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Carissa M. Krane
University of Dayton, ckrane1@udayton.edu

Margaret Pinnell
University of Dayton, mpinnell1@udayton.edu

Courtney Gardner
University of Dayton

Mercedes Thompson
University of Dayton

James Coleman
University of Dayton, jcoleman1@udayton.edu

See last page for additional authors

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Author(s)
Carissa M. Krane, Margaret Pinnell, Courtney Gardner, Mercedes Thompson, James Coleman, and Robert Wilkens

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Carissa Krane,[1] *Margaret Pinnell,*[2] *Courtney Gardner,*[3] *Mercedes Thompson,*[1] *James Coleman,*[4] *and Robert Wilkens*[3]

Mechanical Test Methods for Assessing Porcine Carotid and Uterine Artery Burst Pressure Following Ex Vivo Ultrasonic Ligature Seal and Transection

ABSTRACT: A test method was developed to identify those variables important for assessing the performance of ultrasonic surgical devices in ex vivo ligature sealing of porcine carotid and uterine arteries. Ruggedness testing using a small sample size in pilot experiments was conducted using a newly developed test method in an effort to assess the usefulness of this methodology and to identify test variables that might warrant further testing. The development of this test method included the use of a custom-designed prototypic tension device for load-controlled ex vivo vessel stretching during saline perfusion and subsequent seal and transection of porcine arteries with an advanced energy surgical device. The quality of the seal was evaluated as a burst pressure (mmHg). The experimental set-up allowed for either monitoring or controlling specific test conditions, including blood vessel tension during cutting and sealing, saline infusion rate, cutting time, pressure generated in the vessel during cutting, and burst pressure. Both muscular-type uterine and elastic-type carotid arteries were investigated, since energy based devices are most frequently used on muscular-type arteries but are developed and tested using elastic-type arteries. Although confounded with the age of the animal, in the ruggedness test pilot, it was observed that porcine carotid arteries yielded a comparatively lower burst strength seal as compared to porcine uterine arteries. The data generated during ruggedness testing suggests that the artery type and saline infusion rate during transection may be important variables in ex vivo vessel seal testing.

KEYWORDS: ex vivo porcine blood vessel testing, surgical device testing, burst pressure, ultrasonic scalpel

Introduction

Various surgical devices, including ultrasonic technologies, have been developed to provide an alternative to the traditional scalpel and sutures used for cutting and sealing vessels during a surgical procedure [1–14]. The ultrasonic techniques achieve blood vessel transection using a sharp blade that vibrates at ~55 kHz. Friction associated with the rapid movement of the blade against the tissue causes the temperature of the blade to heat to ~100°C, which promotes the local denaturation of blood vessel proteins with little to no collateral thermal damage to the surrounding tissue. The biochemical changes that are believed to be responsible for sealing the vessel require protein denaturation, which occurs at 60–80°C. This breaks the hydrogen bonds that exist between the collagen and the extra-cellular matrix. The denatured proteins produce a coagulum that, when combined with the vessel coaptation, forms a strong seal in the vessel [1,4,6,12,13].

The development, refinement, and assessment of advanced energy surgical devices involve both in vivo and ex vivo vessel seal testing. Ex vivo device performance testing is required during the initial development of advanced energy surgical tools. Ex vivo device assessment must be performed prior to any in vivo experimentation in model animal systems in order to demonstrate an adequate likelihood of surgical device success within the animal. In general, ex vivo testing allows for a greater number of replicates, since the test samples are vessels harvested from slaughter house animals. Also, the test session does not require preoperative or post operative care of the animal, surgical preparation, or the facilities for surgery. Furthermore, ex vivo testing offers the potential for a more repeatable test environment, where experimental variables can be controlled or directly measured.

Ex vivo burst pressure tests constitute one measure that is routinely used to assess the integrity of seals generated either in vivo or ex vivo [2,5,10,11]. Pressurization of the blood vessel during testing is achieved by saline infusion (0.9 % NaCl). Where documented, a syringe pump or manual syringe are typically used to perform burst pressure testing [2,5,9–14]. The data generated from burst pressure tests is represented as pressure in mmHg as a function of time. The burst pressure is defined as the pressure where saline is observed to leak from the seal and/or a rapid drop in pressure is noted in the pressure versus time curve [2,10]. Most published blood vessel burst pressure tests are pass/fail type tests, where a seal is considered to pass if it is able to withstand a certain amount of pressure (~300 mm Hg) [11]. A vessel "specimen" is considered defective if the vessel cannot be pressurized due to saline leakage from the vessel, vessel wall, or vessel branch, from the tubing connection site, or from an incomplete vessel seal [2]. During ex vivo testing, the vessel length and the outer or flattened diameter are measured using a surgical ruler or digital callipers. Although not consistently categorized, vessels are considered "small" if their outer diameter (o.d.)is 1–3 mm, "medium" if their o.d. is

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[1]Dept. of Biology, Univ. of Dayton, 300 College Park, Dayton, OH 45469.
[2]Dept. of Mechanical and Aerospace Engineering, Univ. of Dayton, 300 College Park, Dayton, OH 45469.
[3]Dept. of Chemical and Materials Engineering, Univ. of Dayton, 300 College Park, Dayton, OH 45469.
[4]Univ. of Dayton Research Institute, Univ. of Dayton, 300 College Park, Dayton, OH 45469.

