Performance of a Novel Temporary Arterial Shunt in a Military-Relevant Controlled Hemorrhage Swine Model

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Brief Title: Vascular Shunt Comparison

Abstract

Background: In military trauma, temporary vascular shunts (TVSs) restore arterial continuity until delayed vascular reconstruction, often for a period of hours. A novel US Air Force-developed trauma specific vascular injury shunt (TS-VIS) incorporates an accessible sideport for intervention or monitoring which may improve patency under adverse hemodynamic conditions. Our objective was to evaluate TS-VIS patency in the setting of volume-limited resuscitation from hemorrhagic shock.

Study Design: Female swine (70-90kg) underwent 30% hemorrhage and occlusion of the left external iliac artery (LEIA) for 30min. Animals were allocated to one of three groups (n=5/group) by LEIA treatment: Sundt shunt (SUNDT), TS-VIS with arterial pressure monitoring (TS-VIS), or TS-VIS with heparin infusion (10u/kg/h, TS-VISHep). Animals were resuscitated with up to 3 units whole blood to maintain a MAP >60mmHg and were monitored for 6 hours. Bilateral femoral arterial flow was continuously monitored with transonic flow probes, and shunt thrombosis was defined as the absence of flow for greater than 5 minutes.

Results: No intergroup differences in MAP or flow were observed at baseline or following hemorrhage. Animals were hypotensive at shunt placement (MAP 35.5±7.3 mmHg); resuscitation raised MAP to >60 mmHg by 26.5±15.5 min. Shunt placement required 4.5 ± 1.8 minutes with no difference between groups. Four SUNDT thrombosed (3 before 60 min). One SUNDT thrombosed at 240min, two TS-VIS and one TS-VISHep thrombosed between 230 and 282 min. Median patency was 21 min for SUNDT and 360 min for both TS-VIS groups (P=0.04). While patent, all shunts maintained flow between 60 and 90% of contralateral.

Conclusions: The TS-VIS demonstrated sustained patency superior to the Sundt under adverse hemodynamic conditions. No benefit was observed by the addition of localized heparin therapy over arterial pressure monitoring by the TS-VIS sideport.

Keywords: Vascular shunt, hemorrhage, patency, swine, vascular trauma, military trauma

Introduction

Vascular injuries to the extremities have accounted for a significant portion of battlefield morbidity in recent conflicts.(1, 2) These casualties often have multiple severe injuries, and vascular damage control is performed at field surgical units to establish distal perfusion as rapidly as possible in the face of limited surgical resources and multiple competing resuscitation and stabilization priorities. Delays in revascularization, especially when accompanied by hemorrhagic shock, are associated with increased risks of ischemic necrosis, reperfusion injury, and amputation.(3–6) In order to mitigate these risks in the austere and resource-constrained forward-deployed surgical setting, temporary vascular shunts (TVS) are frequently employed as a primary vascular damage control maneuver to establish temporary perfusion until the casualty can be transported to a level of care capable of definitive vascular reconstruction.

Amputation rates in extremities with vascular injuries from current conflicts are less than half of those seen in World War II, indicating a high number of salvageable extremities in the setting of modern combat casualty care.(7–12) Thrombosis is a known complication of TVS which has been reported to be associated with poor limb outcomes.(13–16) Shunt patency appears to depend on a variety of factors including timespan of shunt placement, injury location, and patient resuscitation status.(2, 15–17) Recent studies in civilian populations suggest that patients with a shunt in place for over six hours are at increased risk of shunt complications. That time may be shorter for military populations due to additional challenges faced in the far-forward setting including limited blood supplies for resuscitation.(14, 15, 18) These challenges illustrate the need for a shunt that is tolerant of limited resuscitation and longer dwell times which may be seen in military casualties undergoing evacuation.

Multiple commercially produced TVS are available, but none are designed specifically for use in vascular trauma applications. The ability to easily provide local anticoagulation and/or continuous monitoring of shunt patency would add significant value to a product for use in combat casualty care. The Trauma-Specific Vascular Injury Shunt (TS-VIS) is a novel United States Air Force-developed temporary vascular shunt that seeks to address these needs. The shunt has an integrated side port in its midportion which allows for continuous monitoring of shunt pressure and for the delivery of therapeutic agents to the limb**. Figure 1**

The aim of this first translational study using the TS-VIS was to evaluate the device against a commercially available TVS in a military-relevant swine model of hemorrhagic shock and extremity vascular injury with limited resuscitation and to assess the functionality of the side port for arterial blood pressure monitoring and medication delivery.

