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Comparison of Torsional and Linear Mode Ultrasonic Coagulating Shears for Sealing Veins

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Abstract

Background: Torsional mode ultrasonic coagulating shears are an alternative device to linear mode shears for hemostatic cutting. The aim of this study was to compare the vessel-sealing quality of torsional and linear mode ultrasonic coagulating shears on human veins.
Materials and Methods: Veins were harvested from 15 patients during varicose vein surgery. Each vessel was sealed and cut by both devices at different sites. The seals were either tested for burst pressure or examined microscopically to compare mural thickness, seal length, and extent of coagulation and lateral thermal effect.
Results: For veins 2.0–3.0 mm in diameter, the median burst pressure was higher on seals made with torsional mode shears (245, IQR 161–360 mm Hg vs. 133, IQR 101–165 mm Hg; $P = 0.001$). Similarly, for veins 3.5–4.5 mm in diameter, the median burst pressure was higher with torsional mode shears (149, IQR 118–212 mm Hg vs. 94, IQR 82–126 mm Hg; $P = 0.001$). There was no significant difference in the median burst pressure for veins 5.0–6.0 mm in diameter (82, IQR 61–132 mm Hg vs. 76, IQR 40–114 mm Hg; $P = 0.268$). Seals made with torsional mode shears showed significantly greater seal length (517 ± 300 μm vs. 316 ± 147 μm; $P = 0.016$), more tissue coagulation (467 ± 197 μm vs. 335 ± 128 μm; $P = 0.015$), and greater lateral thermal effect (1479 ± 340 μm vs. 1116 ± 253 μm; $P < 0.001$).
Conclusion: Torsional mode ultrasonic shears produced more secure seals on veins up to 4.5 mm in diameter. This can be explained by the greater seal length produced by torsional mode shears.

Introduction

One of the most important aspects of safe surgery is the control of bleeding. Increasingly, sophisticated minimally invasive procedures have become possible with the development of a wide armamentarium of techniques to achieve hemostasis. Besides the use of titanium and polymer clips, vascular endostaplers, ligatures, and tissue sealants, an increasing number of devices utilizing energy sources have been introduced. These energy sources can be laser light, electrical current (i.e., monopolar or bipolar), or ultrasonic coagulation shears. The sealing of blood vessels involves the simultaneous application of energy to denature tissue proteins and pressure to facilitate the bonding of the proteins, forming a coagulum that seals the vessel lumen.

Over the past decade, ultrasonic coagulating shears have become popular alternatives to electrosurgery because they possess certain advantages over traditional diathermy, including the avoidance of injury due to insulation failure, capacitative coupling, and electrical burns from an indifferent electrode. The shears also operate at relatively lower temperatures and result in minimal lateral tissue injury.[1,2] Initially, commercial devices utilized the ultrasonic vibration of a waveguide along the longitudinal axis (i.e., linear mode) to deliver energy to the tissues. This technology is common to the existing systems, such as the Harmonic Scalpel® (Ethicon Endo-Surgery, Cincinnati, OH), the AutoSonix® (US Surgical Corporation, Norwalk, CT), and the SonoSurg® (Olympus Medical Systems Corporation, Tokyo, Japan). More recently a torsional mode device, the LOTUS™ (S.R.A. Developments, Ltd., South Devon, UK), has been introduced. The waveguide of the LOTUS vibrates in a short arc of 3–4 degrees around its axis. This novel device was designed to focus the direction of energy released into the tissues, so that

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it could achieve coagulation and perform cutting more effectively.

To date, there have been relatively few published data on the efficacy of different ultrasonic coagulating shears on vessel sealing.[2–6] Only limited data on the efficacy of the torsional mode shears have been published since they were first launched in the United Kingdom in 2003. Recently published data have shown that the torsional mode shears produced a more secure sealing of fresh cadaveric porcine arteries than linear mode shears.[7] The aim of this study was to compare the vessel-sealing quality of torsional and linear mode shears on human veins by determining the burst pressure of seals and evaluating the seal length and spread of thermal injury on the vessels.