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TABLE 1—*Test matrix used for ruggedness testing of newly developed test method.*

Animal	Test Type	Blood Vessel	Sample	Condition
Slaughterhouse pig	Mechanical burst strength	Carotid	Infused effused	0.9 % NaCl
		Uterine	Infused	0.9 % NaCl

3–5 mm, and "large" if their o.d. is greater than 5 mm [2,5,8].

A search of the ASTM test standards revealed that the method determined to be most relevant to the testing done to assess the efficacy of energy based surgical devices is the ASTM F 2392-04el: Standard Test Method for Burst Strength of Surgical Sealants. This standard is specific to assessing the performance of surgical adherents and adhesives to soft tissue; however, it is not highly transferrable to assessing surgical devices [15]. Several methods for evaluating the efficacy of laser and ultrasonic based vessel sealing devices are reported in the literature, including the clinical evaluation of seal success and surgical outcome and ex vivo burst pressure testing. However, no common or consistent protocols or methods of evaluation appear to exist, which makes it difficult to compare the outcomes of different studies [5,8,10,14].

Many of the studies reported using porcine carotid arteries (elastic-type artery) for ex vivo assessment of energy based surgical devices [5,8,10,14]. However, energy based surgical devices are typically used to cut and seal muscular arteries. Since muscular and elastic arteries differ in composition and structure, generating information on a surgical device using elastic-type arteries such as the carotid arteries may not provide information that is representative of how a surgical device will perform on a muscular artery, particularly since collagen is believed to play a significant role in the formation of the seal with these devices [1,4,6,12,13]. As such, consideration should be made with regards to the vessel type when performing ex vivo tests.

None of the published reports provide information about the method used to "hold" the vessel during the cutting process and the amount of tension or strain applied to the vessel during ex vivo vessel transection, yet McCarus reported that tissue tension can greatly affect the quality of the seal formed [5,8,10,14,16]. In addition, the inherent variability in the characteristics of the blood vessels obtained from animals of different age, size, sex, and source (slaughter house versus research animal) can be difficult to identify, control, and quantify, especially if such parameters are not available or documented. As a result, the data generated from ex vivo test programs has high variability, and therefore, the test programs require a large number of replicates in order to generate data that is statistically significant ($6 < n < 116$) [2,4,8,12,13].

Because there is no standardized test method or accepted practice for assessing advanced energy surgical devices, inconsistencies may exist in the way the cutting/sealing and testing is done both within a particular organization and among the various organizations. This makes comparing data longitudinally or among devices difficult if not impossible. Thus, a well-defined, documented, controlled, and repeatable test method has the potential to provide a more meaningful comparison of blood vessel seal data generated from various sources and may assist with further development and improvement of advanced energy sealing devices. The primary objective of this investigation was to develop and document a method for testing and analyzing the ex vivo performance of advanced energy surgical devices that is more physiologically relevant than the methods described in the literature and might serve as the basis for developing a test standard.

Experimental Techniques

The procedures described in this paper were designed to assess the capabilities of an ultrasonic surgical device (Harmonic ACE® Curved Shears, product code ACE 14S model with scissor handle and hand control, 14 cm long, 15 mm active blade, 5 mm diameter; and Harmonic® Generator 300). The test matrix used in this pilot investigation is provided in Table 1. This sample size ($5 > n > 12$) was notably insufficient to generate statistically significant data, but was adequate as a form of ruggedness testing in identifying key parameters that warrant further testing.

Preparation of Porcine Carotid and Uterine Arteries

Porcine uterine and carotid arteries were obtained from Animal Technologies, Inc., (Tyler, TX). Arteries were harvested by laboratory technicians at Animal Technologies, and were shipped on wet ice overnight. Once received, the arteries were refrigerated and stored on wet ice for preparation and testing within 24 h of harvest. Carotid arteries were obtained from 6–9 month old pigs. The uterine arteries were obtained from the largest and oldest multiparous pigs available (female pigs >113 kg, 2+years, average age 4–6 years). Although it was desirable to eliminate age as a variable by harvesting carotid and uterine arteries from pigs of the same age, this was not possible, since the uterine arteries from the 6–9 month old pigs were too small to test, while the carotid arteries of the older pigs were too large to test.

The preparation of the arteries included visual inspection for adipose and other extra-vascular tissue, vascular branches, blood clots, and overall vessel quality. The arteries were trimmed using small surgical scissors. The inner diameter (i.d.) and o.d. of each end of the blood vessel and the prepared length were measured using a surgical ruler. Male Luer locks were inserted and secured via suturing with silk sutures to both ends of each carotid artery. Extensive preparation was required to remove the extra-vascular adipose and connective tissue from the uterine artery, and to separate the uterine artery from the uterine vein. The i.d. and o.d. were measured at both ends, and the prepared length was also measured. A male Luer lock was inserted at only one end of each uterine artery, since the smallest end of the uterine artery was too small to accommodate a Luer lock (Fig. 1). A knotted suture replaced the Luer lock at the smaller end and was used to connect the uterine

