. Demodulated currents produce neuromuscular activity which is usually of no significance unless directly coupled to the heart through a catheter or during a cardio-thoracic surgical procedure. An example of demodulated currents is muscle fasciculation at the site of a laparoscopic cannula during the use of electrosurgery. This results in the unusual muscle twitching around the cannula site. Modern generators have filters stopping these currents from being delivered to the patient so only appropriate current is delivered.

Insulation Failure

Insulation failure is thought to be the most common reason for electrosurgical injury during laparoscopic procedures [11,14]. In large part, this stems from the inability to see the entire instrument during the procedure.

The key factor that determines the magnitude of injury from insulation failure resides in the size of the break in the insulation. Paradoxically, the smaller the break, the greater the likelihood of injury if contact of tissue with that site occurs. This is related to the concept of power density. The small break results in current concentration at a small surface area. Since the current is not dissipated over a large area, injury results. Unfortunately, these small breaks are often not visible without very careful inspection. Furthermore, they occasionally are the result of imperfections in the insulator itself.

Protection against insulation failure is provided by the active electrode monitoring system (AEM®) [14,15]. This system uses conductive sheaths that are placed over laparoscopic instruments used with electrosurgery or specially designed instruments that contain this sheath. The conductive sheath collects any stray energy that results from insulation failure or capacitive coupling and returns this current to the generator. If this current reaches a threshold value where injury may be possible, the generator shuts off and the user alerted through an audible tone.

Current Concentration

Although the goal of electrosurgery is to initiate thermal damage of tissues, it must occur only at the intended surgical site. Current passing through structures of small cross sectional area may have current unknowingly to the surgeon concentrated there with resultant unintentional thermal injury [16,17]. For example, if the testicle and cord are skeletonized and mobilized from the scrotum, application of energy to the testicle can result in damage to the cord. This is because the surface area where the energy is applied, the testicle, is much larger than the surface area or diameter of where the cord enters the abdomen. Since the current must all return to the indifferent electrode, it must pass through the small diameter cord before it is dissipated in the body through numerous pathways. This means the concentration of current at the small diameter cord will be much greater than at the testicle.

Sparking and Arcing

Jumping of sparks from the electrode to tissues does occur and is the mechanism for fulguration and true electrosurgical cutting. However, the important question is whether this is likely to occur in an unintended fashion such that injury results. The ability of electrical sparks to travel over a distance in a gaseous environment is increased when the tissue desiccates and there is a moist, smoky environment. Since the electrical resistance at the surgical site is high, the current will seek an alternate pathway of lower resistance. For example, current applied to tissue near the duodenum by an electrode passing over the duodenum can jump to the duodenum if the resistance at the surgical site is greater than at the duodenum. Current can jump from any place on the uninsulated end of the electrode and need not jump from the tip. In addition, build up of eschar on the electrosurgical instrument may promote arcing to a secondary site.

Overall, the risk of sparking with monopolar electric current is small. At 30-35 watts, the standard power setting used for laparoscopic surgery, sparks jump 2-3 mm 50% of the time [17]. Furthermore, the standard maximum voltage used in electrosurgery is not enough to allow significant air gaps to be bridged. For example, at 5000 volts only 4 to 5 mm can be bridged. Therefore, under normal operating circumstances, the voltage used in electrosurgery is not enough to allow significant air or carbon dioxide gaps to be bridged.

Direct Coupling

Direct coupling occurs when an electrosurgical device is in contact with a conductive instrument. Direct coupling is reduced by using insulated instruments and paying careful attention to avoid contact with any metallic object in the operative field. Also, electrosurgery should never be used at a staple line because the tissue beneath the staples can subsequently undergo necrosis with anastomotic dehiscence resulting.

Surgical Glove Injuries

Studies have documented the presence of holes in 15% of new surgical gloves and 50% of gloves after use in surgery [18]. Some of these holes result from the use of electrosurgery as is known to every surgeon who has ever gotten zapped. Three mechanisms exist for these holes and burns. High voltage dielectric breakdown occurs because the high and repetitive voltages across the glove (dielectric) break the insulative capacity of the glove resulting in conduction of current to the surgeon and a burn in the glove. DC Ohmic conduction is the result of insufficient conductive resistance of the glove. The resistance of gloves decreases with time and with exposure to saline (sweat). The third mechanism is capacitive coupling. The risk of capacitive coupling is inversely proportional to the thickness of the gloves. No surgical glove can withstand maximum voltage from an electrosurgical generator in the open coagulation mode. This is likely to occur when a current is applied to a hand held hemostat. The higher the voltage and the longer the contact time, the more likely dielectric breakdown will occur. Therefore, energizing the active electrode in the air and then touching a hemostat subjects the surgeon to a potential burn and the patient to low frequency demodulated currents because of sparking from ionization of air between the two [18]. This practice should be avoided.

Explosion

While most causes of explosion have been removed from the modern operating room, the gas mixture that exists within the gastrointestinal tract still represent a significant explosive hazard. Gas mixtures between 4-7% hydrogen and 5-15% are potentially explosive and 43% of unprepared bowel contains a potentially explosive mixture of gases.

An explosion occurs when a very rapid, oxidative reaction occurs that produces heat. The gases are produced so rapidly that the product gases cannot diffuse out of the way of subsequent combustion products. If this occurs in excess of the speed of sound a shock wave is formed creating an explosion as it moves away from its source. Nitrous oxide is another gas which is capable of supporting such a reaction. Studies have shown levels of nitrous oxide during laparoscopy capable of supporting combustion [19]. For this reason, nitrous oxide should not be used as the insufflating gas when the use of electrosurgery is planned or contemplated and has been completely substituted with carbon dioxide.

Electrosurgical byproducts

The burning of tissue by electrosurgery results in the production of numerous by-products. These can be broadly classified as biologicals (viral particles and other microbes) and chemicals/irritants [20]. The best studied chemicals in laparoscopy patients that are potentially generated by laparoscopy are methemoglobin and carboxyhemoglobin. Methemoglobin is the oxidative product of hemoglobin in which the reduced ferrous iron form (Fe^{+2}) has been converted to the ferric form (Fe^{+3}) which cannot carry oxygen or carbon dioxide. Carboxyhemoglobin is a high affinity form that prevents oxygen transfer because of the high affinity of hemoglobin for carbon monoxide. While studies indicate concentrations in the blood of both these products are increased during laparoscopy with electrosurgical devices [20,21], none report toxic or dangerous levels. Also, other studies [22-24] show the concentrations do not increase. Therefore, there seems to be insufficient evidence to support any danger from the potential generation of methemoglobin and carboxyhemoglobin during laparoscopic surgery in combination with electrosurgery.

2.1.5 Bipolar electrosurgery

Bipolar energy differs from monopolar in that the active and passive electrodes are positioned adjacent to each other, creating an efficient pathway for the electrical current to follow.

Bipolar electrosurgical processes are created by placing the active and passive electrodes necessary to complete the circuit within a few millimeters of each other. Therefore, current does not travel throughout the patient's body to reach the passive electrode. The tissue effect primarily achieved with bipolar electrosurgery is thus tissue coagulation through desiccation as the electrodes are in direct contact with the tissue. Since the area between the two electrodes is 2-3 mm, the current is concentrated. Whereas the current density of a monopolar circuit is based on the second power of the radius of contact, the current density of a bipolar circuit is based on the fourth power of the radius of contact [25]. Clinically, this means less power is needed to produce a similar effect with bipolar electrosurgery when compared to monopolar electrosurgery. Tissue damage is also reduced with bipolar electrosurgery since less energy passes through the tissue [25-29]. Overall, the area of tissue damage by bipolar electrosurgery is two times less than that of monopolar electrosurgery. Furthermore, the conduction of heat is considerably less and over a much shorter distance in a bipolar circuit when compared to a monopolar one [29].

Not only is overall tissue injury reduced with bipolar electrosurgery, so is the depth of penetration when compared to a monopolar circuit [26]. With bipolar energy the depth of penetration cannot be much greater than that present between the electrodes. However, in a monopolar circuit the current disperses over a much larger area. Monopolar electrosurgery is therefore more effective at deeper hemostatic coagulation.