Methods

Overview

This study was approved by the Institutional Animal Care and Use Committee for the U.S. Air Force 59th Medical Wing Clinical Investigation and Research Support facility (Lackland Air Force Base, TX) and complied with the regulations and guidelines of the Animal Welfare Act, the National Institutes of Health Guide for the Care and Use of Laboratory Animals, and the American Association for Accreditation of Laboratory Animal Care. Animals were allocated to one of three groups (n=5/group) based on shunt treatment: commercially available Sundt shunt (SUNDT, 10 cm long, 3.1 mm proximal interior diameter, 2.1 mm distal interior diameter, Integra Lifesciences, Princeton, NJ), TS-VIS (30 cm long, 3.6 mm proximal and distal interior diameter) with arterial pressure monitoring via the side port (TS-VIS), or TS-VIS with heparin

infusion at 10u/kg/h through the side port (TS-VISHep). Experiments were carried out between March 2019 and February 2020. **Figure 2**.

Pre-operative Preparation

Fifteen female Yorkshire-landrace swine (70-90 kg) procured from a local USDA registered vendor were individually housed and allowed at least seven days to acclimate to the facility. Animal housing rooms were maintained at 67-72°F, 35-75% humidity and 10-15 air changes/hr. Enrichment was provided in the form of toys, chains, fruits and/or vegetables. Each animal had unrestricted access to fresh potable water and was provided twice a day a feed ration of Minipip Breeder diet, LabDiet 5082 (Brentwood, MO). Food was withheld the night before experimentation. On the day of the experiment, animals were sedated with an intramuscular injection of 4.4 mg/kg tiletamine-zolazepam and 2.2 mg/kg ketamine. Buprenorphine was also given by intramuscular injection at 0.01 mg/kg for pre-emptive analgesia. Anesthesia was initially induced using a nose cone with 2-4% isoflurane and adjusted to a minimum alveolar concentration of 1.2 or higher following intubation. Fraction of inspired oxygen (FiO_2) was set between 40 and 45% and maintained there for the remainder of the procedure. Animal temperature was kept between 37°C and 39°C using external warming.

Vascular access was achieved via cutdown and 8.5 Fr introducer sheaths were placed in the right carotid artery for blood pressure monitoring and blood sampling, and in the right external jugular vein for fluid administration. Flow probes (Transonic Systems Inc. Ithaca, NY) were placed around the surgically exposed bilateral femoral arteries. Near Infrared Spectroscopy (NIRS, Medtronic, Minneapolis, MN) sensors were placed over the medial thigh muscle of both legs to monitor regional tissue oxygenation. The following interventions were performed through a midline laparotomy: 1) splenectomy to prevent auto-transfusion, 2) ligation of the bilateral

internal and circumflex iliac arteries to prevent antegrade collateral flow during shunting 3) isolation and control of the left external iliac artery (LEIA) for injury simulation, blood removal (controlled hemorrhage), and shunt placement.

Injury, Therapeutic Administration, and Observation Phase

A 6 Fr introducer was inserted into the midportion of the LEIA and vessel loops secured around it to ensure arterial occlusion; confirmed by a minimal value from the left femoral flow probe. Blood was removed via this introducer at 100 mL/min to a total of 30% of the animal's estimated blood volume and stored in citrated (CPDA-1) blood donation bags. Removal was paused when the systemic mean arterial pressure (MAP) fell below 30 mmHg and resumed above 30 mmHg. Thirty minutes from the initiation of hemorrhage, the introducer was removed, and the LEIA opened longitudinally (incorporating the existing arteriotomy) over a 2 cm segment. The assigned shunt was inserted through distal end first, followed by the proximal end once backbleeding from the distal end was noted. **Figure 1** Initial shunt patency was confirmed with continuous-wave Doppler interrogation of the shunt and by an increase in left femoral flow. The TS-VIS shunt side ports were connected to a standard fluid column arterial pressure monitor and the TS-VISHep sideports to a pump infusing unfractionated heparin in normal saline at 10 u/kg/h at 50 mL/hr. Concurrently, resuscitation with shed blood at a rate of 25 mL/min was performed to maintain a MAP > 60 mmHg until up to 3 units (1,500 mL) was given.

Systemic blood pressure, blood flow in both femoral arteries, and leg muscle oxygenation were continuously monitored for six hours or until shunt thrombosis. Thrombosis was defined as absence of a positive flow value from the left femoral flow probe for five minutes and was confirmed using Doppler interrogation of the shunt. Euthanasia was performed with pentobarbital at 100 mg/kg in accordance with the 2020 AVMA Guidelines for the Euthanasia of

Animals. Arterial blood samples were taken at baseline and at 30, 90, 150, 210, 270, 330, and 390 minutes following hemorrhage.