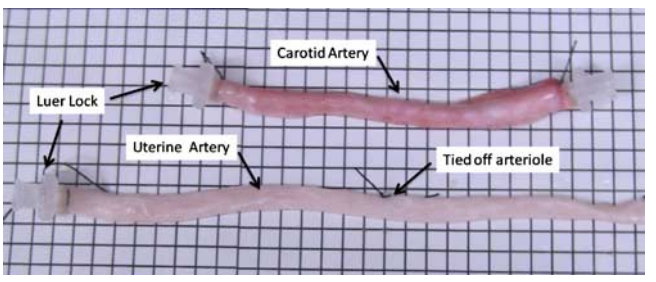

FIG. 1—*Porcine artery preparation.*

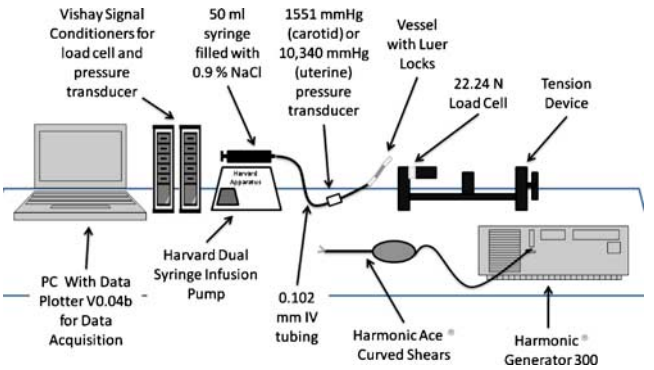

FIG. 2—*Ligature seal and burst strength test set-up.*

artery to the tension device in a manner that did not restrict the flow of saline through the vessel during the cutting/sealing process. It was noted that segments of the uterine arteries longer than ~0.5 cm were interrupted by extensive arteriolar branching. Thus, each 3–4 cm segment of testable uterine artery typically required several sutures to tie off vascular branches. Normal saline (0.9 % NaCl) from a saline bag suspended from an intravenous (IV) pole was infused into the vessel through a 0.102 mm IV tubing by gravitational force to check for vascular branches and for leakage at the Luer locks. The prepared vessels were then placed in a labelled, capped 15 mL conical tube and stored on wet ice until tested.

Experimental Set-Up

The test set-up used for cutting and sealing the porcine uterine and carotid arteries and subsequently subjecting them to a vessel burst pressure test is shown in Fig. 2. An HA2001 PHD2000 Harvard Apparatus dual syringe infusion pump was used to instil a constant flow of 0.9 % saline through the blood vessel during vessel transection. Initially, it was desired to have the flow rates during cutting and sealing mimic physiological blood flow rates in adult porcine carotid arteries (~200–225 mL/min). However, practical limitations precluded this from being done. Among these practical limitations were: (1) It was not possible to deliver a constant flow of saline at a rate ~200–225 mL/min for the total time required to stretch, cut, and seal the vessel using the Harvard infusion pump and (2) successful seals could not be achieved at the higher flow rates given the small (~3–6 cm) length of the vessel and the inability of the vessel walls to absorb the pressure build up that occurred at the site of occlusion. The flow rate in this ex vivo perfusion system affected the amount of saline that was infused into the vessel during the cutting and sealing process, since, unlike in vivo conditions, no alternative routes existed to divert the flow away from the occlusion. This, in turn, affected the amount of pressure that was built up in the infused side of the cut and sealed vessel. The unrelieved pressure build up in the small segment of the vessel, which was more compliant than the surrounding infusion tubing, likely affected the ability of the vessel to obtain a successful seal. As such, an investigation was done to determine the maximum flow rate that could be used while still achieving successful seals. The following flow rates were tested: Fluid filled via saline bags but no flow (0 mL/min), 1.25, 2.5, 5, and 10 mL/min. Data generated from this investigation is provided in the results section. From this study, a flow rate of 1.25 mL/min was chosen as the default flow rate, since it was the highest flow rate for which successful seals could be achieved. Use of the infusion pump resulted in pressurizing one

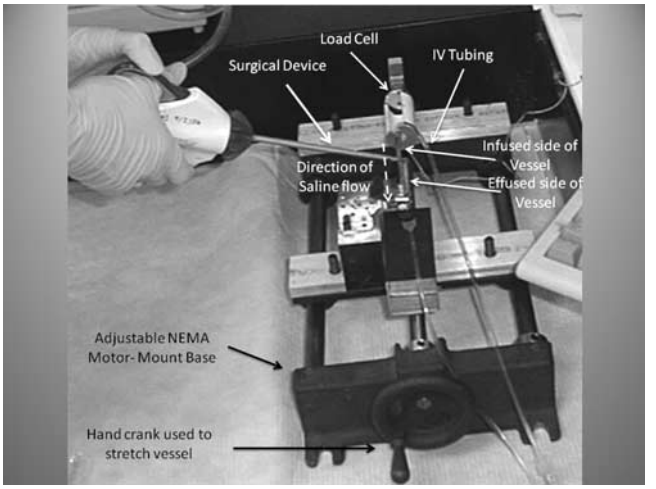

FIG. 3—*Prototypic vessel tension device.*

side of the blood vessel as it was infused with saline ("infused" side) and the other side of the vessel being depleted of saline during the cutting/sealing process ("effused" side). Since this pressure difference may affect the seal quality, the vessels were identified as infused and effused during testing (Fig. 3).

