A NEW THERMAL DEVICE FOR SEALING AND DIVIDING BLOOD VESSELS

Michael R. Treat* MD
Associate Professor of Clinical Surgery, Department of Surgery, Columbia University, New York, NY

ABSTRACT

Background: The limitations and hazards of monopolar electrosurgical instruments in laparoscopic surgery are well known. Bipolar and ultrasonic instruments address these problems but may be less than ideal in certain applications. A new type of instrument is described which produces effective coagulation and division with extremely little collateral tissue damage. These instruments use direct thermal energy and simultaneous pressure to sequentially denature, bond and then cut protein based tissue structures. Because of the underlying technical simplicity, these new instruments could be very cost effective. The mode of action and tissue effects are described and contrasted to monopolar and bipolar electrosurgical and ultrasonic devices.

Methods: In a porcine mesenteric vessel model, collateral thermal damage and blood vessel bursting strength were made

Results: The new instruments appear capable of producing effective tissue sealing with bursting pressures over 300 mmHg and with minimal collateral damage of less than 1 mm.

Conclusions: This cost effective direct thermal technology may be a useful alternative to existing coagulating and cutting modalities, particularly in applications where minimizing collateral damage is important.

INTRODUCTION

A new type of surgical instrument has been developed which uses thermal energy and pressure to simultaneously coagulate and divide blood vessels and other tissue. This device was developed in the Department of Surgery of Columbia University (New York, NY, USA) and at Starion Instruments Corporation (Saratoga, CA). The device offers the surgeon an alternative to existing technologies including the bipolar and ultrasonic coagulating and sealing instruments. The purpose of this paper to describe how the new device functions and to point out how it differs from the other instruments, particularly the ultrasonic coagulating shears.

BACKGROUND

Coagulation of blood vessels involves the application of energy to denature tissue proteins so that these proteins essentially become sticky and form a coagulum or clot. At the molecular level, what happens is that the applied energy changes the three-dimensional conformation of tissue proteins so that the protein chain is unraveled. This unraveling of the protein chain exposes hydrogen-bonding side groups. In the unraveled state, new hydrogen bonds can form, not between groups on the same protein chain but between adjacent chains. In essence, these unraveled protein chains get stuck together and form a tangled intertwined matrix of protein strands. This is a physico-chemical process and does not involve the biological coagulation cascades of the normal clotting mechanism.

In order to seal blood vessels, it is advantageous to simultaneously apply pressure to facilitate the sticking together of these denatured tissue proteins. This process has been referred to as "tissue welding" [12]. A variety of energy sources can be used to produce the heat ultimately needed to denature the proteins. These energy sources can be laser light, radiofrequency electricity (monopolar or bipolar), or ultrasonic. These energy sources can be regarded as intermediaries, since thermal energy is the final common pathway.

The developers of the new thermal instrument hypothesized that the desired protein denaturing effects could be accomplished most efficiently by using direct thermal heating of the tissue instead of an intermediate form of energy. The thermal energy producing element chosen was a simple resistance heating wire driven by low voltage direct current.

The active part of the instrument (the black lower jaw in Fig 1) is comprised of a nichrome heating element with a thermally insulating backing. This thermal insulating layer isolates the heating effect of the nichrome wire from the rest of the instrument and prevents the underside of the jaw from becoming hot. Closing of the instrument jaws presses the thermal element against a conformable silicone "boot" which is mounted on the other jaw of the device.

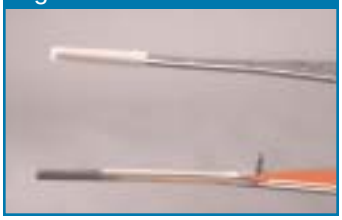
The silicone "boot" helps to create a graded thermal profile as shown in Figure 2. The thermal profile consists of a narrow high temperature cut zone that is flanked on each side by a lower temperature coagulating zone.

The graded temperature profile is crucial to the functioning of the instrument and in fact enables the device to perform both cutting and coagulation simultaneously. The bilateral and symmetric shape of the profile allows the device to seal both ends of a vessel on either side of the cut zone. Due to radiation of the heat from the nichrome element, the width of the cut zone is somewhat greater than the actual physical diameter of the wire. In this region, the temperature is high enough to actually cut tissue by means of direct vaporization with very little charring. This temperature has been measured in the range of 300-400 degrees C. At distances greater than approximately 500 microns (thousandth of a millimeter) from the center of the wire, the temperature has fallen down to below 100 degrees C, which is the ideal temperature range to coagulate and seal tissues by means of denaturation of proteins.