Data and Statistical Analysis

The primary outcome of the study was shunt patency time. Sample size was estimated at five animals per group to provide 80 percent power to detect a 60% difference in shunt patency between groups with a significance level of 0.05. Overall shunt patency was compared by analyzing Kaplan-Meier curves using the log-rank test. Continuous variables were analyzed with one-way analysis of variance with Student-Neuman-Keuls post hoc testing. Data are presented as mean +/- standard deviation, except in graphs where data are mean +/- standard error of the mean. Excel 2016 (Microsoft, Redmond, WA) was used for data management, and statistical tests were performed with Sigmaplot 12 (Systat Software, Chicago, IL).

Results

Baseline Characteristics

Fifteen animals weighing 78.4 ± 6.3 kg were used; five animals per experimental group. The three groups were homogeneous at baseline in terms of central and limb hemodynamics, and thigh tissue oxygenation. **Table 1.**

Hemorrhage and Shunt Placement

Hemorrhage of 30.1% ± 0.7% of estimated blood volume resulted in significant hypotension with a MAP of 35.5 ± 7.3 mmHg across all groups at the time of shunt insertion, with no intergroup differences. Prior to shunt placement, occlusion of the LEIA resulted in left femoral flow values of 0.4 ± 1.2 mL/min versus 90.9 ± 25.9 mL/min in the right femoral artery, with no significant intergroup differences. A decrease in NIRS readings was also measured in

the left thigh muscle (26 ± 5.6%) across all groups when compared to the right thigh (55.6 ± 11.7%). Shunt placement required an average of 4.5 ± 1.8 minutes with no difference between groups. **Table 2.**

Resuscitation and Hemodynamics

Resuscitation required an average of 15.5 ± 3.8, 32.8 ± 20.0, and 28.6 ± 14.3 minutes to raise MAP to greater than 60 mmHg in the SUNDT, TS-VIS, and TS-VISHep groups respectively with no intergroup differences ($p = 0.315$). All three units of shed blood were infused in 1, 3, and 5 animals from the SUNDT, TS-VIS, and TS-VISHep groups respectively. The remaining animals either had shunts thrombose prior to the completion of infusion or did not require all three units to maintain MAP > 60 mmHg. **Figure 3.**

Shunt Patency

The TS-VIS and TS-VISHep groups outperformed the SUNDT group based on log-rank analysis of shunt patency ($p=0.04$). **Figure 4.** Two TS-VIS and one TS-VISHep thrombosed, all between 230 and 282 minutes. The remainder were patent for the entire six-hour observation period, with a median patency of 360 minutes for both TS-VIS groups. Only a single SUNDT maintained patency for six hours. Three thrombosed within 20 minutes of placement and one thrombosed at 241 minutes. Median patency for the SUNDT group was 21 minutes ($P=0.04$ versus TS-VIS and TS-VIS Hep).

A comparison of left (distal to the shunt) and right (native) femoral arterial flow values are presented in **Figure 5A**. Flow rates in the left were ~80-90% of the flow in the right leg. Similar results were observed when left and right leg muscle tissue oxygenation was compared. **Figure 5B.** Arterial pressure was monitored in the TS-VIS via a side port following successful insertion of the TS-VIS shunt in both the TS-VIS group and the TS-VISHep group. When

compared to the blood pressure monitored in the carotid artery, both groups had consistently lower pressure compared to the Carotid. **Figure 6.**

Discussion

Vascular injuries account for approximately 17% of all battlefield trauma.(1, 2) Vascular damage control is an integral component of the forward surgical care of these injuries, and shunting is frequently employed, especially for extremity injuries. Battlefield arterial shunts are often placed at forward surgical units prior to casualty transportation to more sophisticated field hospitals where definitive surgical vascular reconstruction can occur, and transport/shunt dwell times can reach or even exceed six hours.(14) With the known risk of shunt thrombosis and its association with poor limb outcomes,(13) we demonstrated the superior patency of a novel, trauma-specific arterial shunt in a military-relevant, long dwell time, arterial injury model.

Long shunt dwell times can be a risk factor for shunt thrombosis, though in the civilian literature, shunt dwell times are predominantly under six hours.(13, 15, 19) The novel TS-VIS with its uniquely designed side port has the potential to mitigate this risk of thrombosis through the localized administration of anticoagulant medication or by facilitating continuous invasive shunt pressure monitoring. The findings of this study reveal that the TS-VIS is effective at restoring distal blood flow in an injured extremity and that the device has a superior patency rate when compared to a conventional vascular shunt during whole blood resuscitation from significant hypotension following a vascular injury.