Prototypic Blood Vessel Tension Device

A prototypic tension device was designed and manufactured (Figs. 3 and 4). The base of the tension device was created by modifying an Adjustable NEMA Motor-Mount Base (Universal Sliding-Bars Base McMaster–Carr item number 653K12). The tension device was equipped with a 22.24 N (5 lbf) Honeywell Model 31 load cell that was attached to a vessel holder manufactured from PVC tubing and aluminium plate with a cut out that was used to secure the Luer lock on the infused side of the vessel (Fig. 4). A small hole ~13 mm in diameter was drilled in the bottom of the PVC tube vessel holder to accommodate the 0.102 mm IV tubing that delivered the saline to the vessels via the syringe pump or saline bag. This tubing was equipped with either a 1551 mmHg (30 psi) Measurement Specialties MSP-300-030-P-2-N-1 pressure transducer (used for carotid arteries) or a 10 340 mmHg (200 psi) Measurement Specialties MSP-200-030-P-2-N-1 pressure transducer (used for uterine arteries). This set-up was capable of stretching the vessel and measuring the resultant tensile load applied to the saline-infused vessel as it was stretched and cut, the amount of pressure that the infused side of the vessel was subjected to during the cutting process, and the time required to stretch and cut the vessel. A sample of the data generated from this device is provided in Fig. 5. The vessels were stretched to a corresponding tensile load of ~1 N (0.25 lbf) during the cutting and sealing. The vessel tension was chosen based on information obtained from the literature regarding in vivo vessel strain as well as experimental trials. In vivo vessel strain is ~40–60 %, which, through experimentation, was found to correspond to a tensile load of ~1 N (0.25 lbf) for unpressurized porcine carotid and uterine arteries [16].

Blood Vessel Sealing and Burst Testing

A test method for burst pressure testing the sealed arteries was developed using the existing ASTM F 2392-04el Standard Test Method for Burst Strength of Surgical Sealants as a guide [15]. The

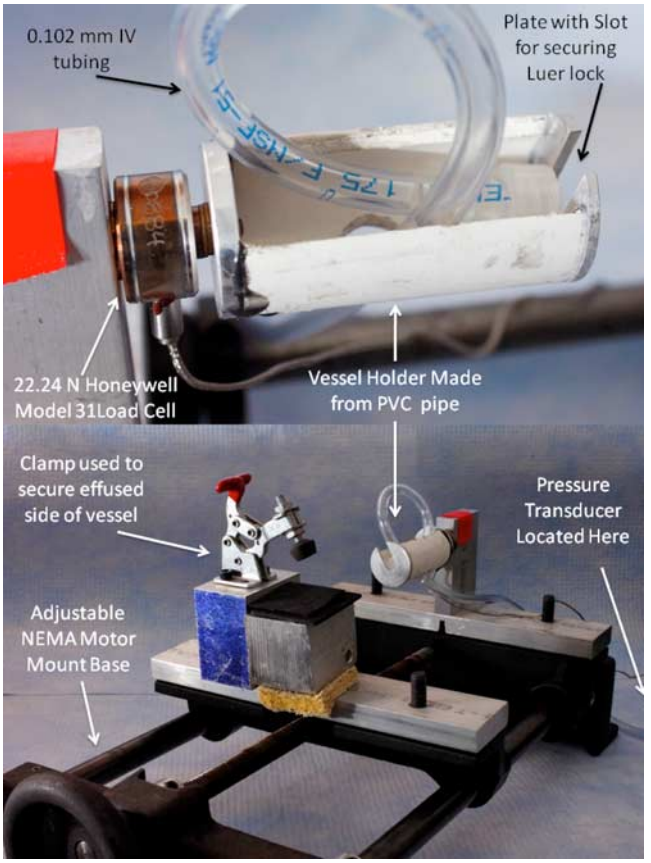

FIG. 4—*Close-up of vessel holder (top) and prototypic tension device (bottom).*

porcine carotid and uterine vessels were measured and prepared as described above. Tubing (0.102 mm IV tubing) was connected between the 0.9 % NaCl (normal saline) filled 50 mL syringe that was secured onto the Harvard Syringe Pump and the male Luer lock that had been inserted and secured via silk sutures onto the large diameter (infused) end of the vessel. The vessel was secured into the tension device using the specially designed holders (mating notch on infused side, clamp for Luer lock–carotid, or silk sutures–uterine on the effused side) in such a manner that the fluid flow through the vessel was not disrupted. Once inserted into the tension device, the vessel was marked with India ink to identify where the apex side of the surgical device was applied during cutting. The infusion pump was set to a flow rate of 1.25 mL/min and then turned on to allow saline to flow through the vessel. The vessel was then stretched by slowly turning the hand crank on the Adjustable NEMA Motor-Mount Base until a load of ~1.33 N (0.3 lbf) was read on the computer based data acquisition system. Because the vessel is viscoelastic, it would then relax to the desired load of ~1 N (0.25 lbf). The vessel was then cut and sealed using the Harmonic ACE® Curved Shears with the generator set to power level 3.