Materials and Methods

The devices compared were the torsional mode LOTUS with a SV2-370 handpiece and 5-mm diameter SV2-370D jaw actuator exposing 12 mm of active blade (S.R.A. Developments, Ltd.) and the linear mode Harmonic Scalpel, using the LCSC5 disposable 5-mm diameter curved shears with a 15-mm active blade (Ethicon Endo-Surgery). Both systems comprised a generator, foot-activated pedals, a handpiece, waveguide, and blade. In each system, the transducer was housed within the handpiece. At the tip of each instrument, a moveable jaw holding a polytetrafluoroethylene (PTFE) insert was used to compress the tissue against the blade. The components of the acoustic systems vibrate harmonically at 36.0 kHz in the case of the LOTUS and at 55.5 kHz in the case of the Harmonic Scalpel.

The subjects for this study were 15 patients who underwent surgery for varicose veins that involved the ligation and stripping of uni- and bilateral long and/or short saphenous veins and their tributaries, with multiple stab avulsions of the more distal veins. Patients had consented to allow the researcher to seal segments of the excised veins and then either test for burst strength or examine the seals microscopically. The local ethics committee approved this study.

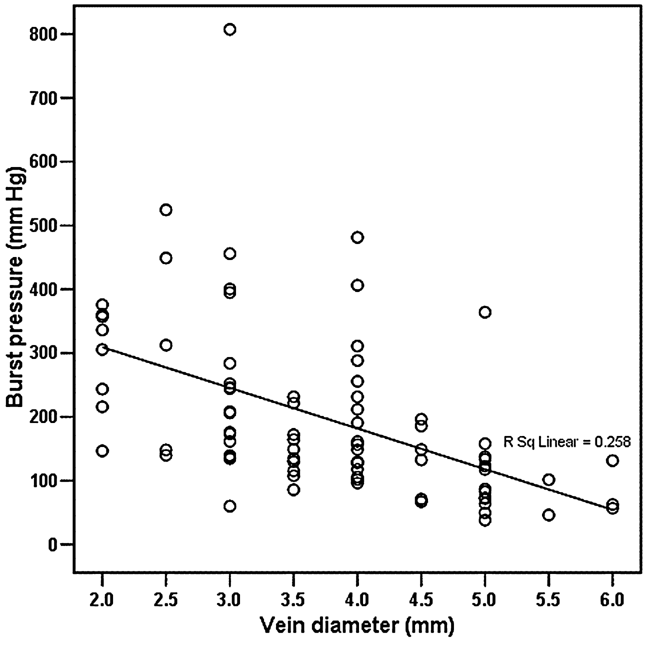

FIG. 1. Scatter plot of burst pressure versus vessel size for torsional mode shears.

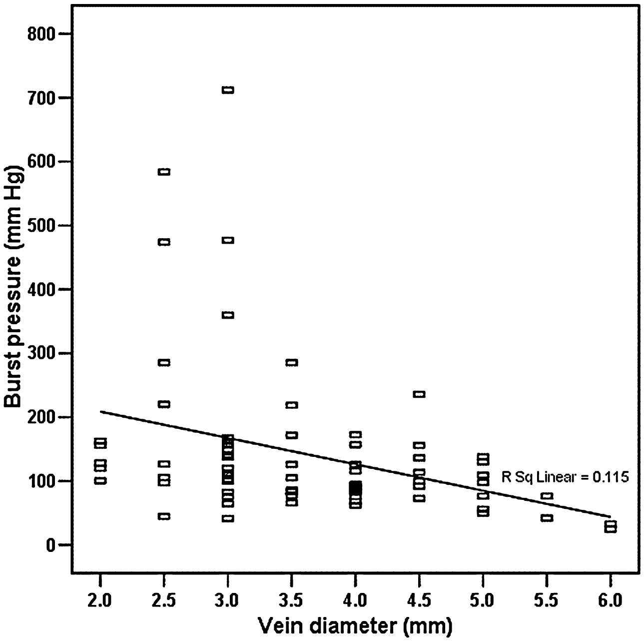

FIG. 2. Scatter plot of burst pressure versus vessel size for linear mode shears.