Both the Sundt and the TS-VIS were found to be effective at restoring distal blood flow in a swine model of hemorrhagic shock and extremity vascular injury. Similar placement times of the shunt show that there was no increase in difficulty in positioning the TS-VIS despite its

side port. However, there was a significant difference between the patency rate of the SUNDT group compared to the TS-VIS and TS-VISHep groups. The majority of SUNDT shunts thrombosed within the first 30 minutes of the protocol while both TS-VIS groups had median patency rates lasting until study termination. Gross analysis of the MAP and thrombosis curves suggest that maintenance of early shunt patency was dependent on perfusion pressure and flow through the shunt. The study design mimicked shunt placement in a state of severe shock with corresponding hypotension and ongoing whole blood resuscitation, which is the current standard in combat casualty care.(20) At the point the shunts were put in place, mean arterial pressures were around 35 mmHg, resulting in a low flow state through the shunt. This likely explains the high degree of early thrombosis seen in the SUNDT group, whereas the TS-VIS, both with and without heparin, was shown to be more tolerant of hypotension, maintaining patency until blood pressure was restored through resuscitation.

Both the Sundt and TS-VIS shunt devices are constructed of silicone elastomer with internal mural reinforcing stainless steel springs and both have similarly shaped bulbs at the proximal and distal ends to facilitate fixation within the vessel. With this similar construction, the differential in early patency can best be explained by the experimental conditions of side port treatment in the TS-VIS groups. There were no patency differences between the TS-VIS and TS-VISHep groups. In the TS-VISHep group, constant infusion of heparin likely both provided a pharmaceutical anticoagulant effect as well as an augmentation of flow within the shunt, maintaining patency during systemic hypotension and a local low-flow state. In the TS-VIS group, improved patency may be due to the constant luminal pressurization that the invasive arterial monitoring provides. Just as a small caliber radial arterial line can stay patent for extended periods of time, the pressure exerted by the pressure bag/arterial monitoring system

may provide enough luminal pressure within the shunt to maintain patency during periods of low flow. Further studies are warranted to assess if localized heparin infusion would result in improved patency when assessed over an extended observation period greater than 6 hours and in other physiologic conditions.

We found the functionality of the TS-VIS to be excellent and the device performed as expected in the model. The TS-VIS maintained distal arterial flow and tissue oxygenation similar to the SUNDT shunt and to the uninjured and unshunted contralateral limb. There were no difficulties in placing the novel shunt, as evidenced by the similarity in time to placement with the SUNDT animals. The luer-lock TS-VIS side port was effectively employed for administration of localized heparin therapy at a rate of 10 u/kg/hr using a standard intravenous infusion pump. Throughout the protocol no difficulties were noted in the ability to infuse heparin via the side port while the shunt was patent. Similarly, the invasive blood pressure monitoring was also successful using a standard fluid column pressure bag system. We have also demonstrated the feasibility of monitoring shunt pressure using the TS-VIS side port, with consistent readings obtained throughout the experiment.

While this study thoroughly assesses the TS-VIS shunt's characteristics and usability and provides a comparison to the SUNDT shunt in a military-relevant model, its translatability to clinical practice has limitations. We used adult female swine (70-90kg) to attempt to approach the weight, vessel size, and blood volume of an average military member, however swine anatomy and coagulability profiles present major disparities inherent in swine models. An attempt was made to overcome these differences by performing a splenectomy and ligating the internal and circumflex iliac arteries. to eliminate distal collateral flow and provide a rigorous test of patency. Ligation of these vessels decreased distal collateral circulation and provided

single vessel in-line flow to the femoral vessels, ensuring a rigorous test of patency. Additional limitations are that the study involves a controlled hemorrhage, there is no simulation of polytrauma, and there was no simulation of patient transport or movement to explore the potential for the complication of shunt dislodgment.

Conclusion

We have demonstrated the usability of the TS-VIS with heparin infusion and with shunt pressure monitoring in a military-relevant large animal hemorrhage model. The TS-VIS with and without heparin infusion demonstrated sustained patency superior to that of the Sundt shunt under adverse hemodynamic conditions. Early patency appears dependent on blood pressure and this model of volume-limited resuscitation provides a rigorous test for peripheral arterial shunts. No discernable benefit was observed by the addition of localized heparin therapy over constant arterial pressure monitoring by the TS-VIS side port within the first 6 hours of placement.

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Tables

Table 1.

