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Damage control of caval injuries in a porcine model using a retrievable Rescue stent

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ABSTRACT

Objective: Early hemorrhage control before the operating room is essential to reduce the significant mortality associated with traumatic injuries of the vena cava. Conventional approaches present logistical challenges on the battlefield or in the trauma bay. A retrievable stent graft would allow rapid hemorrhage control in the preoperative setting when endovascular expertise is not immediately available and without committing a patient to the limitations of current permanent stents. This study details a refined retrievable Rescue stent for percutaneous delivery that was examined in a porcine survival model of penetrating caval hemorrhage.

Methods: A retrievable caval stent was reduced in delivery profile to a 9F sheath using finite element analysis. The final stent was constructed with a "petal and stem" design using nitinol wire followed by covering with polytetrafluoroethylene. Seven Yorkshire pigs (79-86 kg) underwent 22F injury of the infrarenal vena cava with intentional class II hemorrhage (1200 mL). Percutaneous deployment of the Rescue stent was used to temporize hemorrhage for 60 minutes, followed by resuscitation with cell saver blood and permanent caval repair. Hemorrhage control was documented with photography and angiography. Vital signs were recorded and laboratory values were measured out to 48 hours postoperatively. Data were examined with a repeated-measures analysis of variance.

Results: The profile of the caval Rescue stent was successfully reduced from 16F to 9F while remaining within fracture and shape memory limits for nitinol. In addition, both rapid deployment and recapture were preserved. Following intentional hemorrhage after caval injury, animals revealed a significant drop in mean arterial pressure (average, 30 mm Hg), acidosis, and elevated lactate level compared with before injury. Compared with uncontrolled hemorrhage, which resulted in death in <9 minutes, the Rescue stent achieved hemorrhage control in <1 minute after venous access in all seven animals. All animals were successfully recovered after permanent repair. There was no significant change in levels of transaminases, bilirubin, creatinine, or hemoglobin at 48 hours compared with preinjury baseline.

Conclusions: A retrievable Rescue stent achieved rapid percutaneous hemorrhage control after a significant traumatic injury of the vena cava and allowed successful recovery of all injured animals. Further development of this approach may have utility in preoperative damage control of caval injuries. (J Vasc Surg: Venous and Lym Dis 2018;6:646-56.)

Clinical Relevance: Noncompressible traumatic hemorrhage from injuries of the cava continues to have a high mortality, largely due to the inability to mitigate hemorrhage before arrival to the operating room. Current preoperative open and endovascular options for damage control present logistical challenges. A retrievable stent would offer a means to deliver hemorrhage control with continued venous return to the heart and yet without the limitations of current permanent stent designs. This study demonstrates a retrievable stent design for damage control of hemorrhage after caval injury in a porcine model.

Keywords: Retrievable; Stent; Hemorrhage; Cava; Porcine

Traumatic hemorrhage from the vena cava represents a challenging surgical dilemma with a significant mortality rate between 31% and 58%.[1-4] This may result from penetrating or blunt trauma or, alternatively, occur as an iatrogenic injury. The noncompressible nature of caval injuries presents additional challenges, as external manual compression is ineffective to mitigate ongoing blood loss. Aside from the obvious hemodynamic effects

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of hemorrhage, early blood loss exacerbates coagulopathy and increases the risks for other complications, such as long-term organ failure, even despite eventual replacement of lost blood volume.[5] As a result, early hemorrhage control is critical for optimal surgical outcome.

Current approaches to caval injury present several obstacles to temporizing hemorrhage, especially outside of the operating room. Open clamp control of a caval injury is not well suited for the trauma bay or battlefield hospital, limited by brisk nonpulsatile caval bleeding, absence of qualified surgical staff, and compromised sterility. Endovascular options also present logistical challenges as "permanent" stent grafts require endovascular expertise, trained staff, properly sized inventory, and high-resolution imaging. Optimal initial placement of current stent grafts is essential as current permanent stents cannot be easily removed if they are improperly selected or placed.

