Biodesign: Engineering an aortic endograft explantation tool

Solyman Hatami, MD,[a] Vamsi Maturi, MD,[a] Alwin Mathew, MD,[a] Shannon Lu, MD,[a] Paul Haddad, MD,[b] Daanish Sheikh, BS,[c] *and* Maham Rahimi, MD, PhD,[b] *Houston and San Antonio, TX*

ABSTRACT

Endovascular aortic repair (EVAR) graft failure can be as high as 16% to 30% owing to endoleak, graft migration, or infection, often necessitating explantation, leading to potential morbidity (31%) and mortality (6.3%). Graft prongs frequently tear through the endothelium during explantation, leading to endothelial damage and subsequent fatal bleeding. The current standard of care involves different suboptimal techniques such as the syringe technique in which a cylinder is improvised by cutting a syringe in half and pushed over the graft hooks in a rotating motion, until covered for manual explantation. Because there is no commercially available product to address this shortcoming in graft explantation, we engage in the biodesign process to produce a functional explantation device. We designed and prototyped multiple potential solutions to remove EVAR endografts safely. Silicone tubing with EVAR endografts deployed in the lumen were used to simulate a grafted aorta and test each prototype. Prototypes were compared in their ability to meet design criteria including decrease in graft diameter, prevention of arterial dissection, ease of use, and decrease in procedure time. After determining the single best prototype, surgeon feedback was elicited to iteratively improve the original design. The most effective design uses a tapered lumenal geometry that decreases the EVAR graft diameter and uses stainless steel beads to prevent shear stress to the simulated aorta. A distal grip allows for easy single hand manipulation of the device, while a latching mechanism allows for smooth placement and removal over the endograft. After rigorous prototyping, our device proved feasible and effective for safe EVAR explantation, allowing this procedure to be performed safely. (J Vasc Surg Cases Innov Tech 2024;10:101599.)

Keywords: EVAR explantation; Open endograft explantation; Biomedical innovation; Abdominal aortic aneurysm; Aortic graft infection

Open endograft explantation is the definitive treatment of endovascular aortic repair (EVAR) graft failure; however, the current standard of care involves the use of off-label tools to aid in complete graft removal. EVAR graft failure can be as high as 16% to 30% owing to endoleak, graft migration, or infection, necessitating endograft explantation. Graft failure leads to potential morbidity (31%) and mortality (6.3%).[1,2] Although many reinterventions to address graft failure can be conducted percutaneously, approximately 5% of the approximately 40,000 EVAR grafts inserted would eventually require open conversion, of which 66% were accomplished with complete explantation. Complete explantation was sometimes difficult owing to a well-incorporated graft or avoided in favor of partial graft removal.[3,4] Graft prongs frequently tear through the endothelium during explantation, causing endothelial damage and subsequent fatal bleeding. Tearing of the aorta, injury to visceral arterial origins, or prolonged suprarenal cross-clamp time are further possibilities, all contributing to poor outcomes.[5] One improvised technique commonly used in our practice includes a modified syringe to sheath, separate, and isolate the graft from the surrounding aorta.[6] A 20- to 50-mL syringe is cut and shaved to make a smooth cylinder that is inserted and rotated upward over the endograft until the hooks are covered and the syringe-graft assembly is removed together. Although this method decreases tearing forces between the graft barbs and the endothelium, its insertion results in a snowplow effect owing to shear stress between the cylinder and the aorta, causing endothelial damage regardless. We engaged in the biodesign process and developed the following need statement: A way to remove compromised aortic endografts that reduces damage to the aortic wall and associated complications. We discussed subsequent steps including needs screening, concept generation, concept selection, prototyping, testing results, and incremental improvement. Our proposed solution is the use of a flexible cylinder with an interior lumenal taper as a base design to sheath the graft barbs and decrease the graft hook diameter, thus mitigating endothelial tearing from the hooks.

From the Texas A&M School of Engineering Medicine,[a] the Department of Cardiovascular Surgery, Houston Methodist,[b] Houston; and the UTHSCSA Long School of Medicine, San Antonio.[c]

Correspondence: Maham Rahimi, MD, Department of Cardiovascular Surgery, Houston Methodist Hospital, 6565 Fannin St, Houston, TX 77030 (e-mail: mrahimi@houstonmethodist.org).