The silicone "boot" has another important function that is important to the production of a strong seal on the ends of the cut vessel. This function is to exert pressure or crimp the vessel walls together in the lower temperature coagulation zone. This pressure effect along with the thermal denaturation of the tissue produces coagulation and sealing.

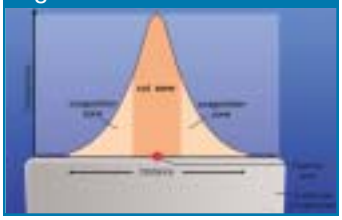
The effect produced on a vessel by the instrument is to cut it cleanly while producing a coagulated (sealed) zone at the ends of the vessel on either side of the cut.

Figure 1



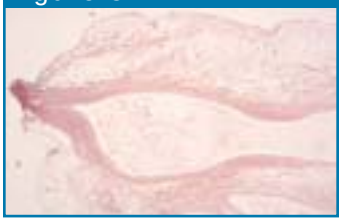
Close up view of tip of Starion instrument. The lower (black) jaw is covered by thermally insulating material. The nichrome heating element runs down the middle of the lower jaw. The (white) upper jaw is covered with a silicone "boot".

Figure 2



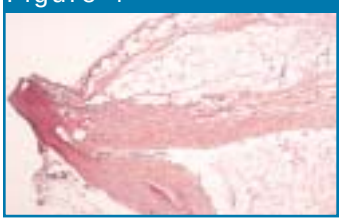
Thermal profile created within the jaws of the Starion instrument. The maximum temperature of the cut zone is high enough to cleanly vaporize and divide tissue. In the coagulation zone, the temperature is between 60 and 100 degrees C.

Figure 3



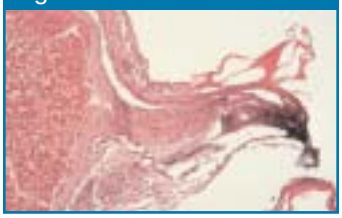
Photomicrograph of 2mm porcine gastroepiploic vessel welded shut with Starion laparoscopic device. Weld is darker upturned crimped area to the left. Magnification is 50x.

Figure 4



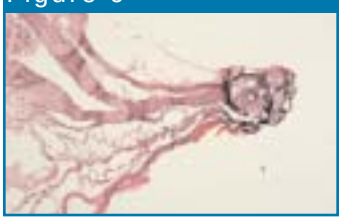
Higher power view of this same weld showing absence of thermal damage beyond the actual weld. Magnification is 150x.

Figure 5



Photomicrograph of 0.67mm porcine mesenteric vessel welded with Starion device. There is no change in the vessel wall beyond the actual welded area (the dark "beak"). 150x

Figure 6



Photomicrograph of 0.54 mm porcine mesenteric vessel welded shut with ultrasonic device. There is extensive collateral damage denoted by the separation and disruption of the tissue layers around the vessel walls and well beyond the actual weld. 150x

Measurement of Thermal Damage and Bursting Pressure

Materials and Methods

The direct thermal devices used were the Cautery Forceps (CF) and the 5mm laparoscopic Thermal Ligating Shears (TLS), (Starion Instruments Corp, Saratoga, CA, USA). Both types of Starion direct thermal devices use an essentially identical active part of the instrument. The ultrasonic instrument used was the Ultracision 5mm LCS (Ethicon Endo-Surgery, Cincinnati, OH, USA).

The experimental work was done via laparotomy on an anesthetized 40kg pig, in a non-survival surgery setting. The work was performed according to university IACUC standards.

In the first part of the experiment, we performed gross and histologic measurement of the collateral damage associated with welds produced by the new thermal device and the ultrasonic coagulating shears. Mesenteric vessels measuring approximately one mm in diameter were used. The mesenteric vessels were bluntly isolated and then were sealed and divided using the direct thermal or ultrasonic instruments. It was noted whether the weld failed immediately or later during the course of the four-hour experiment. Visible collateral damage was measured by means of a magnifying lens and a digital caliper. The measurements were made on either side of the sealed and divided vessels. Tissue that was visibly blanched was measured as thermally damaged (coagulated). The vessels were removed and submitted for histologic examination.

Histologic sectioning of the vessels was done longitudinally. A microscopic visual assessment was made of the weld's integrity and of the amount of thermal damage adjacent to the weld.

Because of the abundance of pig mesenteric vessels, we were able to do 137 welds using the thermal device (74 CF, 63 TLS) and 14 with the LCS device. The LCS device was run in the full-on mode as were the Starion thermal devices.