All operations were performed under general anesthesia. During the stripping of the long saphenous vein, the vessel wall became inverted, with the endothelial surface on the outside and adventitial surface on the inside. Once removed from the patient, the vessel was manipulated back to the normal configuration gently to avoid causing additional trauma to the vessel. Each seal was made by applying a maximum grip to the device's handles that translated into a compression force between the jaw and the blade, and the device was activated on "normal" power with the LOTUS or on power "level 3" with the Harmonic Scalpel, as recommended by the manufacturers, for optimal coagulation. With each activation of the ultrasonic shears on the vessel, one seal at each side of the cut was obtained. This was done repeatedly along the length of the vessel about 3 cm apart, using both torsional and linear mode ultrasonic shears in an alternate sequence to obtain a number of seals.

The seal on each short segment of vein was inspected for leakage and the caliber of the vein was measured to the nearest 0.5 mm, in the nondistended state, using a ruler. The majority of seals were then tested for the bursting pressure by using a pressure transducer method, as previously described in a similar study.[7] Briefly, a tapered plastic cannula was introduced into the vessel at the open end and tied securely with a 2-0 silk ligature. A CTE9002GY7 pressure transducer (SensorTechnics, Puchheim, Germany) with a gage pressure range of 0–2 bars (equivalent to 0–1500 mm Hg) and a 0–5-V output signal was employed. The ADC-12 analog to digital converter (Pico Technology Limited, St. Neots, Cambridgeshire, UK) was used to convert the voltage output signal from the transducer to pressure readings in mm Hg.

Table 1. Comparison of Median Burst Pressure and Interquartile Range (IQR) Based on Vessel Size for Seals Made with Torsional and Linear Mode Ultrasonic Coagulating Shears

Vessel size	*2.0–3.0 mm*		*3.5–4.5 mm*		*5.0–6.0 mm*	
Device (mode)	N	*Median (IQR) (mm Hg)*	N	*Median (IQR) (mm Hg)*	N	*Median (IQR) (mm Hg)*
Torsional	30	245 (161–360)	34	149 (118–212)	19	82 (61–132)
Linear	32	133 (101–165)	30	94 (82–126)	11	76 (40–114)
P-value		0.001		0.001		0.268

The vein's intraluminal pressure was gradually increased at a rate of about 10 mm Hg per second until the seal leaked. This was achieved by manually increasing the pressure on the syringe's piston while observing the real-time graphic presentation of intraluminal pressure against the time displayed on the laptop computer's screen. The acute burst pressure was determined by the maximum pressure recorded at the point when the seal leaked.

A representative smaller number of seals (not tested for burst strength) made with each device from each patient were immersed in 10% formaldehyde and processed for microscopic examination. The specimens were sliced longitudinally and stained with hematoxylin and eosin (H&E) and elastica van Gieson (EVG) before microscopic examination. The seal is defined as the part of the vessel where the vessel walls have fused, thus obliterating the vessel lumen. Each seal was examined for its length in the longitudinal axis. The local effects of energy spread were assessed by a determination of the extent of coagulation (i.e., complete cellular necrosis and loss of cell and tissue structure) and extent of lateral thermal injury (i.e., partial loss of nuclear staining, cellular and elastic fiber morphology). The measurer (CSV) was blinded to the instruments used for each seal.

Statistical analysis

Statistical analysis was performed by utilizing the SPSS 12.0.1 (SPSS, Inc., Chicago, IL) statistical software package. Statistical differences were evaluated by the chi-square test for categoric data, the Mann-Whitney U test for nonparametric data, and the Student's *t*-test for parametric data. Statistical significance was accepted at $P < 0.05$.

Results

In total, 248 seals were made. One hundred and thirty seals were made with torsional mode shears, of which 21 were failed seals (determined by either macroscopic examination or burst pressure less than 20 mm Hg), 83 were tested for burst pressures, and the remaining 26 were processed for microscopic examination. One hundred and eighteen seals were made with linear mode shears, of which 22 were failed seals, 73 were tested for burst pressures, and the remaining 23 were processed for microscopic examination. There was no significant difference in the failure rate between torsional (16%) and linear mode shears (19%; $P = 0.612$).