The major advantage of bipolar electrosurgery over monopolar is the absence of a passive electrode on the patient, eliminating ground pad and alternate site burns. However, other important differences that reduce injury are also present. Direct coupling can occur only if metal is grasped or placed between the electrodes in a bipolar circuit. The typical power output for bipolar circuits is rated for 50 to 150 ohm resistance. This is considerably less than the power output for monopolar circuits in which loads of 30 to 500 ohms are used. This relates to the considerably smaller volume of tissue affected in the bipolar circuit. Overall, the power provided to a bipolar circuit is 10 % that of a monopolar circuit. In this regard, it is imperative that bipolar devices be connected only to the bipolar side of the generator. Otherwise considerable greater and potentially dangerous voltages may be provided.

The fact that both electrodes in a bipolar circuit are active and producing tissue damage means that the tissue is cooked form the outside in. However, as the outer layers of tissue desiccates, the resistance to current flow increases. Coagulation may cease before it is complete. That is, a blood vessel may be cut before it is completely coagulated and therefore bleeds.

The maximum coagulation with the least lateral thermal spread is achieved with bipolar electrosurgery when low voltages of 20 to 30 watts are used. Higher wattage leads to rapid coagulation of the outer layers that can prevent complete coagulation.

Electrode activation on the tissue should not be constant. More uniform coagulation is achieved if the tissue is heated with a brief period of activation, allowed to cool for a few seconds and then heated again by activation of the electrode.

A problem with bipolar electrodes is tissue sticking. This is reduced or eliminated by irrigation of the bipolar electrodes at the time of activation. This concept, originally introduced by Malis [10] for neurosurgery, also reduces lateral thermal damage. Although any solution can be used, non-electrolytic or weakly electrolytic solutions work best [29]. This ability to irrigate particularly with water or saline while activating differentiates bipolar from monopolar surgery. Irrigation will not work in monopolar surgery because it disperses the current before it reaches the tissue, whereas in bipolar surgery the tissue to be coagulated is between the electrodes and the irrigant does not effect the current flow.

The two major manufacturers of bipolar technologies are Valleylab (Boulder, CO) and Gyrus Medical (Maple Grove, MN). Visuals of their systems, the LigaSure™ Vessel Sealing System and the PK™ System, respectively, can be seen in Figure 2 below.

(a) (b)

Figure 2. The Valleylab LigaSure™ Vessel Sealing System (a) and the Gyrus Medical PK System™ (b).

2.2 ULTRASURGICAL ENERGY

2.2.1 Introduction and History

Ultrasonic surgical tools use a piezo electric crystal within the handpiece of the tool to create ultrasonic waves which travel down to the end of the tool to create the desired cutting and coagulation effect. The piezo crystal is a disc-shaped, negatively charged ferroelectric ceramic that expands and contracts when electrical energy is bombarded on it. This expansion and contraction is what creates the ultrasonic waves. A pair of these crystals together will produce a sinusoidal wave form, or a harmonic wave form of high electroacoustic efficiency.

Stacks of these crystals wedged between two metal cylinders form a transducer. The expansion and contraction of the crystals sends the harmonic wave along the cylinders and is carried down the length of the tool shaft to the tip end.

Ultrasonic tools cut and coagulate tissue through three major mechanisms: cavitation, cutting, and coaptive coagulation.

Ultrasurgical devices are those that use ultrasonic energy to cut and coagulate tissue. Ultrasonic waves applied at low power levels have no tissue effect and are used for diagnostic ultrasound imaging. The use of higher power levels and densities, however, allows the cutting and coagulation of tissues. Ultrasound is an alternative to electrosurgery for cutting and coagulating introduced in 1991 and today almost all laparoscopic procedures can be performed with ultrasound [30].

2.2.2 Process

Ultrasonic cutting and coagulating depends on the mechanical propagation of sound (pressure) waves from an energy source (typically electrical) through a medium (crystal) to an active arm. Sound waves are longitudinal mechanical waves that can be progate through solids, liquids or gases [31]. These waves transport energy through matter by creating a motion in the matter without actually displacing it spatially [31]. Earthquakes, ocean waves and audible sound waves are examples. There are a large range of frequencies of longitudinal mechanical waves. Audible sound waves are confined to the frequency range of 20 - 20,000 cycles per second (Hz). Waves of frequencies below 20 Hz are infrasonic waves and those whose frequency is above 20,000 Hz are ultrasonic waves.

Ultrasonic waves can be produced by applying electromagnetic energy to piezoelectric transducers creating a mechanical vibration in response to the electric field. The piezoelectric effect is actually the elastic vibration of a quartz crystal induced by resonance within the applied electric field. Resonance is the phenomena in which a driving force (voltage) near that of the natural frequency of the crystal is applied to cause the crystal to vibrate with larger amplitude at that same frequency [31]. If there is no resonance, the oscillations gradually die out because the motion of the crystals is damped out by the dissipation of energy at the ends and by the resistance of air.

The ultrasonic transducer is typically housed within the hand piece and is comprised of a stack of piezoelectric crystals sandwiched under pressure between two metal cylinders. The transducer is attached to a mount which is attached to the blade. Heat is generated in the hand piece when electric current activates/vibrates the crystals, which must be dissipated. The crystals will malfunction at higher temperatures and the overall functionality of the decay will decrease as a result.

The mechanical vibration created in the hand piece travels to the blade via an extending rod used to make laparoscopic use feasible. The extending rod must be kept in isolation from the laparoscopic cannula or the oscillations will be dampened by contact with the cannula. This, in turn, will generate heat at the cannula. Furthermore, the active extending rod must be sheathed to prevent transmission of any energy to tissue at sites other than where it is in contact with the blade. This is accomplished by silastic rings that are placed at the nodes of the extender. The mechanical wave traveling down the shaft is longitudinal and travels as a plane down the shaft. Furthermore the wave is a standing wave rather than a traveling wave. That is, the wave travels down the shaft and then returns to the origin rather than traveling down the shaft and exiting out the end and stopping. As waves travel in both directions, they cancel or augment each other depending on if they are in or out of phase. This results in a standing wave with definable nodes that occur one wavelength apart where no motion occurs as well as antinodes where the motion is greatest in amplitude. By placing rings at the nodes, the extending rod is mechanically isolated from the sheath. The wave suffers a loss of energy as it moves towards the blade, but the loss is negligible.

The hand piece of ultrasurgical devices is electrically grounded which eliminates electric injury to the sorgeon and patient from the hand piece. Since there is no current flow through the patient, risks of electrical injury to the patient and surgeon are eliminated altogether. As a result, problems with sparking, capacitance and injury away from the visual field are eliminated.

There are presently three main distributors of ultrasurgical devices: Harmonic Scalpel® by Ethicon Endo-Surgery, Inc. (Cincinnati, Ohio); AutoSonix® by Tyco Healthcare (Norwalk, Conn.); and SonoSurg® by Olympus Corp. (Melville, NY). The Harmonic Scalpel® and AutoSonix® systems both operate at 55.5 kHz, while the SonoSurg® system uses 23.5 kHz. Ultrasurgical devices are composed of a generator, hand piece and blade (Figure 3). The Harmonic Scalpel cools the hand piece with air. The AutoSonix® and SonoSurg® systems rely principally on a large diameter hand piece made of materials that remove the heat and prevent its build up.

(a) (b) (c)

Figure 3. Ultrasurgical devices currently used for laparoscopic suregery. (a) AutoSonix® by Tyco Healthcare. (b) SonoSurg® by Olympus Corp. (c) Harmonic® by Ethicon Endo-Surgery.

Ultrasurgical generators are microprocessor controlled and supply high frequency pulses of alternating current to the hand piece. The pulsing vibrates the transducer at the natural harmonic frequency of the crystals (55.5 kHz for the Harmonic and AutoSonix systems and 23.5 kHz for the SonoSurg system). Errors can result from: cracks in the blade; too high of an exerted pressure (high impedance), contact against an object disallowing blade vibration (high impedance) and/or overheating of the blade. These errors result in no pulsing of the crystals and therefore no vibration of the blade.

Although the frequency of displacement is constant for each system, the amplitude of displacement is variable. Differences in the amplitude of displacement vary by changing the power provided to the crystals. Higher voltages result in higher amplitudes. However, an upper limit exists thereafter the crystal will shatter.

2.2.3 Ultrasonic Effects

The basic mechanism for coagulating bleeding vessels ultrasonically is similar to electrosurgery. Vessels are sealed by coapting the vessel with a denatured protein coagulum. The manner in which protein is denatured, however, is different for each of these technologies. Electrosurgery uses electrons to excite molecules in the tissue. The kinetic energy expended in the motion of these molecules is released as heat [32]. Water molecules are not excluded from this process and as the temperature rises, the water in cells is turned to steam and evaporated. Once all the water has evaporated from an area of tissue it is considered dessicated. A further increase in the temperature of the tissue is then possible and the tissue temperature rises more steeply. The tissues are subsequently oxidized producing the characteristic charring seen with electrosurgery. However, complete desiccation is not necessary for tissue coagulation. Tissues coagulate between 60-80 ºC whereas desiccation is complete at 100ºC [33].

