The AorTech VULCAN: Intraoperative Aortic Clamp for Use During Open Abdominal Aortic Aneurysm Procedures

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ABSTRACT

Abdominal aortic aneurysms (AAA) are the 10th leading cause of death in men over 60 and are caused by arteriosclerosis, smoking, high blood pressure, and genetics. If the aneurysm reaches a diameter of 5.5 cm or greater, surgical intervention in recommended. The two surgical approaches currently utilized are: the less invasive endovascular approach for small aneurysms, and the open approach, in which the surgeon makes an incision in the abdomen and replaces the weakened part of the aorta with a graft. During this highly invasive procedure, the blood flow through the aorta must be occluded by use of an aortic clamp to allow the physician to remove the clot and insert a graft.

Current clamp technology poses many opportunities for improvement in order to create a safer procedure. These clamps have standard ratcheting mechanisms which make smooth release from the aorta difficult, can cause trauma to tissue, and can slip down the aorta during surgery. After interviewing several vascular surgeons to determine customer needs, a design was created to address these needs of providing a smooth and controllable ratcheting mechanism, occluding arteries without damaging tissue, and ensuring a constant clamping force for the duration of surgery. After a plastic prototype was created, additional feedback was obtained from surgeons that resulted in further modifications. The final clamp design, the AorTech Vulcan, incorporates a novel ratcheting mechanism, cam lever lock, and soft jaw inserts to provide atraumatic cushioning. Testing was performed which validated full occlusion for the duration of surgery, determined the amount of force applied at each ratchet position, and compared visual tissue damage and holding force for several jaw insert surface characteristics. While further improvements can still be made, the AorTech Vulcan has shown success in addressing customer needs and shows promise in entering the surgical instrument market.

INTRODUCTION

AorTech's Mission:

AorTech will be a leader in reliable and safe surgical instruments. AorTech strives to develop a vascular clamp to optimize ease of use and application as well as safety in highly invasive vascular procedures. Our company will collaborate with vascular surgeons with the intent of reducing associated surgical risks to the patient and will ensure a return on investment for our shareholders.

Background:

Abdominal aortic aneurysms (AAA) are the 10th leading cause of death in men over 60

- Causes
  - Arteriosclerosis
  - Smoking, high blood pressure, diabetes and genetics
- Surgery recommended for aneurysm 5.5+ cm wide
- Aortic clamp utilized to occlude blood flow through the aorta during open AAA procedure

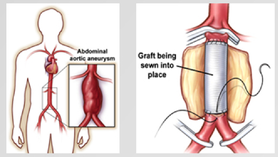

Figure 1. *(left) An abdominal aortic aneurysm. Image illustrates the dilation of the artery within the abdominal cavity; (right) a Dacron graft being sewn into place during open AAA procedure. Note position of the clamp, placed directly beneath the renal arteries [1]*

Problems with current vascular clamps:

- Can cause trauma to tissue
- Lack of security
- Minimal control while removing clamp from surgical site
- Risk of sliding down aorta during procedure due to highly pressurized artery
- Difficult to use ratcheting mechanism

Customer Needs and Specifications:

- Clamp must be able to occlude arteries without damaging tissue
- Clamp must be easy to close and open
- Clamp must be able to provide a constant clamping force for the entire duration of the procedure
- Clamp must be immobile relative to the aorta
- Clamp must be able to withstand aortic blood pressure

THE AORTECH VULCAN

- Novel ratcheting mechanism to allow for more control and incremental application and release
- Cam lever at fulcrum to ensure locked position during surgery
- Removable jaw inserts with innovative surface characteristics
  - Reduces slipping along aorta during surgery
  - Provides atraumatic cushioning
  - Prevents snagging at metal-insert interface

