Examination of Seal Strength and Thermal Spread from the New Starion Instruments™ TLS^3 Thermal Ligating Shears in the Porcine Model

Rhonda Albright, DVM, Amanda O'Brien, DVM

Abstract

In order to determine the versatility of the new Starion Instruments™ TLS^3 device, a variety of arterial and venous vessels ranging from 1-10 mm were sealed and cut in two female pigs. Harvested vessel segments were internally pressurized and thermal spread measured. The average arterial vessel burst pressure was 1125 mmHg. During this series of tests an ovariohysterectomy was successfully performed on one sow. Based on seal testing and the performed surgical procedure, the new Starion Instruments™ TLS^3 has shown to be an effective general surgery instrument in providing hemostasis on a variety of vessel and tissue types and sizes.

Introduction

Tissue Welding™ provides for the simultaneous sealing and cutting of vessels and tissue achieving hemostasis in a variety of surgical approaches. Since its introduction, products utilizing Tissue Welding™ technology developed by Starion Instruments™ (Sunnyvale, CA, USA) have been used in thousands of open and minimally invasive procedures including cardiothoracic, ENT and laparoscopic surgeries. The Starion Instruments™ TLS^3 laparoscopic device is the latest device to employ this technology. TLS^3 efficacy is explored in an investigation of arterial and venous sealing and dividing and subsequent vessel burst testing.

Starion Instruments™ Tissue Welding™

All Starion Instruments™ devices employ a resistive heating element in the tip or jaw of each hand-held surgical device. The Starion Instruments™ Universal Power Supply™ (UPS) is a low voltage, direct current (DC) generator which provides a selectable, constant current ensuring that a precise amount of power is generated in the heating element. Unlike existing electrosurgical techniques (i.e. monopolar, bipolar radio-frequency devices), electrical current is not directed through the patient, but is passed through the heating element of the device. Hemostasis through Tissue Welding™ occurs when tissue is heated by the resistive heating element concurrent with the application of controlled pressure from the jaws or tips of the device. The applied thermal energy allows the denaturation of tissue to form a protein coagulum while the pressure facilitates the grouping of these denatured proteins to occlude the vessel. Further application of heat and pressure divides the tissue or vessel.

Starion Instruments™ TLS^3 Thermal Ligating Shears and Universal Power Supply™ (200-006R UPS)

Starion Instruments™ newest generation of Thermal Ligating Shears, TLS^3, seals and divides vessels and tissue through proven Tissue Welding™ technology. This 5mm general surgery product is unique from existing Starion instruments in that it incorporates two resistive heating elements which heat tissue between the jaws of the device from both sides. Heating the grasped tissue from both sides results in improved hemostasis, lower peak tissue temperatures and faster sealing and cutting times. Because the seal is initiated from both sides of the tissue at the same time, the temperature gradient across the tissue is reduced and the possibility of unwanted thermal collateral damage is significantly reduced. The TLS^3 when combined with Starion's new 200-006R UPS generator (Figure 1) is able to quickly seal and divide tissue.

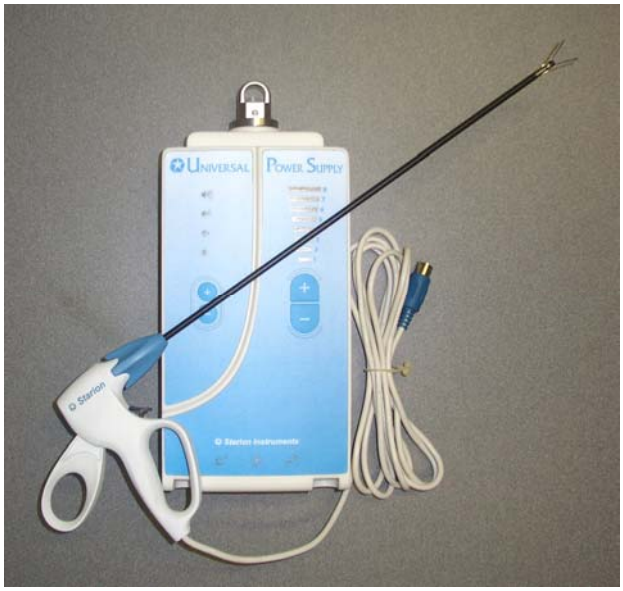

Figure 1 – Starion Tissue Welding™ System. A TLS^3 and 006 UPS generator were used to seal and divide porcine tissue.

Materials and Methods

Two commercial breed female pigs, weighing 98.2 kg and 106.4 kg were used in this study and housed at LyChron, LLC (Mountain View, CA, USA). Subjects were placed in dorsal recumbency and a laparotomy, midline sternotomy and surgical cutdowns at the neck and rear legs were performed to expose arteries and veins for vessel harvesting and burst testing (Figure 2).