The burst pressure of seals

Overall, the median burst pressure for 83 seals made with torsional mode shears was 149 mm Hg and for 73 seals made with linear mode shears was 109 mm Hg ($P = 0.007$). There was a reduction of burst pressure with increased vein diameter for both devices (Figs. 1 and 2). In order to further compare the two modes, the veins were divided into three groups: 2.0–3.0, 3.5–4.5, and 5.0–6.0 mm (Table 1). The median burst pressure of seals made with the torsional mode shears for vessels in the 2.0–3.0- and 3.5–4.5-mm groups were statistically higher than that achieved with the linear mode shears. The burst pressure of seals for larger vessels 5.0–6.0 mm in diameter was similar for both shears (Table 1).

The histologic examination of seals

Twenty-six seals made with torsional mode ultrasonic coagulating shears and 23 seals made with linear mode ultrasonic coagulating shears from 12 patients were examined microscopically. Of these, 22 of 26 seals made with the torsional mode device were prepared satisfactorily to enable useful measurements to be made. Similarly, 19 of the 23 seals made with the linear mode device were prepared satisfactorily for this purpose. A representative microscopic appearance of venous seal made with ultrasonic coagulating shears is shown in Figure 3. There were no significant differences in the external diameter and mural thickness of the vessels. The seal length was significantly greater on vessels sealed with the

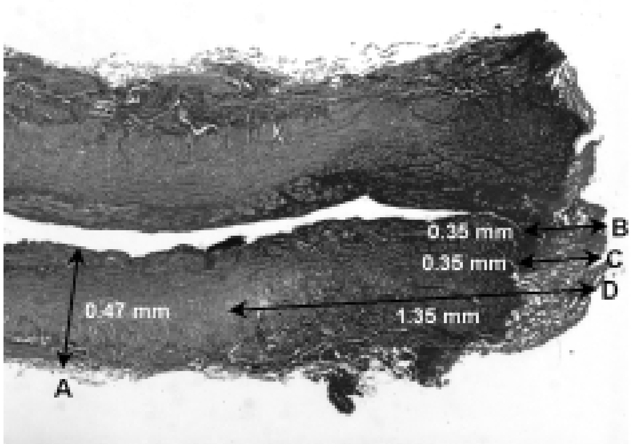

FIG. 3. An example of microscopic appearance of venous seal made with ultrasonic coagulating shears. Slide was stained with elastica van Gieson to allow an appreciation of lateral thermal injury (darker areas on the right half of the slide). Measurements for mural thickness (**A**), seal length (**B**), extents of coagulation (**C**), and lateral thermal injury (**D**) have been added.

Table 2. Comparison of Vessel Size, Mural Thickness, Seal Length, Extent of Coagulation and Lateral Thermal Injury for Seals Made with Torsional and Linear Mode Ultrasonic Coagulating Shears

	Mode	N	*Mean*	*Standard deviation*	P-*value*
External diameter (mm)	Torsional	22	4.341	1.062	0.297
	Linear	19	4.026	0.841	
Mural thickness (mm)	Torsional	22	0.415	0.114	0.155
	Linear	19	0.363	0.116	
Seal length (mm)	Torsional	22	0.517	0.300	0.016
	Linear	14	0.326	0.147	
Coagulation (mm)	Torsional	22	0.467	0.197	0.015
	Linear	18	0.335	0.128	
Lateral thermal injury (mm)	Torsional	22	1.479	0.340	<0.001
	Linear	19	1.116	0.253	

torsional mode ultrasonic coagulating shears. This greater seal length was associated with significantly greater loss of cellular morphology at the cut edge of the vessels, as well as more extensive lateral thermal injury (Table 2).