The AorTech Vulcan: Clamp and Jaw Insert Renderings

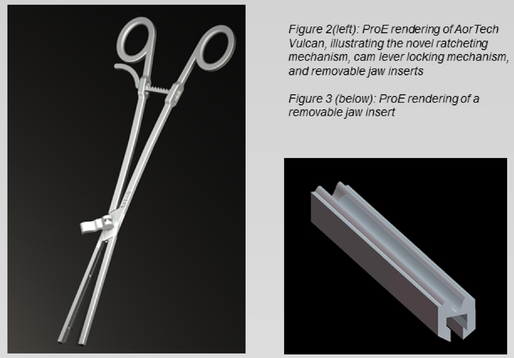

Figure 2(left): ProE rendering of AorTech Vulcan, illustrating the novel ratcheting mechanism, cam lever locking mechanism, and removable jaw inserts

Figure 3 (below): ProE rendering of a removable jaw insert

The Aortic Clamp

- Created from aluminum (final product will be created in 316L stainless steel)
- Cut out using wire electrical discharge machine (EDM) and assembled and polished by hand

Figure 4: (left) Disassembled clamp; (right) fully assembled clamp (pictured with removable jaw inserts)

The Jaw Inserts

- Aluminum molds were created using computer numerical control (CNC) machine—bottom molds and top molds with desired surface characteristics
- Jaw inserts created from Plastisol (durometer of 40.5)

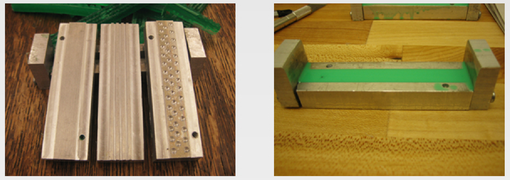

Figure 5: (left) Jaw insert molds with variety of surface characteristics; (right) Plastisol in a mold prior to being heated to create a jaw insert.

TESTING

Force Distribution Testing of Clamp

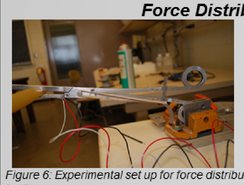

Figure 6: Experimental set up for force distribution testing:

Subject Task: Measure the force distribution along the jaws.

Parameters: A rubber tube was placed at a given position along the jaw. The clamp was closed to the first ratchet position and the strain was measured. This was repeated for nine ratchet positions. The rubber tube was moved to a different position along the jaw and the procedure was repeated.

Results

This test confirmed that there is an unequal force distribution when clamping the tube along the metal jaws. It also provided numerical results for the amount of force needed to deform the tubing at each ratcheting position.

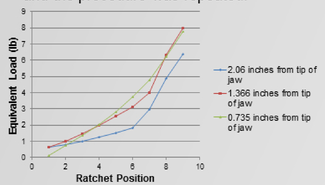

Figure 7: Equivalent load versus ratchet position

Holding Force (Slipping) Test

Subject task: Determine holding force of three jaw inserts with different surface characteristics to determine which results in the least slipping.

Figure 8: Experimental setup of slipping test: tubing is used to model the aorta.

Parameters: The AorTech Vulcan was clamped to the table surface with a vice grips. For each jaw insert tested, the jaw was opened to positions that applied equivalent strain. A base weight of 508 g was hung from the tubing, and additional weight was added in increments of 10 g. The holding force was measured to be the amount of weight added before the tubing slipped completely from the jaw inserts.

Results: The smooth jaw inserts had a significantly higher holding force than both the square and round inserts. Based on this test, the smooth jaw inserts would be expected to slip the least on the aorta.

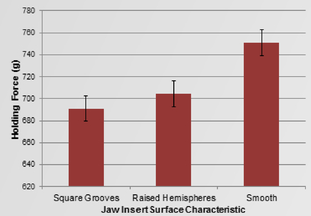

Figure 9: Holding force for various jaw insert surface characteristics

Visible Damage Testing of Jaw Inserts on Aorta

Subject task: Determine which jaw insert surface characteristic provides the least amount of visible damage.