Baseline Measurements

	SUNDT	TS-VIS	TS-VISHep	p-value
n	5	5	5	
Weight (kg)	78.6 ± 6.5	79.3 ± 7.1	77.2 ± 6.5	0.882
MAP (mmHg)	66.0 ± 4.8	72.8 9.9	67.0 ± 13.0	0.518
Left Leg Arterial Flow (mL/min)	169 ± 27	173.6 ± 54.7	184.8 ± 42.5	0.856
Right Leg Arterial Flow (mL/min)	190.8 ± 47.6	159.6 ± 37.2	181.4 ± 30.1	0.454
Left Leg NIRS	67.4 ± 12.8	56.2 ± 14.8	64.8 ± 4.1	0.311
Right Leg NIRS	70.8 ± 7.7	64.6 ± 9.7	64.2 ± 6.4	0.379

Table 2.

Post-Hemorrhage Measurements before Shunt Insertion (T=30)

	SUNDT	TS-VIS	TS-VISHep	p-value
Hemorrhage Volume (% EBV)	30.3 ± 0.0	30.4 ± 0.1	29.7 ± 1.3	0.372
MAP (mmHg)	38.4 ± 7.2	36.4 ± 5.8	31.6 ± 8.4	0.344
Left Leg Arterial Flow (mL/min)	1.2 ± 1.9	0.2 ± 0.4	-0.2 ± 0.4	0.122
Right Leg Arterial Flow (mL/min)	100.4 ± 24.2	95.6 ± 25.5	76.6 ± 26.7	0.329
Left Leg NIRS (%)	26.8 ± 7.3	24.2 ± 5.4	27.0 ± 5.5	0.730
Right Leg NIRS (%)	59.2 ± 14.2	49.2 ± 15.1	58.4 ± 2.8	0.377
Time to Place Shunt (min)	4.2 ± 1.3	4.8 ± 2.5	4.6 ± 1.9	0.888

Figures Legends

Figure 1. TS-VIS **A)** TS-VIS alone **B)** TS-VIS inserted into the left external iliac artery.

Figure 2. Experimental Schematic.

Figure 3. Blood Pressure and Blood Flow. A) MAP measured in carotid artery B) Left leg femoral artery flow C) Right leg femoral artery flow. Left leg is at a no flow state during hemorrhage (0-30 min) until shunt placement at T30. Data is shown only while shunt is patent. MAP, Mean Arterial Pressure; n.s., not significant.

Figure 4. Patency curve of different shunt groups. Patency is defined as positive flow value from the left femoral flow probe for five minutes.

Figure 5. A) Femoral artery flow ratio of the left (shunted) leg to the right (control) leg. B) Leg muscle tissue oxygenation (StO2) ratio of the left (shunted) leg to the right (control) leg. Outlier readings in the Sundt group between 250 and 285 minutes in both panels represent artifacts from equipment malfunction. n.s., not significant.

Figue 6. Carotid vs TS-VIS blood pressure. Data is shown as MAP measured in the side arm of the TS-VIS as a percentage of the carotid MAP. MAP, Mean Arterial Pressure; n.s., not significant.

Figure 1.

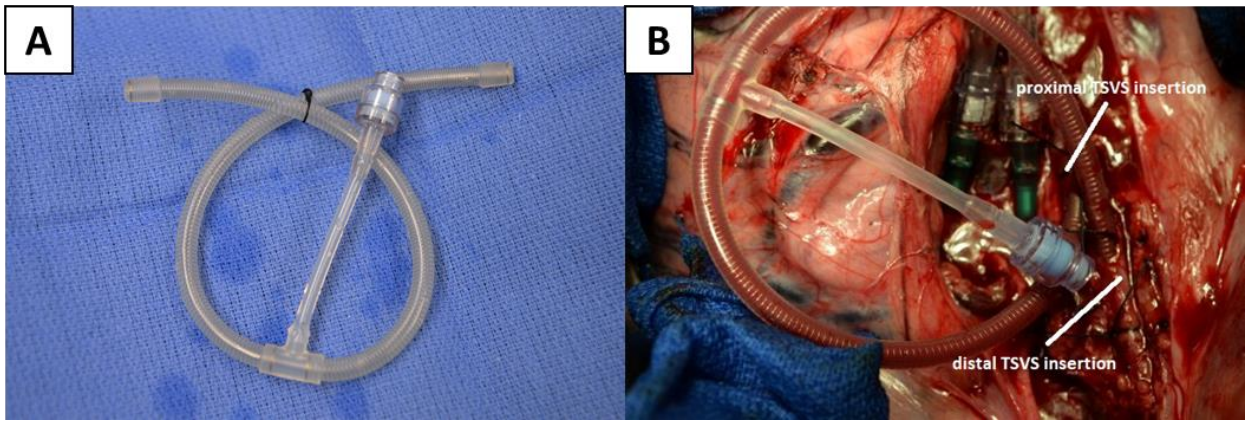


Figure 2.