Discussion

Ultrasonic coagulating shears are used to coagulate and cut tissues and vessels by causing tissue heating by high-frequency vibration. This enables a more precise control of coagulation than can be achieved with monopolar diathermy because carbonization is largely prevented. Ultrasonic coagulating shears occlude blood vessels by frictional heat generated when the vibrating blade comes into contact with the vessel. This frictional heat produces lower maximum temperatures, when compared with conventional electrocoagulation, by avoiding the exponential increase in tissue temperature associated with the rise in tissue resistance as tissue dehydrates.[1] The relatively mild increase in temperature is sufficient to cause the proteoglycans and collagen fibers in the vessel wall to become denatured by a disruption of tertiary hydrogen bonds and to mix with intracellular and interstitial fluids to form a glue-like substance or coagulum.[1,8] This coagulum plays an important role in the occlusion of vessels. The shears enable coaptive closure by exerting mechanical pressure on vessel walls to allow the fusion of collagen and elastic tissue fibers. The strength of the union depends upon the integrity of the connective tissue fibers. Excessive heating, leading to amorphous coagulation, destroys the fiber arrangement of the connective tissue and can result in weaker bonds.[8]

Linear mode ultrasonic shears were initially developed, the most widely used version being the Harmonic Scalpel. This has been compared with other nonultrasonic modalities of hemostasis in a few small studies. Spivak et al.[5] reported the results of a study performed in vivo on porcine arteries and showed the Harmonic Scalpel to be equal to titanium clips for small vessels less than 0.5 mm in diameter, with all seals resisting a pressure of >300 mm Hg. The Harmonic Scalpel was similar in efficacy to the LigaSure™ (Valleylab®, Boulder, Colorado, USA), an electrothermal bipolar vessel sealer, for vessels in the 2.0- to 3.5-mm range. Similar studies performed *in vitro* by Kennedy et al.[9] and Harold et al.[3] showed poorer results with the Harmonic Scalpel, when compared with LigaSure. The burst strengths for 3- to 7-mm arteries exhibited considerable variability, often extending well below physiologic systolic pressures and significantly less than the LigaSure. The Harmonic Scalpel was only more effective than the LigaSure for arteries in the 2- to 3-mm range, 226 versus 128 mm Hg, respectively.

The actions of linear and torsional mode shears are illustrated in Figure 4. In linear mode shears, the stack of piezoelectric ceramics and the end plate are placed along the axis of the waveguide within the transducer and transmits a lon-

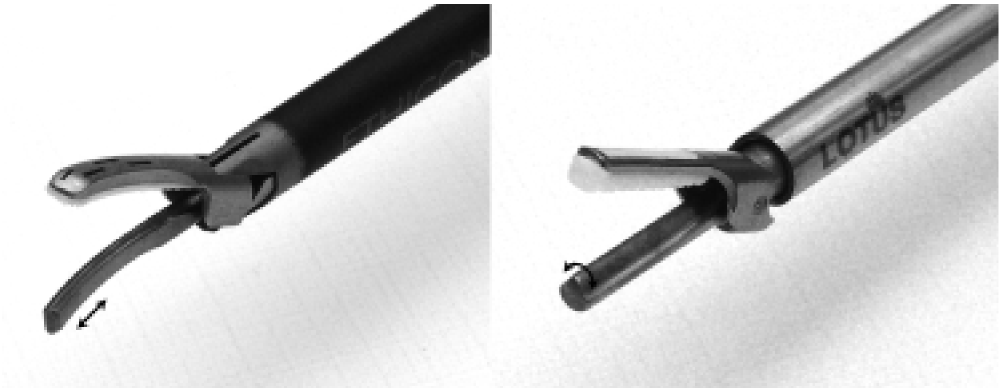

FIG. 4. Illustration of linear mode vibration of the Harmonic Scalpel® (left) and torsional mode vibration of the LOTUS™ (right), indicated by the double arrow in each diagram.