Ultrasurgical devices denature protein by transferring mechanical energy to tissues sufficient enough to break tertiary hydrogen bonds as well as by generating heat from the internal tissue friction that results from the high frequency vibration of the tissue. Vibration occurs not only on the surface but also within the tissue. Thus, frictional forces exist both superficially and internally. Furthermore, the metal rod used to transmit the energy has heat capacity that allows it to accumulate heat. As a result, more time is required for the tissue to heat since blade heating takes away from the tissue heating. Ultrasurgical coagulation is therefore slower electrosurgical coagulation. Studies comparing the depth and lateral thermal damage of ultrasurgery and electrosurgery show the same depth of thermal damage achieved with both technologies but maximal depth of coagulation is achieved with electrosurgery in less than three seconds while ultrasurgery requires ten seconds to achieve the same effect [34]. These studies also showed a greater depth of thermal injury with ultrasurgery than electrosurgery if activation lasts longer than 10 seconds. Therefore, one cannot assume deep structures cannot be injured with ultrasound. The amount of injury achieved with ultrasound is proportional to the duration of activation and the pressure or tension exerted on the tissues.

The absence of coagulated tissue sticking to the active element is a unique feature of ultrasurgical coagulation compared to electrosurgery. This results from two mechanisms. First is the vibration of the blade on the tissue preventing the tissue from sticking to the blade. The second mechanism is related to the lower amount of heat generated at the interface of the tissue. However, it is to be noted that electrosurgical tissue sticking can be eliminated by using Teflon coated electrodes or, with bipolar electrosurgery, by irrigation.

CHAPTER 3

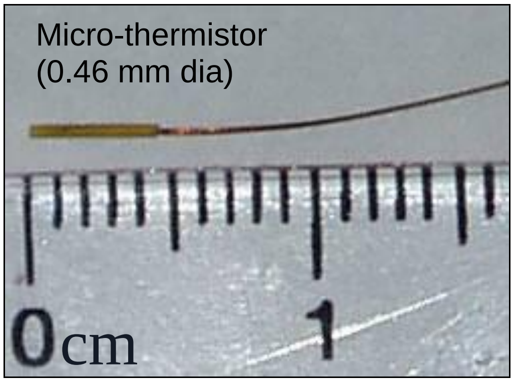
EXPERIMENTAL SET-UP

The work presented in this Master's Thesis was performed utilizing two different procedures. The validation of tissue temperature measurement took place in a Pig Lab performed by Arnold Advincula, M.D. while the validation of tissue cooling experiments took place in the Wu Manufacturing Laboratory.

3.1 GENERAL EXPERIMENTAL SET-UP

All experimental procedures used .46mm OD AlphaTechnic MicroThermistors (Model # 56A1002-C3) as shown in Figure 4. While tolerances were only listed up to 70ºC for these thermistors, calibration studies with boiling water and ice water were performed periodically to ensure all thermistors were recording accurate temperatures (Figure 5). Voltage readings were measured via a 24-Channel Wheatstone Bridge composed of 10,000 Ω resistors (Figure **6**). The voltage signals were processed into temperature readings and recorded via a PC-based data acquisition system with a National Instruments ISA-Bus card and LabView software.

Initial experimental trials were performed on commercially available chicken breast tissue using the Gyrus PlasmaKinetic SuperPulse System® generator (Model # 744000) and the Gyrus PlasmaKinetic® 5mm Cutting Forceps (Figure **7**). Thermistors were held in position via a polycarbonate fixture mounted around the surgical tool with appropriately placed positions for the thermistors (Figure 10a).



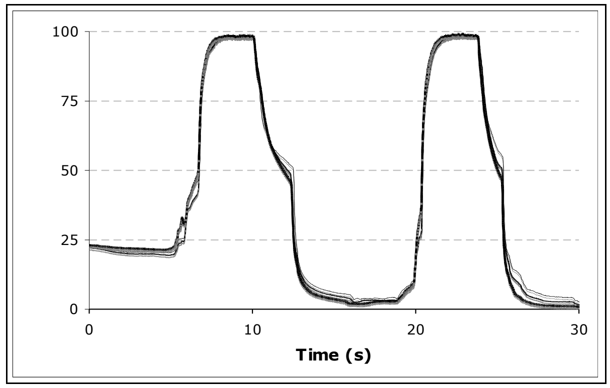


Figure 4. Micro-thermistor used this research.

Figure 5. Representative calibration curve in for micro-thermistor.

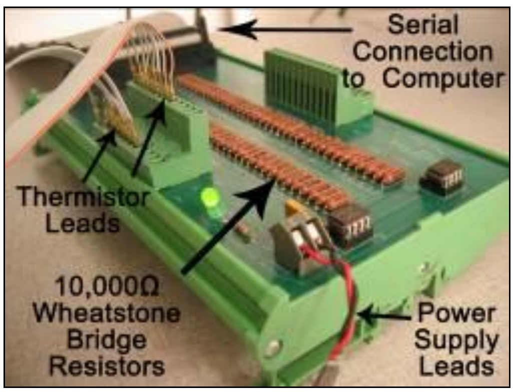


Figure 6. Wheatstone bridge used to determine thermistor voltages.

Figure 7. Gyrus PK Generator with 10mm Cutting Forceps (inset).

All experimental surgical trials were run until the tissue reached a coagulated condition as determined by algoraithms within the PK System® generator or by a surgeon's determination. Temperature readings were recorded for at least 5 seconds after generator power was cut to ensure the complete temperature profile was recorded.

3.2 PIG LAB EXPERIMENTAL SET-UP

One white landrace crossbred porcine (~50kg) was used. All the procedures were performed according to the guidelines for humane treatment of animals at the University of Michigan Medical Center. The surgeon was Dr. Arnold Advincula, Assistant Professor & Director of Minimally Invasive Surgery at University of Michigan Health System, Ann Arbor, MI.

Anesthesia was induced in the animal with intramuscular injections of Telazol (6 mg/kg) and xylazine (2.2 mg/kg), and then each animal was intubated and maintained under general anesthesia with isoflurane (2 to 2.5%). The animal was placed on a ventilator (10 ml/kg) at 12 bpm. Oxygen saturation, pulse rate, respiratory rate, mucous membrane color, and blinking reflex were monitored with pulse oximetry at regular intervals. Upon completion of the lab the animal was euthanized via barbiturate overdose as stated in the UCUCA document *Methods of Euthanasia by Species* adapted from the *Report of the AVMA Panel on Euthanasia*.

The swine was placed supine, facing up. An incision was made with a cold scalpel to expose the abdominal cavity and allow access to the spleen. The spleen was removed far enough to perform the surgical procedures and was replaced within the abdominal cavity during periods of no surgery (see Figure 8).

Devices from each energy modality were used: ultrasonic energy represented by the Harmonic ACE (Ethicon EndoSurgery, Cincinnati, OH); bipolar electrosurgery represented by the Gyrus 5 mm Cutting Forceps and Lyons Dissector (Gyrus ACMI, Maple Grove, MN); and monopolar electrosurgery represented by the monopolar spatula (Valleylab, Boulder, CO).

In the forceps devices, the bite size for the surgical procedures were limited to ¾ of the jaw length to avoid variations in tissue effect at the jaw hinge area. Lateral tension to the tissue was avoided and rotational motions were used only when required for by the device (Harmonic ACE) to ensure effects were limited to the devices. Default power settings were used for each device as listed in Table 1.

Table 1. A benchmark of the devices used and activities performed during testing.

Device	Tissue	Application Type	Setting	Duration / Length	No. of Runs	Generator
5 mm Cutting Forceps	Spleen	Coag (Blue) & Mechanical Cut	VP3 35W	To 4 stars	7	Gyrus Superpulse
J&J Harmonic ACE		Coag only	3 Min	Until cut occurs	3	J&J G300
		Coag & Cut	3 Min		3	
		Coag until Cut	3 Min/5 Max		3	
Gyrus Lyons Dissector		Coag only (Blue)	VP3 40W	To 4 stars	5	Gyrus Superpulse
Monopolar Spatula		Coag (Blue) only	Setting 8.5 (20 W)	Until coag complete	6	Valleylab Surgistat

For the Gyrus Cutting Forceps, the tissue was clamped using the ratchet . Bipolar energy was applied until 4 stars were indicated on the generator impedance graph. This indicates that a significant change in tissue impedance has occurred and the surgeon should assess if sufficient coagulation has occurred. The seal was then transected with the Cutting Forcep's cold blade. Any trial resulting in less than 3 seconds to reach 4 impedance stars was omitted as a representative temperature profile would not have been created in that timeframe.