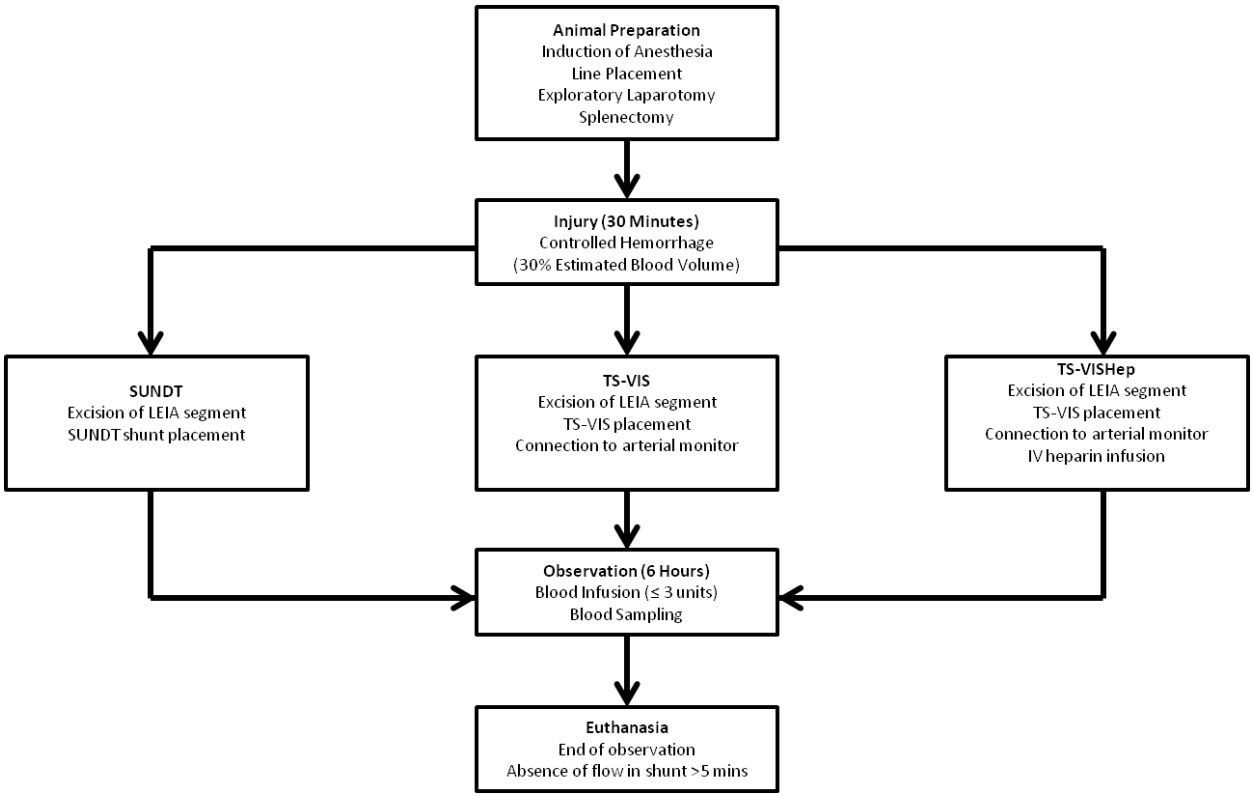

Animal Preparation
Induction of Anesthesia
Line Placement
Exploratory Laparotomy
Splenectomy
Injury (30 Minutes)
Controlled Hemorrhage
(30% Estimated Blood Volume)
SUNDT
Excision of LEIA segment
SUNDT shunt placement
TS-VIS
Excision of LEIA segment
TS-VIS placement
Connection to arterial monitor
TS-VISHep
Excision of LEIA segment
TS-VIS placement
Connection to arterial monitor
IV heparin infusion
Observation (6 Hours)
Blood Infusion (≤ 3 units)
Blood Sampling
Euthanasia
End of observation
Absence of flow in shunt >5 mins

Figure 3.

