A NEW THERMAL DEVICE FOR SEALING AND DIVIDING BLOOD VESSELS

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 is 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.

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 by 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 by the number of pigs. No statistically significant difference was noted between the sizes of the two types of Starion instruments, the Cautery Forceps (CF) and the Thermal Ligating Shears (TLS).

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). There was a 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 8-12 mm from the actual weld.

In all welds done for mesenteric and gastroepiploic vessels, no primary or delayed bursting pressure data was obtained. In all welds done for mesenteric and gastroepiploic vessels, no primary or delayed bursting pressure data was obtained. In all welds done for mesenteric and gastroepiploic vessels, no primary or delayed bursting pressure data was obtained.

**BIBLIOGRAPHY**