In second part of the experiment, individual mesenteric vessels of the pig were cannulated with a very fine gauge needle and connected to an arterial pressure monitor and a pressure-generating syringe via a three-way connector. The vessel was then sealed and divided with either the thermal device or the ultrasonic device. Bursting pressure measurements were obtained by slowly pressurizing the syringe while observing the pressure monitor. For the smaller mesenteric vessels, a total of nine pressure measurements were done with the thermal device (8CF, 1 TLS) and two were done with the LCS. This procedure was also followed for the gastroepiploic vessels of this animal. For the gastroepiploic vessels, four measurements using the thermal device (3 TLS, 1 CF) and one using the LCS ultrasonic device were accomplished.. The number of vessels used in this part of the experiment was limited in the case of the mesenteric vessels by the technical tediousness of cannulating these small vessels and by the relatively limited length of the gastroepiploic vessels.

Results

Collateral damage

In terms of measured visible collateral damage, both the Starion direct thermal and ultrasonic devices had noticeably different collateral effects.

Instrument type	Number of samples	Mean burn width mm	Standard Deviation	95% Confidence Interval for burn width in mm
Starion	137	0.861	0.262	0.817 to 0.905
ultrasonic	14	1.351	0.340	1.1548 to 1.548

There was a statistically significant difference between the mean burn widths of the Starion and ultrasonic instruments with a p-value of <0.0001. There was no statistically significant difference in the burn widths of the two types of Starion instruments, the Cautery Forceps (CF) and the Thermal Ligating Shears (TLS).

A phenomenon observed only with the ultrasonic device was a puffing up of the layers of the mesenteric tissue for a distance of approximately 8 to 12 mm from the actual weld.

We present representative examples of the histologic results obtained.

In Figures 3 and 4, we see an example of a Starion thermal device weld of a 2mm porcine gastroepiploic vessel. The weld is the darker colored upturned "beak" shaped area on the left, where the vessel walls have been welded or fused together. The actual welded region, denoted by the "beak", is approximately 0.4 mm in extent. The weld appears very secure, as indicated by the completely fused appearance of the darker staining tissues that constitute the weld. The vacuolated pattern of the tissue surrounding the vessel wall is essentially intact. In the vessel wall to the left of the actual weld, there is complete preservation of the cellular morphology and detail. The thermally affected region of tissue is essentially the area incorporated in the weld and has a total extent of less than 1mm.

In Figure 6, we see an ultrasonic weld of the same kind of mesenteric vessel. Again, the measured extent of this weld is approximately 0.4 mm. This weld is secure in appearance, as indicated by the fused appearance of the tissue at the tip of the specimen on the right. However, the tissue to the left of the actual weld is thermally damaged for a distance approaching 2 mm. The damage is shown by the disruption of the vacuolated pattern of the tissue layers surrounding the vessel wall. These disrupted areas are places where the tissue water was vaporized to steam. There are some red cells in the lumen beyond the weld that appear coagulated.

Bursting pressure data

In all welds done for mesenteric and gastroepiploic vessels, no primary or delayed (over the duration of the experiment) weld failures were observed for both types of thermal device (CF or TLS) or the ultrasonic device (LCS). For the smaller mesenteric vessels, in all cases, for both devices, the welds remained intact to a pressure beyond the maximum that could be recorded on the pressure monitor, 300 mm Hg. Also, for the larger gastroepiploic vessels, the welds remained intact to a pressure beyond the maximum that could be recorded on the pressure monitor, 300 mm Hg.

Discussion

For laparoscopic surgery, questions have been raised about the safety of electrosurgical monopolar methods and instruments [4]. These clinical hazards stem from the tendency of the monopolar electric current to seek unwanted conduction pathways. Mechanisms of the monopolar hazards include insulation breaks, capacitive coupling and unintended direct contact with other electrically conducting instruments [14][8].

Any monopolar instrument is basically a single electrode which sends electrical current into the tissue, so that the energy can flow back to a distant ground plate thus forming a complete circuit. The current density is greatest right near the electrode, since the electrode offers only a small area of contact to the tissue. Once the electrical current enters the tissues, it can spread out and thereby lower the current density. This lowering of the current density should limit the damage caused by the monopolar current to the region near to the electrode. However, sometimes the electricity will find its way back to the ground plate by unexpected pathways. Unintended damage may be done.

In addition to safety concerns, laparoscopic surgeons have also felt the need for a technology that would allow them to easily and rapidly seal significant blood vessels, without having to apply clips or do laparoscopic knot tying. This need was in particular felt in the development of the laparoscopic Nissen fundoplication. Both bipolar and ultrasonic technologies were recognized as answers to this need by the pioneers in performing this procedure laparoscopically [10][11][13].

