ACS 2023 Surgeons and Engineers: A Dialogue on Surgical Simulation Meeting

Research In-Progress

Vascular Surgery Device Innovation: Aortic Endograft Explanation

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Introduction: The standard treatment of abdominal aortic aneurysms (AAA) is endovascular aortic repair (EVAR) during which an endograft is placed within the aorta to stabilize the weakened wall and prevent rupture. 16-30% of grafts will fail which may necessitate endograft explantation. This procedure has 6.3% mortality and 31% complication rate. During the removal process, metal prongs that hold the graft apply a tearing force that damages the endothelium and can result in lethal bleeding. Current standard of care involves a syringe cut and shaved to make a cylinder. It is inserted and rotated upwards over the endograft until the hooks are covered and the graft is explanted. There is currently no off-the-shelf technology for safe endograft explantation.

Methods: Financial analysis and prototype cost estimates were conducted. The current standard of care procedure was broken down to vital steps and failure points; design criteria were developed after addressing inefficiencies and shortcomings. Materials used include 3D printers, filaments, steel wire, and ball bearings. Testing was performed in silicone tubing. Design elements were identified to address. The prototyping process involved exploring varying mechanisms for graft removal.

Preliminary Results: Market analysis identified a need for a low cost multi-use product priced under $100 on a low volume, on-demand basis. Testing criteria were the ease of removal, procedure time, and reproducibility. Modifications were incorporated based on performance in the mock aorta. One major design criterion from consulting vascular surgeons was to reduce the diameter of the graft before explantation. Our top prototype reduced a 25mm diameter graft to 7mm, and adequately fulfills the design requirements. This device is pending intellectual property protection.

Next Steps: Our study has shown that the current standard of care is inefficient in multiple steps of the explantation procedure with high mortality and no available off-the-shelf technology. We described the biodesign process for a technology assisting in aortic endograft explantation. Our prototype indicated the feasibility of use and effectiveness in endograft removal. Next steps are further device development, and in-vivo testing.