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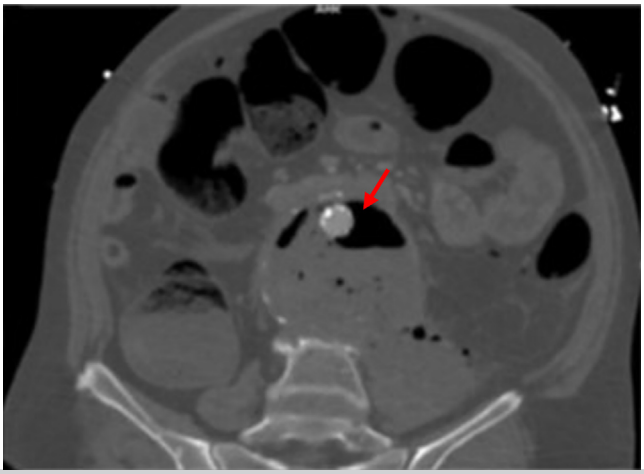

Fig 1. Axial view of computed tomography angiogram (CTA) demonstrating gas within the abdominal aortouniiliac stent graft (*red arrow*).

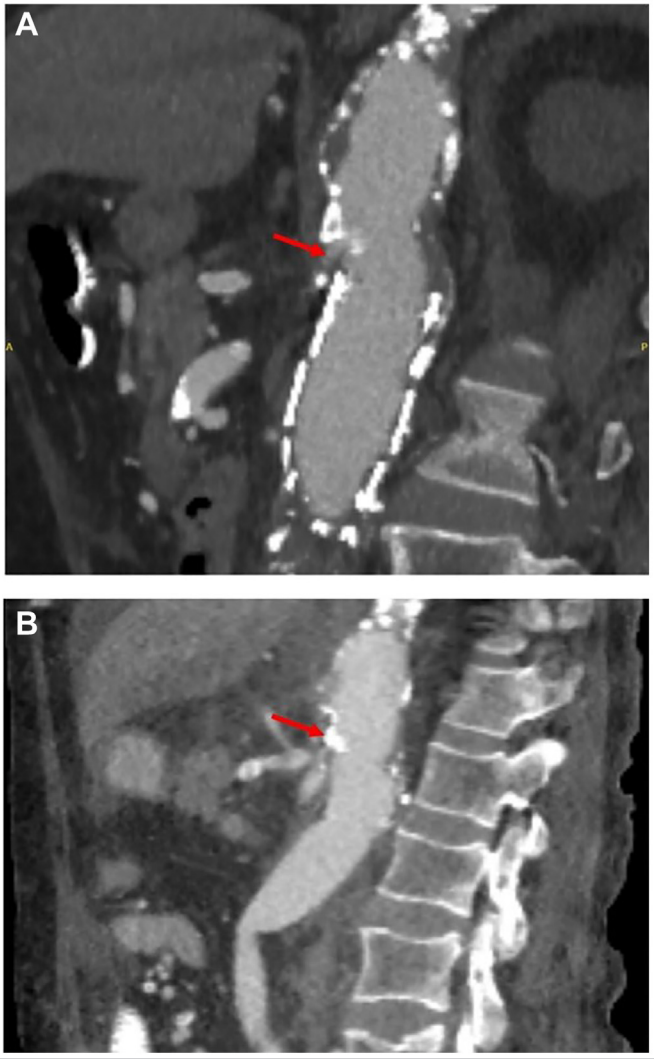

Fig 2. (A) Preoperative views demonstrating patent superior mesenteric artery (*red arrow*). **(B)** Postoperative sagittal view of computed tomography (CT) scan demonstrating occlusion of the superior mesenteric artery (*red arrow*).

Further components included integrated ball bearings to reduce shear stress on the aortic endothelium. A two-part bisected construction was incorporated to enable the device to open and close for ease of use and a built-in fail safe.