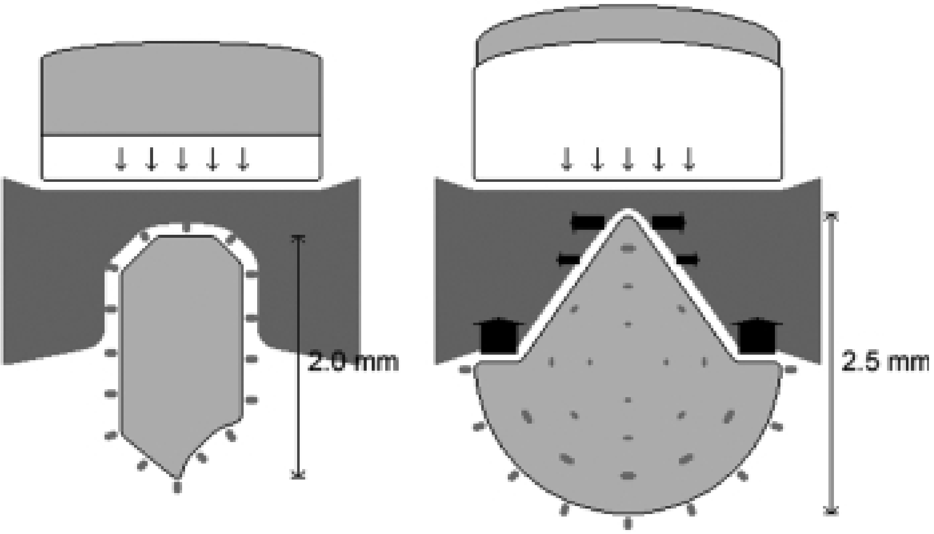

FIG. 5. Force-generation profiles of the Harmonic Scalpel® (left) and LOTUS (right) blades in the cross-sectional planes. Both blades exert a shear force, through friction, on any tissue contacting its sides, as represented by the grey dots. The arrows on both inactive jaws pointing down toward the tissue and blade represent the forces that compress target tissue for coaptive coagulation. The horizontal black arrows represent cutting forces at the apex of the LOTUS blade compressing into the tissue and separating it sideways. The vertical black arrows arising from either side of the LOTUS blade represent compression forces that coagulate tissue.

gitudinal standing wave down the waveguide to provide a compression wave in front of the tip and a shear wave along the sides of the blade. The longitudinal vibration of the blade generates friction heating at the interface between metal and tissue. This is enhanced by the cooperative action of the passive hinged jaw. The efficacy of energy transmission from blade to tissue is related to tissue properties and is critically dependent on jaw pressure.

The LOTUS system is a new generation of ultrasonic shears that operates through a torsional mode vibration. Within the transducer, the stack of piezoelectric ceramics and the end plate are placed perpendicular to, and offset from, the axis of the waveguide. The waveguide vibrates in a short arc around its axis, generated by applying a harmonic torque about the proximal end of the waveguide axis. The blade has a unique design, which features grooves cut into one side of the distal tip to provide a compression force directly into the target tissue between the blade and hinged jaw. This immediately results in the temperature effects required for coagulation. The different energy profiles of the linear and torsional mode waveguides have previously been described,[7] and they are illustrated in Figure 5. The arrows on both inactive jaws pointing down toward the tissue and blade represent the forces that compress target tissue for coaptive coagulation. The horizontal black arrows represent cutting forces at the apex of the LOTUS blade compressing into the tissue and separating it sideways. The vertical black arrows arising from either side of the LOTUS blade represent compression forces that coagulate tissue.[7]

How torsional mode shears achieve the more desired hemostatic effect might be explained by the different force-generation profiles of the two devices. Looking at both blades end-on (Fig. 5), the linear mode blade exerts a shear force, through friction, on any tissue contacting its sides, represented by the gray dots. The torsional mode blade also exerts a similar shear force, including the distal face. When grooves are cut into one side of the torsional mode blade, the exposed facets exert a compressional force on tissue contacting them. These are represented by the bold black arrows traveling in the plane of the page. The compressional force is responsible for direct energy transmission into tissues on both sides of the blades, creating a larger seal and greater lateral thermal effect when coagulating and cutting through a blood vessel. In this study, the gain in coagulating power of the torsional mode shears was obtained at the cost of greater thermal injury. However, the difference was only 0.4 mm, which is not of clinical significance.