If the vessel leaked at the connection points or at the seal site during cutting, the vessel was discarded and not subjected to any additional testing. It is estimated that ~10 % of the vessels had to be discarded for this reason, but this number varied significantly depending on the experience of the person preparing the vessels. Immediately after a vessel was cut and sealed using the surgical device, the two halves of the vessel were removed from the tension device. The pressure was released from the infused side of the vessel by removing the Luer lock from the tubing. The infused and effused sides of the sealed arteries were subjected to individual ves-

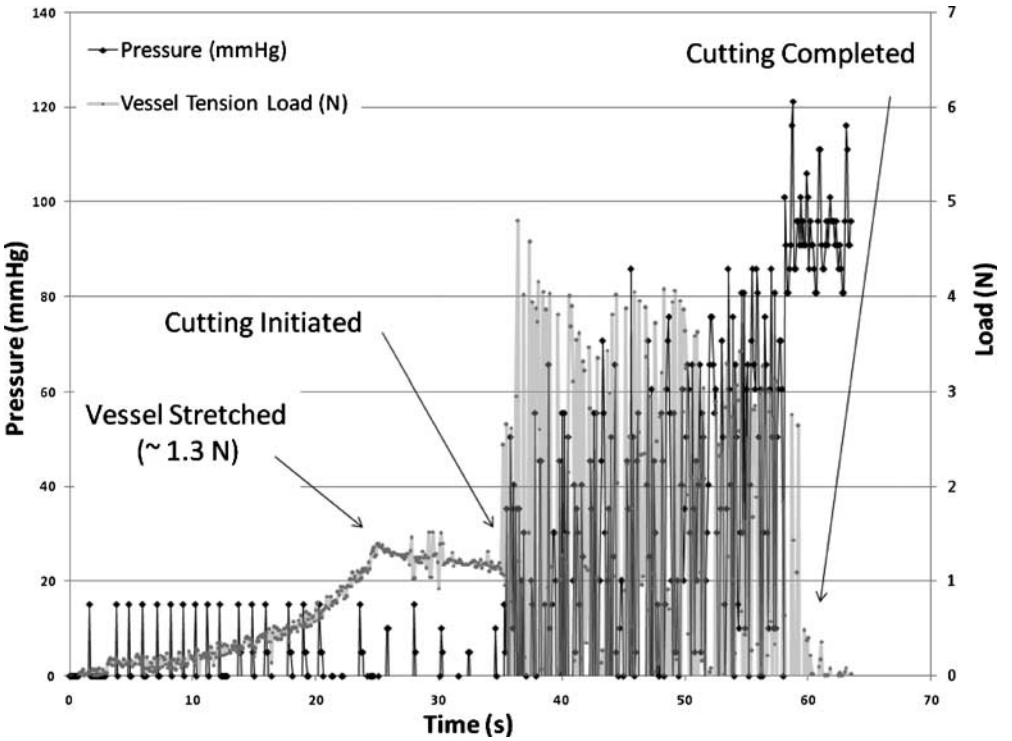

FIG. 5—*Sample plot generated during cutting and sealing.*

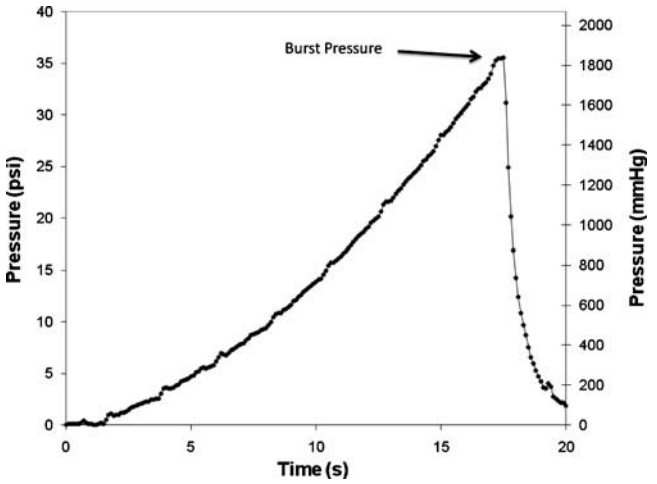

FIG. 6—*Sample plot generated during vessel burst testing.*

sel burst testing. The open end of the cut and sealed vessel was connected to the Harvard syringe pump with Luer locks and tubing. Either a 1551 mmHg (30 psi) Measurement Specialties pressure transducer (MSP-300-030-P-2-N-1) or a 10 340 mmHg (200 psi) Measurement Specialties MSP-300-200-P-2-N-1 pressure transducer was used to record the pressure in the vessel as it was infused with 0.9 % NaCl at 20 mL/min. Burst strength data was discarded if the vessel leaked at the connection points or through arterioles during testing, if the pressure versus time curve showed significant nonlinearity, or if the vessel leaked at the seal site without pressure build up (indicating an incomplete seal). A computer program was created using the Data Plotter V0.04b to provide real-time plots of the pressure versus time data and to store the data in an exportable text file that could later be analyzed, plotted, and stored. A sample of the data obtained from the vessel burst tests is provided in Fig. 6.