CASE REPORT

A 63-year-old man with a past medical history of abdominal aortic aneurysm addressed with EVAR 3 years prior, presented with fever, chills, night sweats and failure to thrive. Computed tomography scan indicated gas inside the aneurysm around the suprarenally fixed endograft (Medtronic, Minneapolis, MN) without evidence of abscess (Fig 1). The patient's blood culture was positive for *Clostridium perfringens*, and the patient was immediately started on broad spectrum intravenous antibiotics. Because the patient was hemodynamically stable, risk stratification was performed, which indicated moderate risk for open vascular intervention, and the patient was scheduled for EVAR explantation 5 days after admission. The endograft was well-incorporated at the level of the renal arteries, and removal of the suprarenal fixation proved difficult, in part owing to high levels of inflammation around the aneurysm sac. Although we considered cutting the graft and leaving the suprarenal fixation in place, we were able to pull the endograft including the suprarenal fixation out of the aorta using the modified syringe technique. Rifampin-soaked Dacron was used to perform the proximal anastomosis; however, removing the proximal clamp revealed posterior and lateral aortic wall tears, resulting in significant blood loss and a longer period of mesenteric and renal ischemia owing to supraceliac reclamping (Fig 2). This led to severe lactic acidosis with coagulopathy requiring large-volume resuscitation. The abdomen was packed after finishing the revascularization and a temporary abdominal closure was placed. The patient subsequently required a return to the operating room and ultimately a partial colectomy. In addition, the patient's hospital course was complicated with acute renal failure requiring hemodialysis with eventual recovery of renal function after 8 months. The patient later provided written consent for the publication of their case details and images.

It is clear that this patient suffered from the inability to safely remove EVAR with suprarenal fixation causing massive blood loss, multiple subsequent transfusions, prolonged ischemia time, bowel ischemia requiring resection, and renal failure. In our practice, we have used techniques such as the improvised syringe technique; however, we often encounter tearing of the aorta owing to the blunt force of the syringe against the prongs. We have also observed the snowplow effect on the endothelium causing dissection of the aorta into the visceral vessels, resulting in renal failure and mesenteric ischemia. The lack of available tools to safely remove EVAR during open explantation has resulted in increased morbidity and mortality in these critically ill patients.

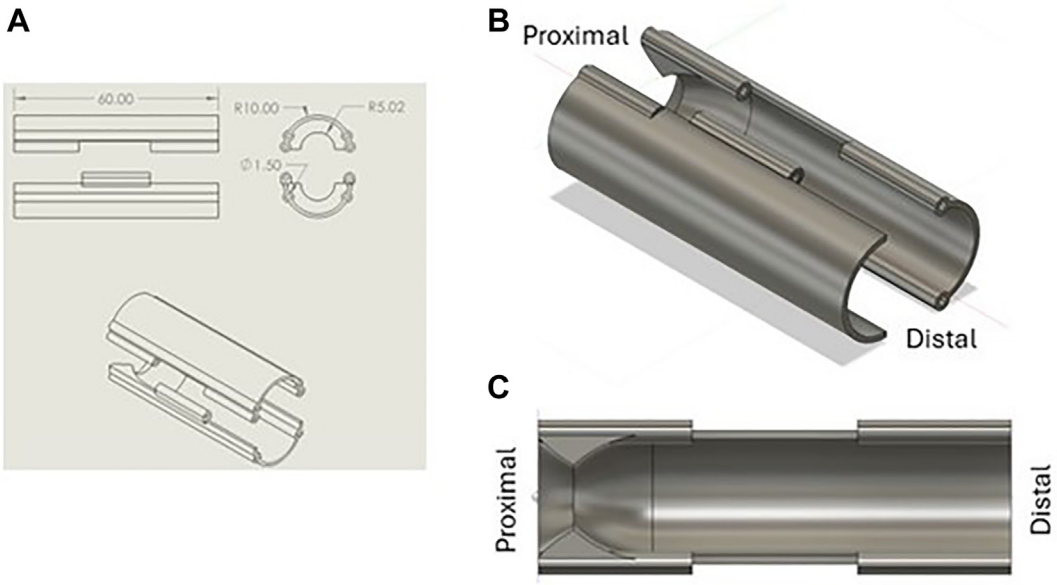

Fig 3. **(A)** Technical drawing and three-dimensional model of the device in **(B)** isometric and **(C)** cross sectional views.