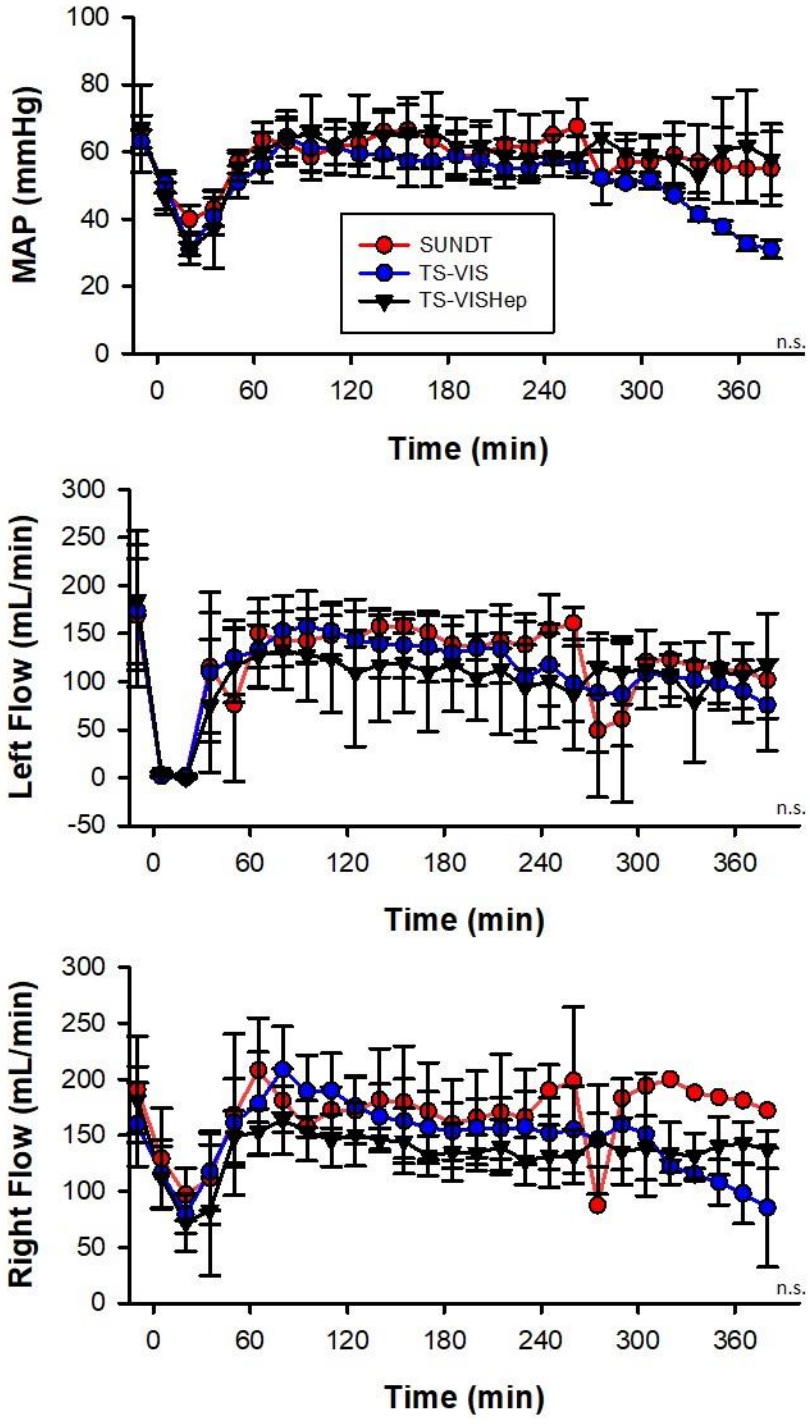

MAP (mmHg)
100
80
60
40
20
0
SUNDT
TS-VIS
TS-VISHep
n.s.
0
60
120
180
240
300
360
Time (min)
Left Flow (mL/min)
300
250
200
150
100
50
0
-50
n.s.
Time (min)
Right Flow (mL/min)
300
250
200
150
100
50
0
n.s.
Time (min)

Figure 4.