For the Gyrus Lyons Dissector, coagulation was performed by clamping the tissue and holding the jaws closed with reasonable pressure. Bipolar energy was applied until 4 impedance stars were indicated on the generator.

For the Harmonic ACE, the active jaw was placed under the spleen to allow the cut to be applied upwards. The tissue was clamped using the ratchet ensuring it was clicked into position. Three clinical scenarios were tested:

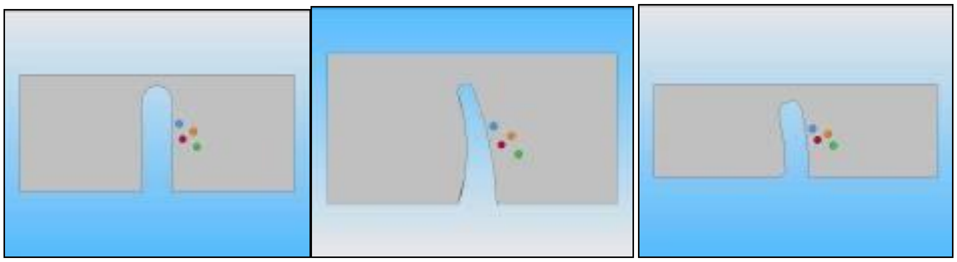
- **Coagulation only** – Min setting applied to only coagulate tissue for a set time of 5 seconds
- **Coagulation until cut** – Min setting applied until the surgeon believes adequate coagulation has occurred and then upward force is applied on the tissue with the active jaw until the coagulated tissue is divided, still using Min setting.
- **Coagulation and then cut** – Min setting to only coagulate tissue for a set time of 5 seconds and then the Max setting is used with upward force applied on the tissue with the active jaw until the coagulated tissue is divided

For the Monopolar device tissue contact was made using reasonable pressure. Monopolar energy using the COAG function was applied for a set time of 5 seconds.

The tissue temperature was measured at a depth of 2.0mm under the tissue surface using thermistors placed at 1.0, 1.5, 3.0, and 3.5mm from each tool edge. Polycarbonate fixtures were created for each of the devices tested to ensure temperature measurements were recorded at precise distances from the tool edge (Figure 10). Upon tissue clamping the fixture was placed around the device as shown in Figure 9 and held lightly in place while the trial proceeded.

Figure 8. View of spleen prior to procedure.

Figure 9. Experimental setup showing surgical tool, fixture, and thermistors.



(a) (b) (c)

Figure 10. Schematic drawings of the fixtures used to position the thermistors. The distance the thermistors were placed from the tool edge is color-coded with the table to the right. (a) Gyrus PK 5mm Cutting Forceps (Note: Monopolar Spatula used edge of this fixture) (b) Gyrus Lyons Dissector (c) Harmonic ACE

Color Coded Distance from Tool Edge (mm)
1.0
1.5
3.0
3.5

3.3 COOLING CHANNEL EXPERIMENTAL SET-UP

Commercially available ex-vivo chicken tissue and bipolar electrosurgery, represented by the Gyrus 10mm Cutting Forceps, was used to test the effects of a cooling channel placed alongside a surgical instrument during coagulative surgical procedures. An Instech P625 Peristaltic Pump with .093”ID tubing was used to flow chilled water through the cooling channel at a flow rate of 3.3mL/min. Both SS 304 and Al 3003 were used as cooling channels with parameters as shown in Table 2. Chilled water was passed through the cooling channel prior to beginning the surgical procedure.

The bite size for the surgical procedures were limited to ¾ of the jaw length to avoid variations in tissue effect at the jaw hinge area. Lateral tension to the tissue was avoided to ensure effects were limited to the devices. The default power setting for the Gyrus 5mm Cutting Forceps was used as listed in Table 1.

Table 2. Properties for Cooling Channel Materials

Material	ID (mm)	Wall Thickness (mm)	Thermal Conductivity (W/m•K)	Electrical Resistivity (Ω•m)
Al3003	0.87	0.34	233.2	$2.65e^{-8}$
SS304	1.23	0.2	16.3	321

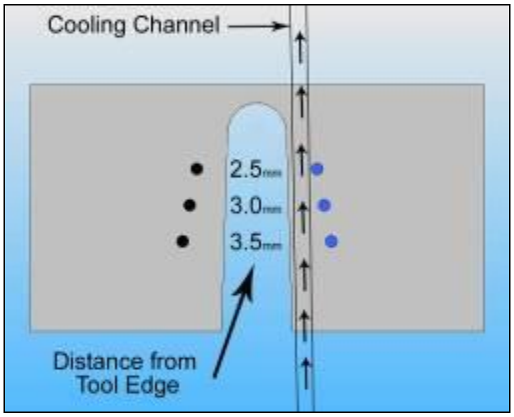


Figure 11. Fixture design for cooling channel experiments.

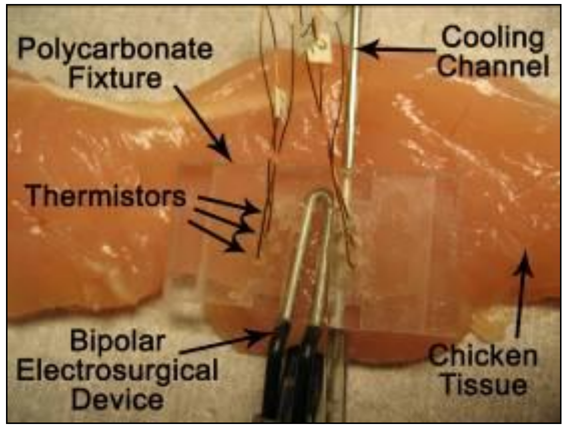


Figure 12. Cooling Channel Experimental Set-up.

The tissue temperature was measured on both sides of the electrosurgical tool at a depth of 2.0mm under the tissue surface using thermistors placed at 2.5, 3.0, and 3.5mm from the tool edge. Polycarbonate fixtures were created for the device tested to ensure temperature measurements were recorded at precise distances from the tool edge (see Figure 11). Upon tissue clamping the fixture was placed around the device as shown in Figure 12 and held lightly in place while the trial proceeded.

CHAPTER 4

RESULTS

4.1 PIG LAB RESULTS

No significant differences in temperature at any of the thermistor positions were observed when comparing the Gyrus PK 5mm Cutting Forceps with the Harmonic ACE. The average maximum temperatures observed at each of the thermistor positions for each of the tools tested are listed in . While the Gyrus PK 5mm Cutting Forceps operated cooler than the Harmonic ACE at all distances measured from the tool edge, the difference in all cases was less than 3ºC. While the Lyons Dissector and Monopolar Spatula both performed at higher temperatures than the 5mm forceps and the Harmonic ACE, all four devices operated in a range less than 100ºC at a distance of 1.0mm from the tool edge.

Table 3. Average maximum temperatures for each of the surgical tools tested.

Device	Color Coded Distance from Tool Edge (mm)							
	1.0		**1.5**		**3.0**		**3.5**	
	Avg. Max. Temp. (ºC)	**St. Dev. (ºC)**	**Avg. Max. Temp. (ºC)**	**St. Dev. (ºC)**	**Avg. Max. Temp. (ºC)**	**St. Dev. (ºC)**	**Avg. Max. Temp. (ºC)**	**St. Dev. (ºC)**
5mm	**56.8**	**7.9**	**52.1**	**4.2**	**41.0**	**2.2**	**38.8**	**1.6**
Harmonic	**58.6**	**6.4**	**54.6**	**5.7**	**43.9**	**7.1**	**41.0**	**6.8**
Lyons	**87.8**	**2.4**	N/A		N/A		N/A	
Monopolar	**81.3**	**7.6**	N/A		N/A		N/A	

4.1.1 Monopolar

The Monopolar Spatula was tested a total of 6 times with a representative set of thermal profiles shown in Figure 13. Due to the small size of the device only two temperature readings were able to be observed; however, since only one of the readings were at a distance comparable to the other devices the second reading (at 0.5mm from the tool edge) was omitted. The average maximum temperature at 1.0mm from the tool edge was 81.3ºC with a standard deviation of 7.6ºC.