Bipolar electrosurgical instruments use one jaw as the active electrode and the other jaw as the ground plate. In a bipolar instrument, the electrical current is more confined and is not allowed to wander through the entire body of the patient. Since bipolar instruments have two jaws and coagulate the tissue between the jaws, these instruments are well suited to applying pressure and energy simultaneously. A bipolar microprocessor-controlled tissue sealing device has proven quite successful especially in terms of very large vessel sealing (7) The technology employs real-time measurement of tissue electrical resistance to determine the optimum point at which the tissue is well denatured and sealed. This technology has been optimized for tissue sealing, and is not designed to perform tissue cutting by means of the energy.

Ultrasonic energy has also been recognized as an advantageous alternative to monopolar electrosurgery [5][6][1][9]. There is experimental data as well as widespread clinical impressions that both ultrasonic and also bipolar technologies do in fact produce less collateral injury than the monopolar technology [2][3]. Ultrasonic devices with an active jaw and an anvil surface for the other jaw are effective for both sealing and division of the tissue. Tissue division is thought to result from cavitation and disruption of tissue by the high frequency vibrations of the piezoelectric element. The coagulation and sealing effect may result from heat produced by the rapid vibrations and internal tissue friction.

The technology described in this paper may be viewed as a further step along the path that has been taken by the ultrasonic and microprocessor-controlled bipolar devices. The new thermal technology has an advantage in terms of collateral damage and complexity of the power source. The power source for the new thermal device is an order of magnitude less expensive than the power source for the ultrasonic device. The cost advantage may be of importance in increasing the number of surgeons and hospitals worldwide that have access to this type of instrumentation. The very minimal collateral damage produced by the device may make it advantageous in certain clinical settings.

BIBLIOGRAPHY

1. Amaral JF. Laparoscopic application of an ultrasonically activated scalpel. Gasatrointest Endosc Clin of NA 3:381-392, 1993
2. Amaral JF, Chrostek CA. Experimental comparison of the ultrasonically-activated scalpel to electrosurgery and laser surgery for laparoscopic use. Min Invas Ther &Allied Technol 6: 324-331, 1997
3. Birch DW, Park A, Shuhaibar H. Acute thermal injury to the canine jejunal free flap: electrocautery versus ultrasonic dissection. American Surgeon No. 65(4) 334-337, 1999
4. Gossot D, Buess G, Cuschieri A, Leporte E, Lirici M, Marvik R, Meijer A, Meltzer M. Schurr O (The E.A.E.S. Technology Group). Ultrasonic dissection for endoscopic surgery. Surg Endosc (1999) 13:412-417
5. Hodgson WJ. Ultrasonic surgery. Ann R Coll Surg Engl 62:459-461, 1980
6. Hodgson WJ, Del Guercio LR. Preliminary experience in a liver surgery using the ultrasoninc scalpel. Surgery 95:230-234, 1984
7. Kennedy JS, Stranahan PL, Taylor KD, Chandler JG. High-burst-strength, feedback-controlled bipolar vessel sealing. Surg Endosc 12:876-878, 1998
8. Nduka, CC, Super PA, Monson JRT, Darzi AW. Cause and prevention of electrosurgical injuries in laparoscopy. J Amer College of Surgeons 179: 161-169, 1994
9. Payne JH Jr. Ultrasonic dissection. Surg Endosc 8: 416-418, 1994
10. Spivak H, Richardson WS, Hunter JG. The use of bipolar cautery, laparoscopic coagulating shears, and vascular clips for hemostasis of small and medium-sized vessels. Surg Endosc (1998) 12:183-185
11. Swanstrom LL, Pennings JL. Laparoscopic control of short gastric vessels. J Amer College Surgeons 181:347-351. 1995
12. Treat MR, Bass LS. Tissue welding: A comprehensive clinical review. Lasers in Surgery and Medicine. 1995
13. Underwood RA, Dunnegan DL, Soper NJ. Prospective, randomized trial of bipolar electrosurgery vs ultrasonic coagulation for division of short gastric vessels during laparoscopic Nissen fundoplication. Surg Endosc (1999) 13: 763-768
14. Voyles CR, Tucker RD. Education and engineering solutions for potential problems with laparoscopic monopolar electrosurgery. Am J Surg 164:57-62, 1992

* *The views expressed in this paper are solely those of Michael R. Treat MD and do not necessarily reflect those of Starion Instruments Corp. or Columbia University. Michael R. Treat MD and Columbia University have a financial interest in Starion Instruments Corp.*