Our results exhibited considerable variability in burst strengths with both devices. The torsional mode shears were superior in sealing veins up to 4 mm in diameter. The number of seals on vessels 5 mm or greater in diameter was not sufficient to make a valid comparison between the two devices. There were also quite high seal-failure rates with a single activation; 16% with the torsional mode shears and 19% with the linear mode shears. Suboptimal hemostasis during surgery can often be controlled with repeated activation(s), using the same device upon the bleeding vessel or tissue. In clinical practice, other back-up measures, such as clips, ties, sutures, electrosurgery, or specialized vessel-sealing devices, should be available when the security of hemostasis is in doubt.

Goldstein et al.[10] studied the extent of thermal injury along divided ureters in a porcine model and demonstrated the mean extent of thermal injury for the Harmonic Scalpel to be 1.92 mm, no different to that the electrothermal bipolar vessel sealer, at 2.11 mm. Harold et al.[3] showed that the Harmonic Scalpel caused thermal injury of 1.6, 2.4, and 2.4 mm in porcine arteries 2 or 3, 4 or 5, and 6 or 7 mm, respectively. Our results showed a lesser extent of thermal injury, with means of 1.5 and 1.1 mm for torsional and linear mode shears, respectively, over a range of similar-sized veins. However, their specimens were stained with H&E, not elastica van Gieson, which was also used for our study. We have found that using elastica van Gieson stain was more precise in demarcating the areas of thermal injury, compared to H&E stain, because elastica van Gieson staining allows a clearer tinctorial discrimination between normal tissue and areas of thermal injury and coagulation at the area of the seal.

Our experimental work microscopically depicts the tissue changes following ultrasonic coaptive closure. Certain features make it possible to formulate a general concept of the mechanism of coaptive blood-vessel closure by the thermal effect from friction and high-frequency vibration. The seal length was approximately the same as the extent of coagulation for both torsional and linear mode devices, suggesting that the temperature required to bond the tissue had to be high enough to also cause coagulation. Our own data obtained by infrared thermal imaging (unpublished) revealed that the peak tissue temperature reached could be as high as 111 and 128°C, respectively, during the ultrasonic dissection of soft tissue. The lateral thermal spread was approximately three times the extent of coagulation and seal length, a feature seen with both ultrasonic devices. The actual lateral thermal effect was probably greater than appreciated on microscopy, as there was always some degree of vessel contraction during the process of coagulation.

Certain practical limitations need to be addressed for this study. The sealing of the vessels took place *ex vivo*, and the study design did not mimic the real physiologic conditions of having warm blood within the vessel lumen. The presence of blood in the vessel lumen is expected to alter the heat dispersion to a certain extent, but in coaptive coagulation, blood flow would be interrupted by the mechanical force used to oppose the vessel walls. Whether components of blood, such as platelets, clotting factors, and proteins, could contribute to the strength of the seal remains unknown. The quality of the veins may have been adversely affected from the traumatic stripping of the veins, although we have no direct way of proving this, even with microscopic examination. However, the researchers believe that this should not have a direct effect on the seal quality. Some thin-walled, severely varicosed veins obtained from one particular patient had an unacceptably high rate of seal failure, suggesting that the integrity of the vessel wall is an important factor for successful vessel sealing with ultrasonic coagulating shears. Our best efforts were used to process the veins for microscopic examination. However, artifacts and technical problems that occurred during the preparation of slides had reduced the yield of good-quality slides and some were considered unsatisfactory for an assessment of the seal integrity.

Conclusion

This study demonstrates that both torsional and linear mode ultrasonic coagulating shears can achieve hemostasis well above physiologic venous pressure in the majority of the cases, although we need to be aware that there may be a moderate risk of failure when using these devices for hemostatic cutting. The torsional mode shears have been shown to be superior in sealing veins up to 4 mm in diameter. When sealing larger vessels, more caution is required, as the seal strengths tend to decrease. The superior seal strength of the torsional mode shears correlated with production of a wider area of fusion of the vessel walls.

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