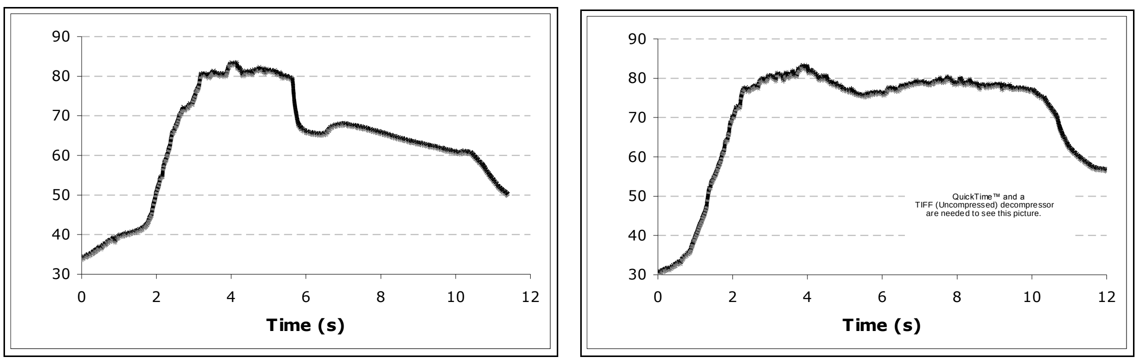


Figure 13. Thermal profiles at 1.0mm for three trial procedures using a monopolar device.

4.1.2 Bipolar

4.1.2.1 BIPOLAR GYRUS PK 5mm CUTTING FORCEPS

The Gyrus PK 5mm Cutting Forceps was tested a total of seven times with a representative set of thermal profiles shown in Figure 14. Two of the trials, however, reached 4 stars (coagulated based on the settings within Gyrus's generator) in less than 2 seconds and were discarded based on the assumption that the surgeon would normally continue applying energy to ensure a good seal was made. The average maximum temperature at 1.0mm away from the tool edge was 56.8ºC with a standard deviation of 7.9ºC.

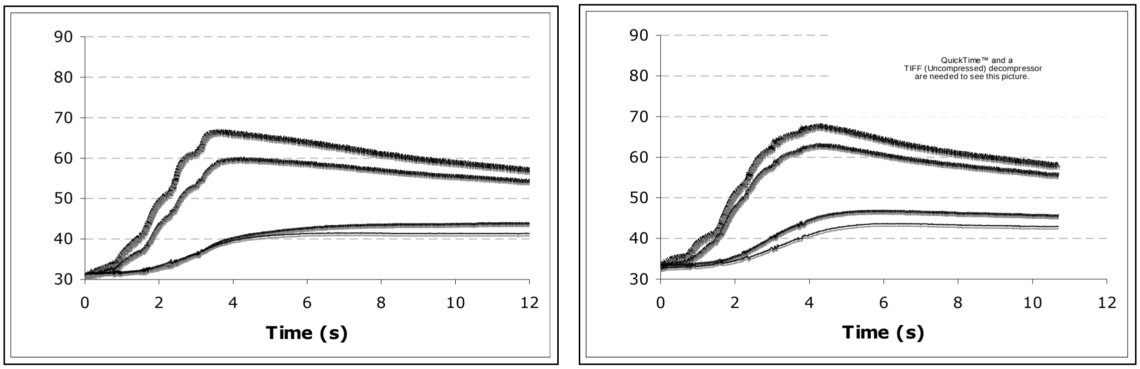


Figure 14. Representative thermal profiles using the Gyrus PK 5mm Cutting Forceps until coagulation occurred.

4.1.2.2 BIPOLAR GYRUS PK LYONS DISSECTOR

The Gyrus PK Lyons Dissector was tested a total of 5 times with a representative set of thermal profiles shown in Figure 15. The thermistor at the 1.5mm distance from the tool edge stopped working part way through the first trial and the thermistors at positions 3.0 and 3.5mm gave readings that suggested their signals were switched so the data from these positions have been left out. The average maximum temperature at 1.0mm for the Lyons Dissector was 87.8ºC with a standard deviation of 2.4ºC.

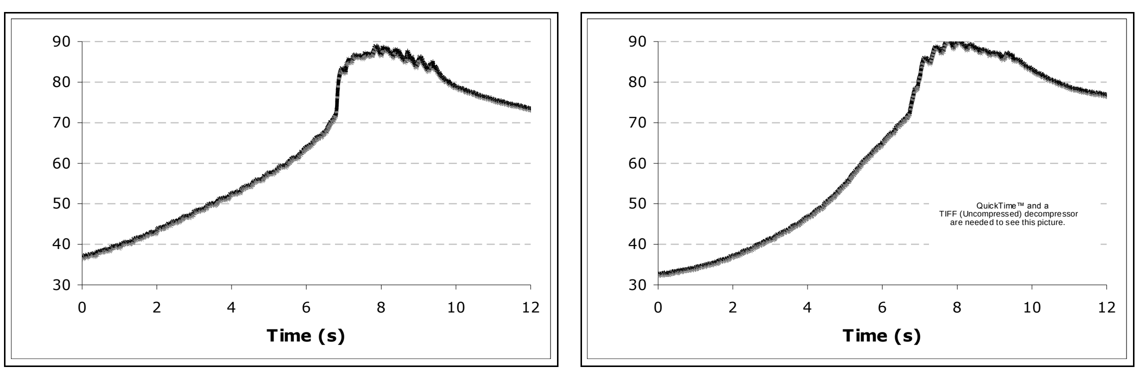


Figure 15. Representative thermal profiles at 1.0mm using the Gyrus Lyons Dissector until coagulation occurred.

4.1.3 Ultrasonic

Three different procedures were used with the Harmonic ACE to benchmark its performance in routinely used surgical procedures. The device was used to perform a strict coagulation at the 'Min 3' setting (Figure 16), a coagulation at the 'Min 3' setting which was continued until a full transection was achieved (Figure 17), and finally a coagulation at the 'Min 3' setting followed by a transection using the 'Max 5' setting (Figure 18). All procedures were run three times for a total of nine trials. The average maximum temperature at 1.0mm was 58.6ºC with a standard deviation of 6.4ºC. Typical post-operative tissue appearance for the Harmonic ACE can be seen in Figure 20.

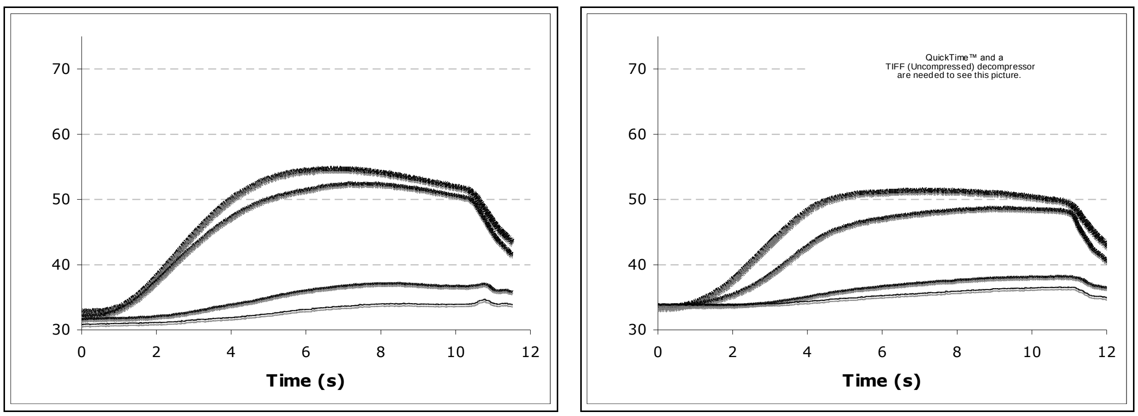


Figure 16. Representative thermal profiles for the Harmonic ACE at 'Min' setting used until coagulation occurred.