A retrievable stent graft would resolve many of these challenges because hemorrhage control could be achieved rapidly in a damage control scenario. We have previously described "proof of concept" for a novel "petal and stem" stent design that allows rapid deployment and eventual recapture. Limitations of that study included a large 16F device profile, a terminal porcine model, and the use of open femoral and iliac vein exposure.[6] This study included two primary objectives. The first was the development of a refined caval Rescue stent that includes percutaneous delivery of a more practical 9F stent profile. The second goal was to examine the refined stent in a more rigorous porcine survival model of caval hemorrhage and resuscitation, with successful postoperative recovery.

ARTICLE HIGHLIGHTS

- **Type of Research:** Experimental study using a porcine model of traumatic caval hemorrhage
- **Take Home Message:** The authors found that a retrievable covered stent can control caval bleeding.
- **Recommendation:** This study suggests the potential utility of a retrievable covered stent technology for traumatic venous injury.

METHODS

Finite element analysis. Finite element analysis was used to examine strain during stent collapse into a 9F sheath using Abaqus CAE 2016 software (Dassault Systèmes, Waltham, Mass). A cylindrical surface model was included in the calculation process as a crimper to compress the stent radially. It was meshed with 1750 SFM3D4R (four-node quadrilateral surface element with reduced integration) elements. The nitinol behavior was simplified as elastic with Young modulus $E = 70$ GPa and Poisson ratio $\nu = 0.3$.[7] Superelasticity was not included to simplify modeling complexity. The stent model was meshed with 14,594 C3D8R (eight-node linear brick with reduced integration and hourglass control) elements for the first design and 20,980 C3D8R elements for the second design. The mesh quality was checked to avoid any element distortions. The contact between the crimper (cylindrical surface model) and the stent outer surface was defined as frictionless in the tangential direction and "hard" contact (penetration not allowed) in the normal direction. Also, the separation was allowed after the contact, suggesting that they were not bonded together during the collapse process. A displacement loading was applied on the crimper surface in the radial direction, and the magnitude was set as the compressed stent diameter being equal to a 9F profile. Finally, the calculation was performed using dynamic explicit to account for the large nonlinear deformation. Both the stress and maximal principal strain (MPS) fields were calculated to determine the device integrity in a 9F sheath. We assumed that the stent strut would be mechanically stable without fracture when it was collapsed into a 9F catheter if the calculated MPS did not exceed the fracture limit of the nitinol material at 12%.[8]

Custom nitinol retrievable Rescue stent scaffolds. The nickel-titanium alloy nitinol was fashioned into a cylindrical design of 25 mm in diameter using 0.0155-inch-diameter nitinol wire (Confluent, Fremont, Calif) by methods described previously[6] but with significant refinement. The wires were first bent 150 degrees to create permanent deformation of the wire onto an aluminum mandrel. Next, the contacting wires were joined by precision-pulsed, microlaser welding (LZR 100; Sunstone Engineering, Payson, Utah) at 20-mm spacing to create diamond-shaped openings in the stent. Thermal shape setting was achieved by heating the stent to 500°C (Lindberg/Blue M Moldatherm Box Furnace; Fisher Scientific, Pittsburgh, Pa) and allowed distribution of stress points caused during welding. Rapid cooling of the stent to 20°C in 10 seconds (quenching) restored superelastic properties to the nitinol backbone. Radial force was measured using a mechanical test system (FMS-500, Starrett; OCS Technologies, Cleveland, Ohio).

Expanded polytetrafluoroethylene (ePTFE) sleeves. ePTFE was manufactured by Zeus Industrial Products (Orangeburg, SC) with a nominal inner diameter of 0.394 ± 0.03 inch and wall thickness of 0.005 ± 0.004 inch (127 μm). Because of manufacturing limitations of the vendor, the ePTFE was extruded at a diameter smaller than needed. A 28-mm angioplasty balloon (Z-Med; B. Braun, Bethlehem, Pa) was used to dilate the PTFE to the final application size of 23 mm. The final thickness of the dilated ePTFE averaged 60 μm. PTFE was adhered to the final stent scaffold using polyglycolic acid suture (Unify 7-0 suture; AD Surgical, Sunnyvale, Calif) and cyanoacrylate glue (Loctite 4902; Henkel