Results and Discussion

Ruggedness Testing

One of the main objectives of this investigation was to develop and document a repeatable method for preparing, cutting/sealing, and testing blood vessel seal strength for the assessment of advanced energy surgical devices. After the test methods were established, ruggedness testing was conducted in an effort to identify test variables that warrant further investigation. The data generated from the ruggedness tests are summarized in Table 2. In comparing this data, it is important to note that the i.d. and o.d. of both the smaller and larger ends of the prepared carotid arteries obtained were ~2 times that of the uterine arteries.

The comparison between mean carotid burst pressures at different infusion rates is presented in Table 2 and represented graphically in Fig. 7. With the exception of the 1.25 mL/min flow infusion rate during cutting, the range of burst pressure data generated for the infused and effused carotid arteries were found to be similar, suggesting that the quality of seal is not dependent on the location of the cut relative to the direction of the fluid flow. Despite using a test methodology where many of the variables, such as vessel tension and infusion fluid flow rate, were better controlled, variations in carotid burst strength pressures were observed within each infusion rate group (Table 2). Moreover, carotid arteries that were infused with saline at a rate of 10 mL/min during cutting failed to achieve successful seals for eight out of the ten trials. After experimenting with various flow rates ranging from fluid filled but no flow to 10 mL/min, a flow rate of 1.25 mL/min was chosen, since successful seals could not consistently be achieved in both the uterine and carotid arteries at higher flow rates.

A comparison of average carotid artery (infused and effused) and uterine artery burst strengths (sealed at a 1.25 mL/min infusion rate) revealed that on average, uterine artery burst pressures were consistently higher than carotid artery burst pressures (Table 2, Fig.

TABLE 2—*Summary of averaged data generated during trial and ruggedness testing.*

						Cutting				Burst Testing	
Vessel	Small i.d. (mm)	Small o.d. (mm)	Large i.d. (mm)	Large o.d. (mm)	Prepared Length (cm)	Infusion Rate (mL/min)	Vessel Tension (g force)	Maximum Pressure (mmHg)	Duration of Cut (s)	Infused Burst Pressure (mmHg)	Effused burst Pressure (mmHg)
Carotid (n=8)											
Ave	3.0	4.3	4.6	6.4	5.6	Saline bag (0)	1.98		17.3	951	878
St. Dev	*1.2*	*1.2*	*1.1*	*1.7*	*1.0*		1.5×10^{-01}		3.9	618	505
Carotid (n=12)											
Ave	2.8	4.3	5.1	6.6	5.7	1.25	1.94	145	17.7	527	1428
St. Dev	*0.5*	*0.6*	*1.1*	*1.1*	*1.1*		1.4×10^{-01}	*56*	*6.2*	*381*	*891*
Carotid (n=18)											
Ave	2.1	4.0	4.9	7.0	6.5	2.5	1.60	203	19.9	913	880
St. Dev	*0.5*	*0.7*	*0.6*	*0.9*	*1.0*		1.0×10^{-01}	*141*	*10.3*	*507*	*420*
Carotid (n=10)											
Ave	2.5	4.3	5.1	7.3	6.0	5.0	1.69	228	24.3	738	1115
St. Dev	*0.7*	*0.4*	*0.7*	*0.6*	*0.5*		8.9×10^{-02}	*54*	*34.7*	*528*	*540*
Carotid (n=2)											
Ave	2.0	4.5	5.5	7.5	5.8	10.0	1.58	564	19.9	435	993
St. Dev		*0.7*	*0.7*	*0.7*	*0.1*		7.9×10^{-02}	*474*	*4.2*		
Uterine (n=14)											
Ave	1.4	2.2	2.3	3.1	4.2	1.25	1.47	273	16.1	2899	
St. Dev	*0.7*	*0.7*	*0.7*	*0.7*	*1.2*		1.6×10^{-01}	*76*	*4.9*	*1077*	

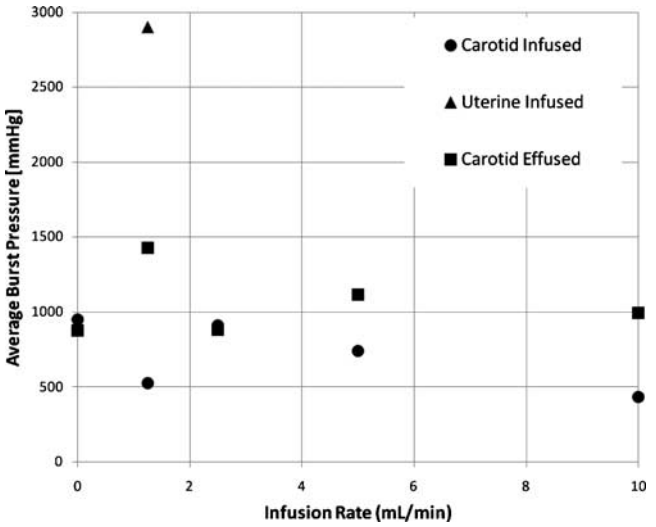

FIG. 7—*Effect of saline infusion rate during sealing on burst pressure.*

8). The horizontal line on Fig. 8 indicates the pass/fail criteria (300 mmHg) used by other researchers for the assessment of similar surgical devices [11]. The value above or within each bar graph shows the final number of successful replicates, *n*, that were used to generate the averaged value. Uterine artery burst pressure averaged 2899±1077 mmHg, which is ~5 times the mean carotid infused burst pressure (724±344 mmHg) and ~2 times the mean carotid effused burst pressure (1604±945 mmHg).