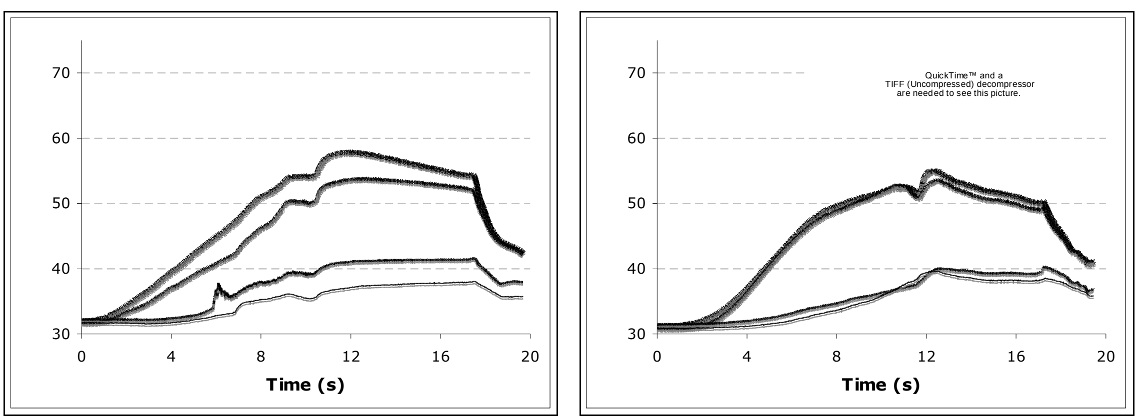


Figure 17. Representative thermal profils for the Harmonic ACE at 'Max' setting used until transection occurred.

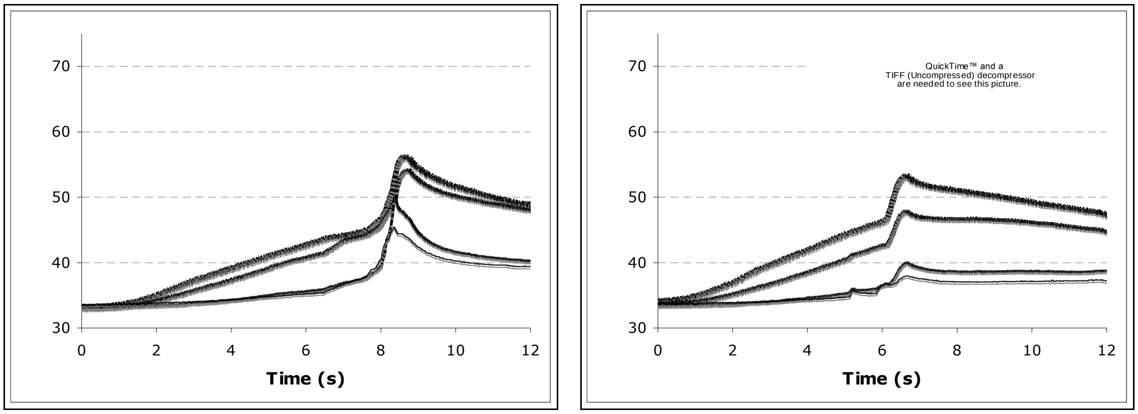


Figure 18. Representative thermal profils for the Harmonic ACE at 'Min' setting used until coagulation occurred and 'Max' setting until transection occurred.

Figure 19. View of post-operative spleen with Gyrus PK 5mm Cutting Forceps.

Figure 20. View of post-operative spleen with Harmonic ACE.

4.2 COOLING CHANNEL RESULTS

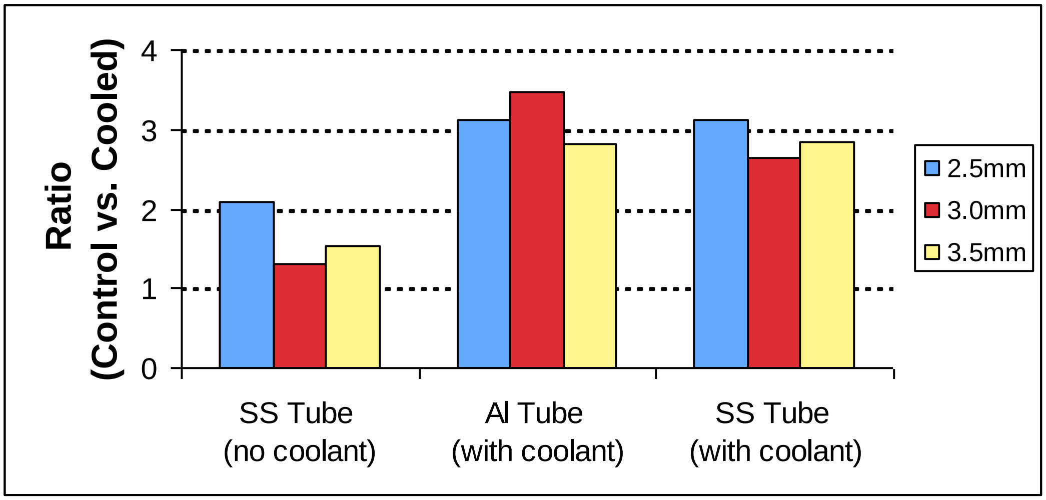
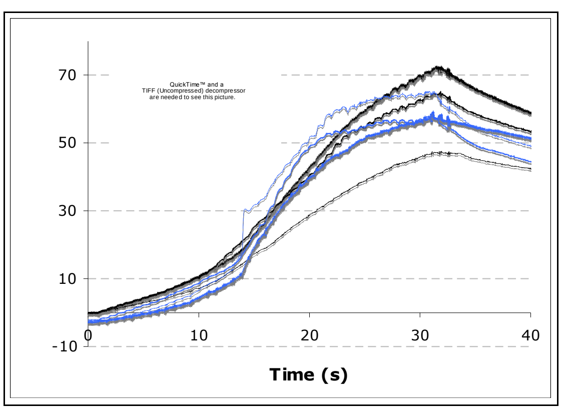


Figure 21. Ratio of temperature profiles between left (control) side of surgical tool and right (actively cooled) side of surgical tool.

4.2.1 No Cooling (Control)

The Gyrus PK 10mm Cutting Forceps was tested a total of seven times with a representative set of thermal profiles shown in Figure 22. In two of the trials select thermistors malfunctioned so the data at 3.0 and 3.5mm is averaged over six trials. The average ratio of temperatures at 2.5, 3.0, and 3.5mm away from the tool edge was 1.14, 0.99, and 1.05 with a standard deviation of 0.12, 0.12, and 0.12 respectively.



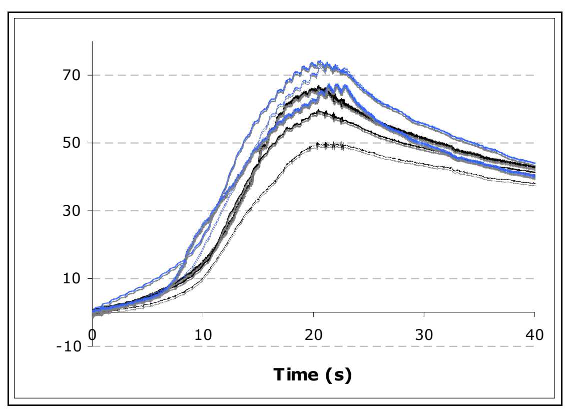


Figure 22. Representative thermal profiles for Gyrus 10mm Cutting Forceps at distances of 2.5, 3.0, and 3.5mm from each side of the surgical tool.

4.2.2 No Cooling with Cooling Tube in Place

The Gyrus PK 10mm Cutting Forceps was tested a total of seven times with a representative set of thermal profiles shown in Figure 23. In two of the trials select thermistors malfunctioned so the data at 3.0 and 3.5mm is averaged over six trials. The average ratio of temperatures at 2.5, 3.0, and 3.5mm away from the tool edge was 2.08, 1.31, and 1.54 with a standard deviation of 0.54, 0.52, and 0.51 respectively (see Figure 21.