Parameters: Experimental set-up matched that of the clamp validation test, except that the tube was inserted into a porcine abdominal aorta. Tissue was clamped under 200 mmHg of pressure until flow was fully occluded, and then examined visually for damage after 20 minutes. Three jaw surface characteristics were tested and compared with a control crushing clamp.

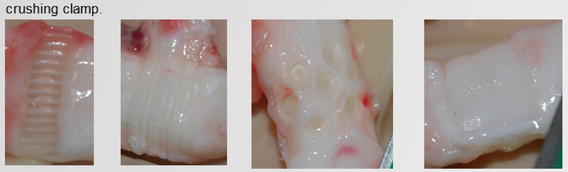

Figure 10: Visible trauma on aorta: (left to right) crushing clamp (control), square grooves, raised hemispheres, and smooth surface

Results: No visible damage was observed from the smooth inserts. Distinct lines and round indentations in the aortic tissue were observed for the square groove pattern and raised hemisphere pattern respectively, though still were less damaging than the crushing clamp. Overall, the smooth inserts resulted in the least visible trauma. No slipping occurred for any of the inserts tested.

TESTING

Ability of Clamp to Occlude Blood Flow (Clamp Validation)

Subject Task: Verify that the AorTech Vulcan can occlude blood flow for six hours

Parameters: Latex tubing 1.5 cm in diameter was used to model an aorta. The tubing was filled with water at a height of 2.71 meters to obtain a pressure of 200 mmHg where the AorTech Vulcan was placed. A collection vessel was placed under the clamp to determine if water was leaking over the six hour time period.

Results:

No water leaked from the testing apparatus over the allotted time period. This confirmed that the clamp can occlude flow for the duration of a standard AAA procedure at physiological blood pressure.

Figure 11: Setup for testing the clamp's ability to occlude flow for six hours under physiological blood pressure.

CONCLUSION

AorTech has developed a vascular clamp to occlude blood flow during an open abdominal aortic aneurysm surgery. It was shown through testing that the AorTech Vulcan is able to occlude flow through tubing for a duration equivalent to a standard AAA procedure. Testing was also performed to quantify the amount of force the clamp was able to apply to rubber tubing. It was found that the distribution of force along the jaw length is uneven with a smaller force being produced toward the tip of the jaw. With the current methods of quantifying clamping force, future developments will include testing force distribution of different shaped jaws.

It was important for the Vulcan to cause minimal damage to tissue during occlusion. Results from testing have shown that smooth jaw surface characteristics visually yield the least amount of damage to a porcine aorta. It was also shown that the smooth jaw surface characteristic had the strongest holding force making it least likely to slip along an aorta.

AorTech will be a leader in reliable and safe surgical instruments. AorTech has collaborated with vascular surgeons with the intent of reducing associated surgical risks to the patient. AorTech has developed a vascular clamp to optimize ease of use and application as well as safety in highly invasive vascular procedures.

Recommendations for the Future

- Integrate a bendable handle mechanism to remove clamp from the visual field of the surgeon
- Change jaw shape to create a more uniform distribution of force
- Create final device in 316L stainless steel
- Further testing in preclinical and clinical models

References

1. Vascular Web. Vascular Conditions, Tests, Treatments [Internet]. Abdominal Aortic Aneurysm; 2007 [cited 2008 Oct 28]. Available from: http://www.vascularweb.org/patients/NorthPoint/Abdominal_Aortic_Aneurysm.html
2. Melin, M. Mark, M.D., vascular surgeon. Personal interview and email correspondence. 18 Sept. 2008.
3. Emery, Robert, M.D., vascular surgeon. Personal interview. 2 Oct. 2008.
4. Kersten, Tom, M.D., vascular surgeon. Personal interview. 3 Oct. 2008.
5. Eales, Frazier, M.D., vascular surgeon. Personal interview. 6 Oct. 2008.
6. Sundt, Thoralf, M.D., vascular surgeon. Telephone interview. 8 Oct. 2008.

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