Compositional and Inter-Individual Differences in Arteries as a Potential Variable

Porcine carotid arteries (elastic-type artery) are often used in the assessment of surgical scalpel performance on blood vessel transection and sealing. In this study, uterine arteries, a muscular type of artery, were also included, since the Harmonic ACE® scalpel is typically used to cut and seal muscular arteries. Since muscular and elastic arteries differ in composition and structure, generating information on a surgical device using elastic-type arteries such as the carotid arteries may not provide information that is representative of how a surgical device will perform on a muscular

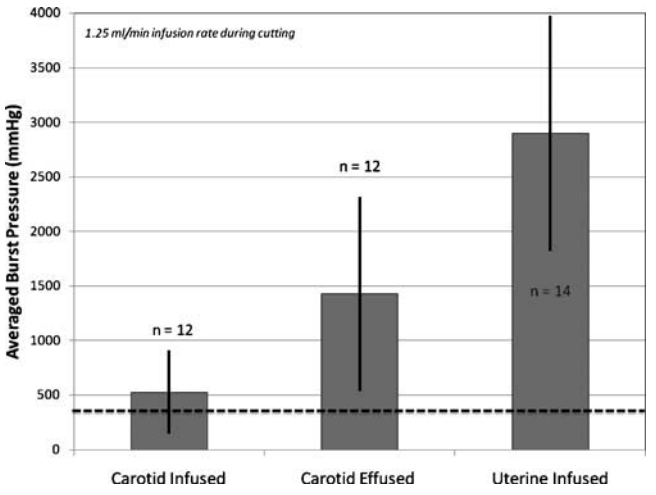

FIG. 8—*Averaged carotid and uterine artery burst pressures.*

artery. In order to eliminate the age of the animal as a variable, it was desired to obtain carotid and uterine vessels from pigs of the same age range. However, the uterine arteries obtained from the adolescent pigs were too small to prepare and test, while the carotid arteries obtained from the older pigs (2+years) were too large (>5 mm) to prepare and test. Therefore, the uterine arteries were obtained from older sows while the carotid arteries were obtained from 6–9 month old pigs. The uterine arteries contained numerous vascular branching and a great deal of connective tissue (broad ligament) and fat, which made them very difficult to work with. Although removing the extra-vascular connective and adipose tissue and dissecting the uterine vein away from the uterine artery was very time consuming, the benefit of testing uterine arteries freed from extra-vascular connective tissue and the uterine vein allowed for a direct assessment of the contribution of the arterial wall and architectural properties to seal formation. As can be seen from Figs. 7 and 8, the small uterine vessels failed at very high vessel pressures. This result suggests that vessel type, diameter, age of animal of origin, and structural changes that occur in the vessel wall architecture as a result of multiple pregnancies may be factors that affect the seal quality.

Control of Infusion Flow Rate during Transection and Sealing

Although not widely reported, the literature suggests that a common method used for saline infusion during cutting and sealing is gravitational flow from a hanging saline bag [2,10,11]. The flow rate of saline into the blood vessels is not monitored and is dependent on the height of the saline bag in relation to the blood vessel. In an effort to control this variable, the test set-up was developed such that the saline solution could be pumped at a constant flow rate through the vessels during the cutting and sealing procedure. The new test set-up provided a means for controlling the rate of infusion solution, so that it could be eliminated as a variable in testing or monitored to assess the effect of this variable on the ability of a surgical device to obtain a successful seal. During trial testing, the arteries were cut and sealed while filled with saline (0 mL/min) and infusing saline at various constant flow rates ranging from 1.25 mL/min to 10 mL/min. Although not statistically significant, the graph provided in Fig. 7 suggests a general trend of decreasing vessel burst pressure with increasing saline infusion rate during the cutting and sealing process. It is possible that at higher flow rates the pressure built up in the vessel during cutting approaches or even exceeds that of the pressure imposed during burst testing. Ultimately, it would be desirable to incorporate physiological flow rates as well as pulsatile flow relevant to the major arteries into the test set-up. In order to accomplish this, a compliance chamber could be included in the design to establish an upper limit of pressure build up in the occluded artery. Once the pressure in the occluded artery reaches the defined limit, the pressure would be maintained while additional flow, and therefore additional pressure, would be diverted. For testing smaller muscular arteries as well as veins, constant flow is appropriate, since the pulse wave dampens as blood moves through the cardiovascular system. The results generated in this study suggest that the amount of pressure built up and the rate of pressure build up may contribute to the quality of the seal generated on perfused arterial segments ex vivo. Therefore, the potential effects of saline infusion rate, velocity, and pressure build up during cutting and sealing on ex vivo seal quality warrants further examination.