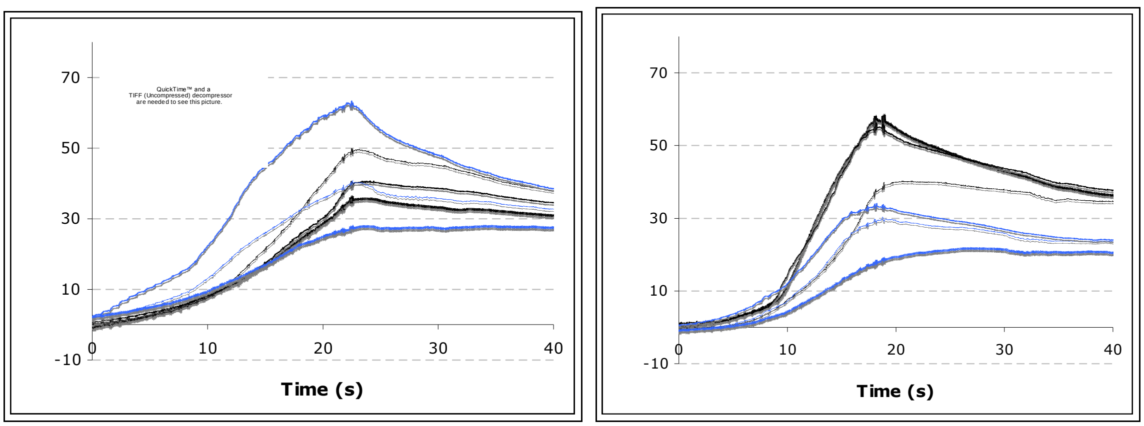


Figure 23. Representative thermal profiles with Stainless Steel cooling channel in position with no coolant used.

4.2.3 Active Cooling with Aluminum Cooling Channel

The Gyrus PK 10mm Cutting Forceps was tested a total of seven times with a representative set of thermal profiles shown in Figure 22. In two of the trials select thermistors malfunctioned so the data at 3.0 and 3.5mm is averaged over six trials. The average ratio of temperatures at 2.5, 3.0, and 3.5mm away from the tool edge was 3.13, 3.47, and 2.82 with a standard deviation of 1.22, 2.56, and 1.26 respectively.

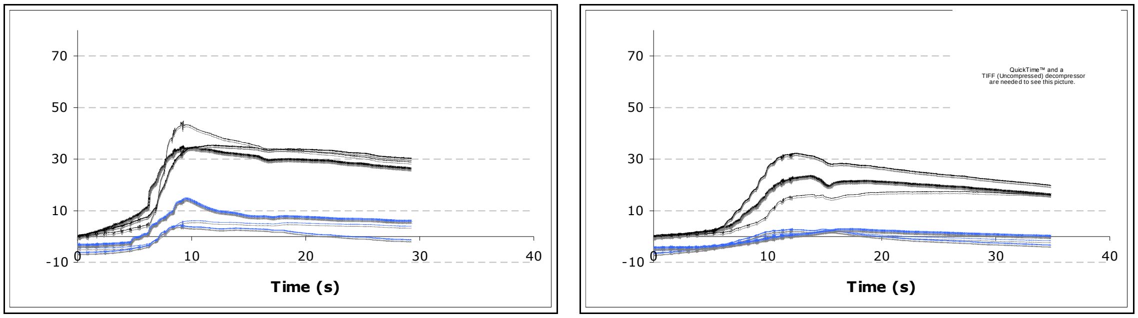


Figure 24. Representative thermal profiles with Aluminum cooling channel to actively cool the tissue.

4.2.3 Active Cooling with Stainless Steel Cooling Channel

The Gyrus PK 10mm Cutting Forceps was tested a total of seven times with a representative set of thermal profiles shown in Figure 22. In two of the trials select thermistors malfunctioned so the data at 3.0 and 3.5mm is averaged over six trials. The average ratio of temperatures at 2.5, 3.0, and 3.5mm away from the tool edge was 3.12, 2.64, and 2.84 with a standard deviation of 1.26, 0.89, and 0.79 respectively.

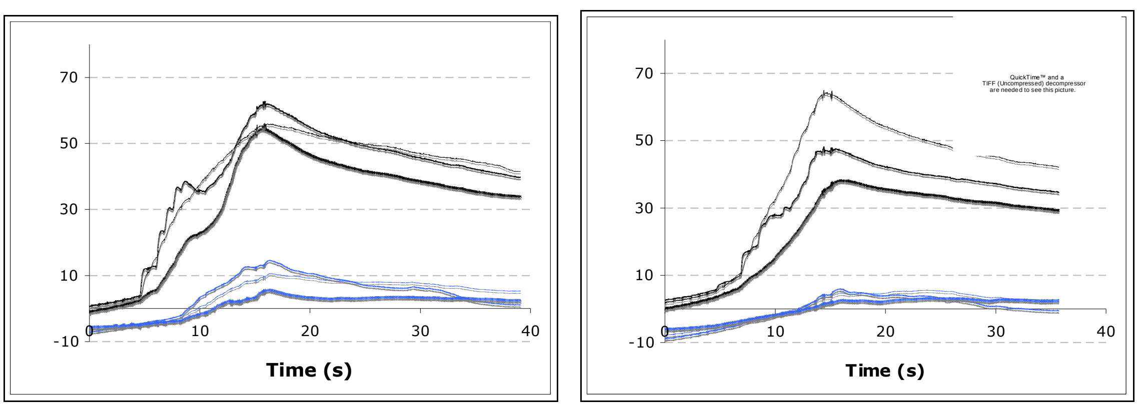
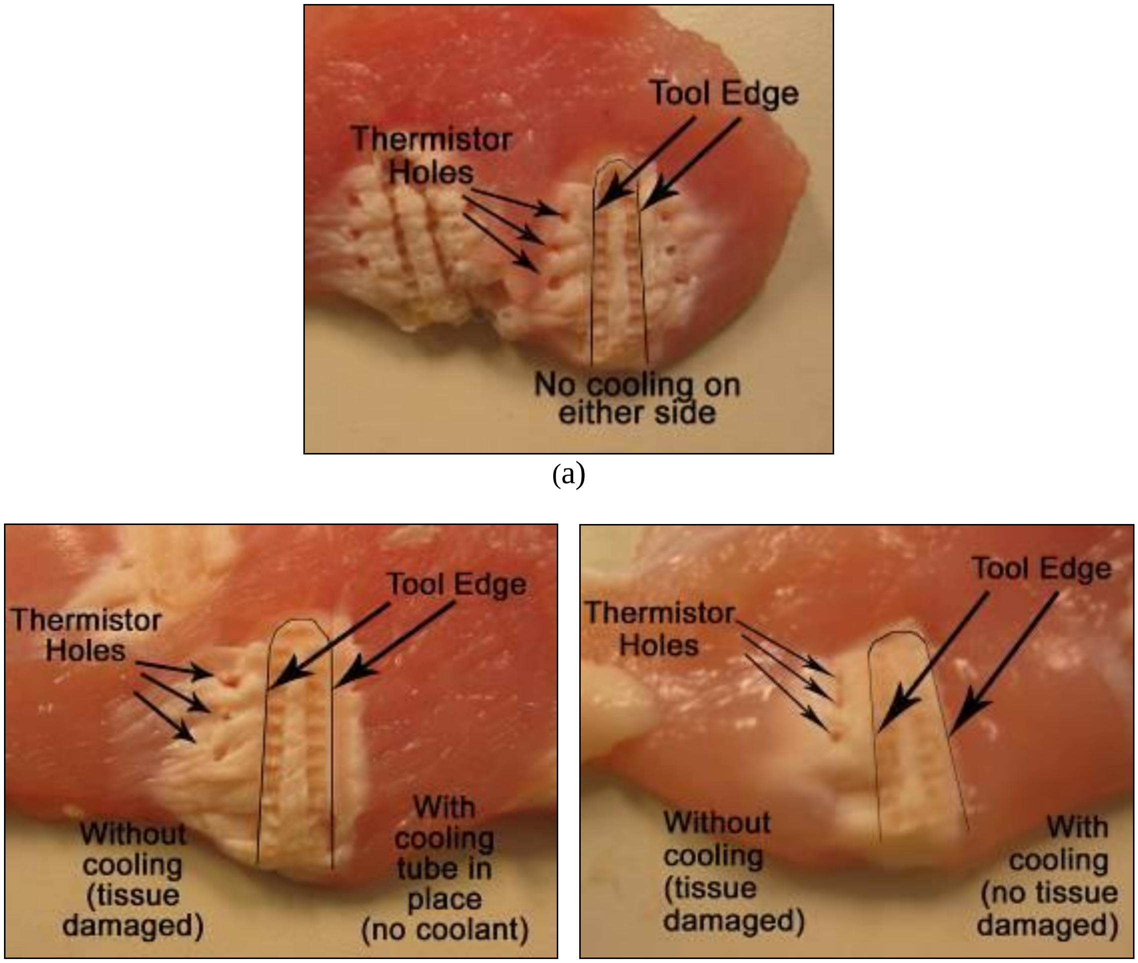


Figure 25. Representative thermal profiles with Stainless Steel cooling channel used to actively cool the tissue.