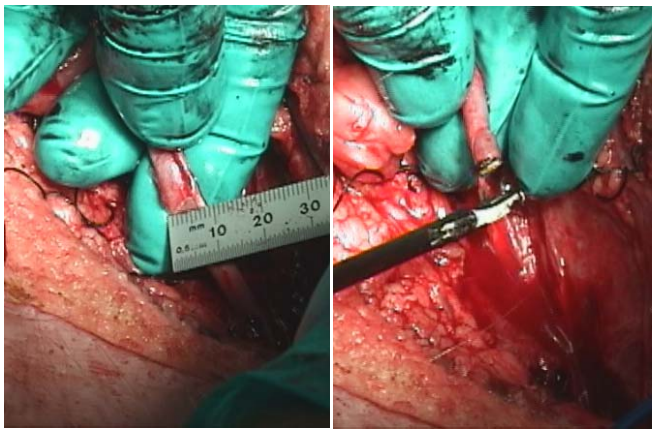

Figure 2 – Vessel Harvesting. A 9mm porcine carotid artery is measured then sealed and divided by the TLS[3].

In addition, an ovariohysterectomy was performed on one sow (Figure 3).

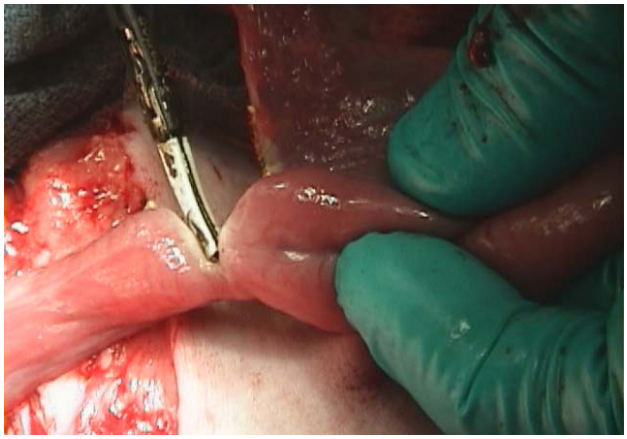

Figure 3 – Ovariohysterectomy. After sealing the uterine artery and vein, the approximately 16mm uterine body was sealed and cut in two passes by the TLS[3]. The end of the first pass is shown above.

All tissue specimens were retrieved with Starion Instruments™ TLS[3] devices. Using a 20cc syringe and 30 gauge needle, saline was injected into the recovered vessels segments until leaking at one of the two seals was observed. Initially a 15 psi (776 mmHg) pressure gauge was connected to the syringe to monitor the burst pressure at seal failure. A 30 psi (1551 mmHg) pressure gauge was then used when samples were demonstrated to exceed the measurement range of the first gauge. Thermal spread was determined by measuring the width of the blanched tissue at the seal by digital calipers.

Results

Table 1 presents the seal burst strengths and thermal spread measurements on vessels harvested on the two animals using the Starion Instruments™ TLS[3] instrument.

Table 1 – Vessel Harvesting Results.

Diameter (mm)	n	Average Thermal Spread (mm)	Burst Pressure Low (mmHg)	Burst Pressure High (mmHg)	Burst Pressure Avg (mmHg)
Arteries					
1.0-3.0	3	1.5	776	1241	1052
3.1-5.0	8	1.4	517	1448	950
5.1-7.0	17	1.7	569	1551	903
7.1-9.0	21	1.7	827	1551	1305
9.1-10.0	3	1.7	1138	1551	1414
All	52	1.6	517	1551	1125
Veins					
1.0-3.0 *	9	1.6	517	776	684
1.0-3.0	6	1.4	517	1138	879
3.1-5.0 *	15	1.4	259	776	631
3.1-5.0	21	1.6	414	1551	855
5.1-7.0	4	1.5	827	1138	983
7.1-9.0	2	1.3	569	1034	802
9.1-10.0	8	1.9	517	1551	1267
All	65	1.5	259	1551	657*/957

* Pressure maximum reading limited by gauge to 776 mmHg. All other samples limited to 1551 mmHg

One arterial sample (2mm) and three venous samples (3, 5, 8 mm) were not included in the tabulated results because the needle positioned in the harvested vessels was placed too distally and pierced through the sample.

Discussion

Seal burst pressures varied from 259 to 1551 mmHg in testing. The average arterial vessel burst pressure for 52 samples ranging from 1-10 mm in diameter was 1125 mmHg.

The Starion Instruments™ TLS[3] was able to cut and seal a variety of vessels and tissue including the porcine uterine body, demonstrating its effectiveness as a versatile seal and divide instrument.