Device to Control Tension during Blood Vessel Transection and Sealing

During trial vessel cutting sessions, the amount of axial strain (tension) applied to the vessel during the cutting and sealing procedure appeared to have an effect on the quality of the seal. McCarus explained that the quality of the vessel seal obtained from an ultrasonic surgical device is inversely proportional to the vessel tension [17]. Since the tension applied to the vessel can greatly affect the vessel's ability to be cut and sealed, inconsistencies in the amount of tension applied to the vessel during ex vivo cutting/sealing and testing could serve as a significant source of variability in the data. The tension device developed for this effort helped to eliminate vessel tension as a variable by facilitating consistent tensioning of the vessel (Fig. 3). As discussed above, the ~1 N vessel tension was chosen to correspond to the 40–60 % physiological strain noted through experimentation and information provided in the literature [16]. Although each vessel was initially tensioned to 1.33 N, the average tension measured during testing was 5–25 % (1.15–1.35 N) lower than the initial load (Fig. 5). This is likely due to viscoelastic properties of the arteries that result in relaxation following tension [16,18]. Although this parameter was not studied through ruggedness testing, the observations made in the trial testing as well as information presented in the literature warrant a more in depth study on the effect of vessel tension on the quality of the seal as measured through vessel burst strength testing.

Comparison with Published Studies

On average, the carotid arteries tested in this study ranged from 4 to 7 mm o.d., placing them in the "medium-large artery" categories, whereas the uterine arteries tested typically were 2–3 mm o.d., placing them within the "small artery" category [2,5,8]. The average carotid artery burst pressure for the 4–7 mm carotid arteries tested in this study was in the supraphysiological pressure range (307–1604 mmHg) (Table 2, Fig. 8). These average burst pressures are comparable to the burst pressures achieved by Clements et al. following in vivo sealing of 4–5 mm arteries using ultrasonic devices (SonoSurg, 900±574 mmHg; Harmonic ACE®, 896±481 mmHg) [12]. Moreover, the overall variation in burst pressures observed in this study is comparable to that seen in the Clements study, indicating that the ex vivo methodology developed here, which involves vessel preparation, perfusion, and vessel tension during sealing, closely mimics what occurs under physiological conditions in vivo [12]. Harold et al. reported mean burst pressures of 226 mmHg for 2–3 mm vessels, 205 mmHg for 4–5 mm vessels, and 175 mmHg for 6–7 mm vessels harvested from porcine head and neck, and sealed ex vivo using Ultrasonic Coagulation Shears [8]. In each instance, these mean values are below the accepted 300 mmHg threshold [11]. However, it appears that the vessels sealed in the study published by Harold et al. were not perfused during sealing, nor were they placed under tension during sealing [8]. Thus, in the absence of consistent methodologies which closely mimic in vivo conditions, it is difficult to directly compare published data.

A comparative analysis of uterine artery burst pressure results presented here with other studies is not possible due to the lack of available data sets performed on uterine arteries. However, if only vessel size is taken into account, Phillips and colleagues reported a burst pressure of 439.5 mmHg for abdominal arteries (0–3 mm o.d.) sealed ex vivo using the Harmonic ACE®, whereas Person et al. reported failure at 678±184 mmHg for visceral/peripheral arteries of approximately the same size (2–4 mm o.d.) [13,14]. It is not possible to correlate data generated from this study with that generated by Person et al. or Phillips et al., since the type of artery used in these studies is different from what was used in this study. Moreover, the uterine arteries harvested for this study were obtained from multiparous pigs (>113 kg), whereas the studies by Person et al. and Phillips et al. used 30–45 kg young pigs [13,14]. It is well-documented that arterial wall characteristics, mechanical properties, and physiology change with age [16,17]. Thus, as discussed above, the absence of consistent testing methodologies confounds a comparative interpretation of results.

Conclusions

The objectives of this investigation were to develop a method for performing ex vivo assessments of surgical devices used for cutting and sealing vessels and to conduct ruggedness testing using this method. A method was developed for qualitatively assessing the blood vessel appearance and for measuring the i.d, o.d., and length of the vessel via a surgical ruler. Additionally, a protocol was developed to provide for consistent blood vessel preparation. A prototypic instrumented vessel tension device was designed and built and a test method was developed that made use of this device. The prototypic blood vessel tension device allowed the blood vessel tension to be controlled and monitored during transection and sealing. A saline infusion pump was incorporated into the test set-up to allow for a controlled and constant saline infusion rate during vessel transection and sealing and subsequent vessel burst pressure tests. Trial testing was conducted and the maximum acceptable infusion rate of 0.9 % saline during ex vivo transection and sealing was determined to be 1.25 mL/min. Additionally, test protocols for burst pressure testing and data analysis were developed and documented. The resultant test methods developed through this work monitored and/or controlled the test conditions, including the vessel tension during transection, saline infusion rate, cutting time, pressure in the vessel during cutting, and burst pressure. Furthermore, muscular uterine arteries were studied as well as elastic carotid arteries since ex vivo tests are often conducted on elastic arteries but energy based surgical devices are most often used to cut and seal muscular arteries. The efficacy of the surgical device may be affected by compositional and structural differences between these artery types.

Data generated during trial testing suggests that seal quality is inversely proportional to the rate of saline infusion during the cutting and sealing process. However, more work needs to be done to verify this result and to further understand the effect that the fluid flow has on the effectiveness of a surgical device to cut and seal a vessel. Data generated from the ruggedness tests suggests that uterine arteries, although difficult to prepare and test, are capable of achieving seals which are much stronger than those obtained for the carotid vessels. Uterine arteries represent the type of blood vessels that most likely are cut and sealed using these devices. Therefore, muscular vessel types should be considered for ex vivo testing.

Full Disclosure

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