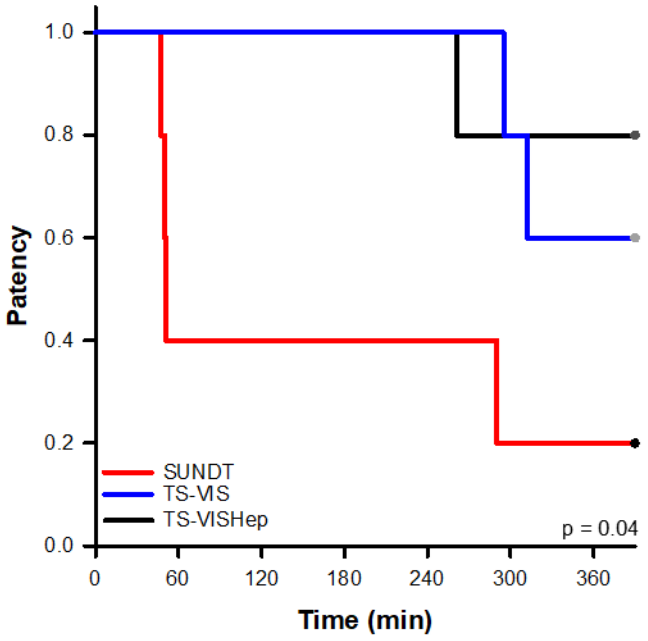
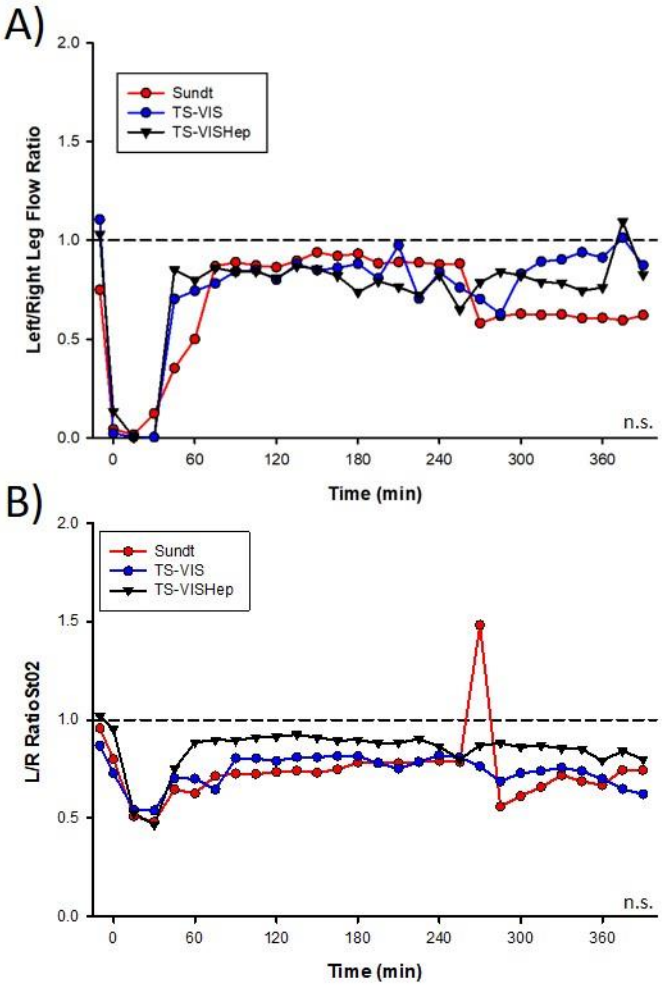
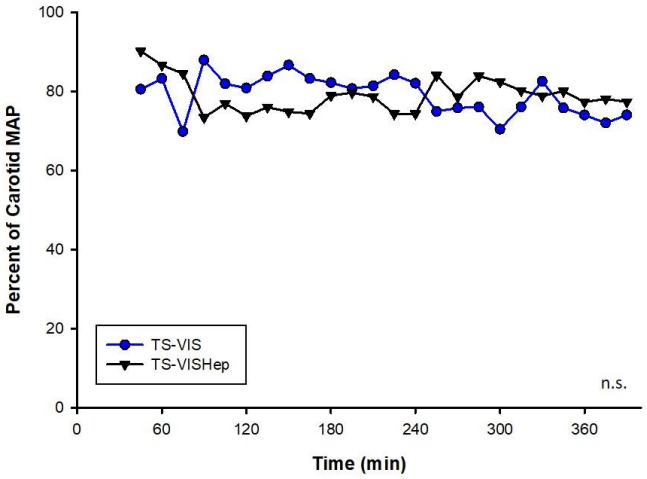

1.0
0.8
0.6
0.4
0.2
0.0
Patency
SUNDT
TS-VIS
TS-VISHep
p = 0.04
0
60
120
180
240
300
360
Time (min)

Figure 5.


A)
Sundt
TS-VIS
TS-VISHep
Left/Right Leg Flow Ratio
2.0
1.5
1.0
0.5
0.0
n.s.
0
60
120
180
240
300
360
Time (min)
B)
Sundt
TS-VIS
TS-VISHep
L/R RatioSt02
2.0
1.5
1.0
0.5
0.0
n.s.
0
60
120
180
240
300
360
Time (min)

Figue 6.


Percent of Carotid MAP
100
80
60
40
20
0
0
60
120
180
240
300
360
Time (min)
TS-VIS
TS-VISHep
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