(a)

(b) (c)

Figure 26. Effects of thermal spread on tissue with no cooling (a), a cooling tube in position with no coolant (b), and active cooling via a cooling channel (c).

As seen in Figure 26, the high thermal gradients created near the right side of the surgical device resulted in much less thermal spread for the case of a SS304 tube being positioned next to the device and was almost completely eliminated when coolant flowing at 3.3 mL/min was passed through either Al3003 or SS304.

CHAPTER 5

DISCUSSION

The lack of a statistical difference between the operating temperatures of the 5mm Cutting Forceps and Harmonic ACE demonstrates their comparable ability to form a moist coagulum that seals tissue rather than desiccates and chars the tissue. However, no histology was performed on the tissue operated on to determine the true extent of seal achieved for each of the two devices. Also, although the similar thermal range for the two devices would indicate a similar thermal margin as well, the lack of histology after the lab precludes this observation from being made in complete confidence. While the Lyons Dissector operated at a higher average maximum temperature at 1.0mm from the tool edge, it too exhibited a thermal profile range lower than 100ºC and therefore within the range needed to avoid desiccation of the tissue at 1.0mm from the tool edge.

The pig lab represents the first known successful attempt of measuring sub-surface tissue temperature in real-time. The ability to acquire instant temperature information within tissue during operative procedures is a major advance not only for the study of surgical tool performance but for the safety of surgical procedures in general. Since thermistors are dependent solely on its own resistance they are believed to be capable of relaying even laparoscopic thermal information in real-time to the surgeon. This advance is expected to have major impacts on the surgeon’s ability to minimize unwanted thermal damage to surrounding tissues during surgical procedures as well as lessen patient recovery times and negative post-surgical effects.

The results obtained from actively cooling local tissue during electrosurgical procedures represents another major advance in the surgeon’s ability to minimize and possibly eliminate the thermal spread associated with surgical tools that rely on the production of heat to coagulate and/or cut tissue. The reduction in thermal spread seen simply with the presence of the cooling channel suggests that even the modest pressure placed on the tissue by the tube increases both the thermal and electrical resistance of the tissue. The significantly increased thermal conductivity of the tube (see Table 2) over the tissue (~.5 W/mK) allows the cooling channel to conduct most of the heat that would normally be retained by the tissue resulting in increasing tissue temperature. The addition of coolant flowing through the tube allows the convective qualities of the coolant to convect the heat conducted by the cooling channel and transmit it away from the surgical site. By maintaining the cooling channel at as low a temperature as possible a high thermal gradient is created allowing for maximum heat conduction by the cooling channel.

It is proposed that a novel electrosurgical and/or ultrasonic surgical device be created using the principles brought forth by this research to reduce and/or eliminate the thermal spread normally accompanying these instruments. The active parts of the device for each modality would be surrounded by a cooling channel positioned slightly closer to the tissue during surgery to induce an increased pressure gradient on the tissue. The gradient would effectively increase both the thermal and electrical (if needed) resistance of the tissue.

In the case of the electrosurgical device this would result in the 'pigeon-holing' of the electrical energy, focusing it on the tissue of interest. Meanwhile, the increased thermal resistance allows the cooling channel to more effectively conduct the thermal energy from the tissue while the coolant convects it away from the surgical area. It is believed this device would not only more effectively before the surgical procedure, but due to the concentration of electrical energy, perform it faster as well.

In the case of the ultrasonic devices, where friction represents the main component of thermal energy production, the cooling channel would again increase the local thermal resistance of the tissue allowing the cooling channel to more effectively conduct the thermal energy from the tissue while the coolant convects it away from the surgical area.

These surgical devices would offer tremendous gains in patient quality of life post-operatively, especially for patients undergoing prostatectomy and hysterectomy. Both of these surgeries routinely manifest in impotence and urinary incontinence, respectively. As evidence has shown that damage to nearby neurovascular bundles is a major factor in these post-operative problems, the above suggested device would offer patients a much healthier life after surgery.

CHAPTER 6

CONCLUSIONS AND FUTURE WORK

The temperature measuring device cannot be considered robust and stable enough for actual surgical use at the present time. However, while there is important work that needs to be done in this area it is not considered to be difficult. The initial success achieved in this lab warrants the continuation of this research coupled in the future with histological tissue analysis as well as burst pressure tests on vessels to ensure proper seals are made with the devices being tested.

The cooling channel design has shown adequate tissue temperature reduction in tissue as close as 2.5mm from the tool edge to avoid permanent thermal damage at those distances. Additional work to be conducted on the cooling channel includes the use of non-conducting materials of sufficient thermal conductivity (i.e. glass) to demonstrate the impact of a metallic cooling channel through electrical conduction. Also, the limiting factor to flow rate in these experiments was the power of pump motor. A more powerful pump can be used to test the cooling channel at varying flow rates to determine optimum rates to run the pump at.

Beyond these experiments, it is suggested that a control system be created to control the temperature of local tissue (Figure 28). The envisioned control system would use microthermistors placed locally in sensitive tissue to monitor the tissue's temperature in real-time during surgery. Algorithms would be developed to continuously monitor the thermal dose the tissue has absorbed as proposed by Sapareto & Dewey [35]. This data would serve as an input in a control system where both the power put out by the surgical generator as well as the flow rate of the cooling channel could be controlled by that input.

In addition, as the complete mechanism by which electrosurgical devices coagulate tissue is not fully understood, further research should be performed with both electrically conductive and non-conductive cooling channels to better understand how electrical energy transmits through tissue. Data collected in this research indicates the cooling channel could be modeled as a circular pipe with constant wall heat flux. Assuming fully developed flow has been established the non-dimensionalized governing equation becomes:

$$T(x,r) = T_{as}(r) + T_{en}(x,r)$$

where

$T_{as} = C_o + C_1 x + \theta(r)$,

$\theta(r) =$centerline temperature and

T_{en} is a Sturm-Louiville problem in r with BC of constant heat flux.

Using the power output from the generator as another input along with the material properties of the tissue, cooling channel, and coolant, the temperature of the tissue at discrete distances from the surgical device can be determined. Also, in surgical practice, the temperature gradient of the coolant could be used as a control input if the distance from the surgical tool is known. If this is so, tissue temperature could be monitored indirectly through the coolant.

Lastly, and before this technology can be used in human patients, it needs to be tested in a canine model (see Figure 27). Quantitative measurement of erectile function will be achieved by measuring penile corporal pressure via a pressure transducer. Procedures will be performed using each of the three common laparoscopic modalities (monopolar, bipolar, and ultrasonic) as well as a control group (no active cooling). Baseline erectile function will be documented for both the right and left neurovascular bundle (NVB) and after dissection of the left NVB each NVB will again be stimulated and the resulting corporal pressure compared to the baseline results with the right NVB serving as a control. Two weeks following NVB dissection a chronic assessment of erectile function will be performed. The dogs will be anesthetized and incisions reopened for repeat stimulation of each NVB and concomitant measurement of corporal pressure. The prostate and periprostatic structures including each NVB will be harvested and prepared for histological assessment.

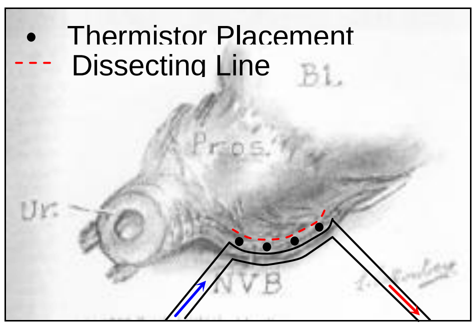


Figure 27. Schematic of prostate with cooling channel running along the NVB.

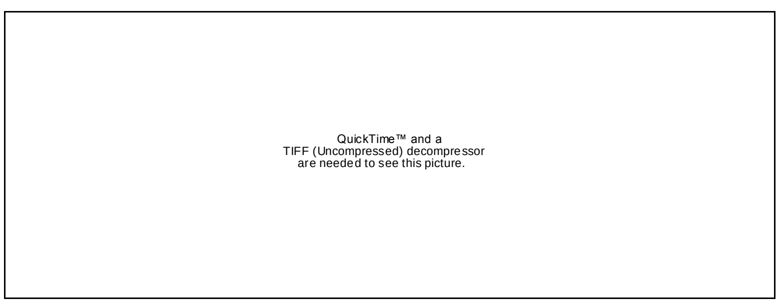


Figure 28. Schematic of proposed control mechanism.

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