METHODS

The biodesign process is a well-documented process that identifies clinical needs, develops solutions to address those needs, and implements those solutions in clinical practice.[4] This process is completed in three phases: identify, invent, and implement, which are further broken down into more detailed steps. We used this process to brainstorm and create multiple potential solutions to remove aortic grafts safely. Our prototype materials included Cook Medical Endografts, silicone tubing, polylactic acid filament, thermoplastic polyurethane filament, biocompatible photopolymer resin, extrusion and stereolithography (SLA) three-dimensional printers, and stainless steel wire, rods, and beads. Cook endografts and silicone tubing were used to simulate endograft removal in benchtop experiments. Cook endografts were chosen based on their availability at our institution and because they use suprarenal fixation. A variety of proposed mechanisms and concepts were developed until deemed no longer feasible.

We tested each prototype using two sets of metrics to quantify the most optimal solution moving forward. Prototype design metrics were developed considering the actual challenge of removing the fixated graft from the vessel. Major design metrics included a decrease in the graft's diameter, the ability to move the explantation device along the endograft without hooking onto the endograft struts, easy transition into aorta without vessel layer dissection, and the ability to safely sheathe the graft while explanting to prevent arterial damage. The efficacy of each prototype in these metrics was compared with others in benchtop simulations. We used 25-mm and 32-mm clear silicone tubing to simulate the aorta. Inside the tube, a Cook Medical EVAR graft was deployed, and each prototype was used to try and remove the graft. After benchtop testing, cadaveric tests were performed on successful concepts; endothelial damage was assessed visually when comparing a given prototype with the traditional modified syringe technique. After testing and discontinuation of prototypes that failed design metrics, a set of outcome metrics were used to assess prototype feasibility and efficacy. Outcome metrics for each prototype included successful graft removal, minimal arterial damage, ergonomic use, ease of use, reproducibility, decrease in procedure time, and device cost. Prototypes were eliminated if any metric failed to the point of suggesting infeasibility in the operating room. Surgeon feedback and performance in simulation provided guidance for further prototype modifications and optimization. Through market analysis, a low cost, multiuse product priced <$100 was deemed appropriate with a low-volume, on-demand basis.

RESULTS

During development and testing, it became clear that the best prototype was the geometric lumenal taper design, providing fast removal with intuitive use. Although a variety of methods to decrease graph diameter were tested, including magnetic retraction of the struts, circumferential pinching, and clamping, the tapered design was best able to apply circumferential pressure along the length of the graft body throughout the explantation. As the device is advanced along the graft, the tapered geometry gradually decreases the diameter and eventually encloses the fixating hooks.

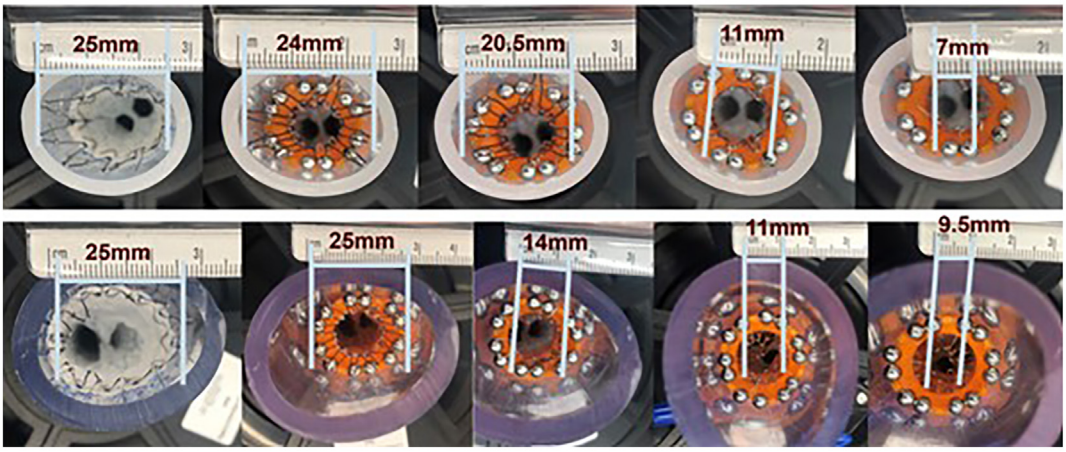

Fig 4. Endovascular aortic repair (EVAR) struts collapsing from full 25 mm diameter to 7 mm and 9.5 mm.

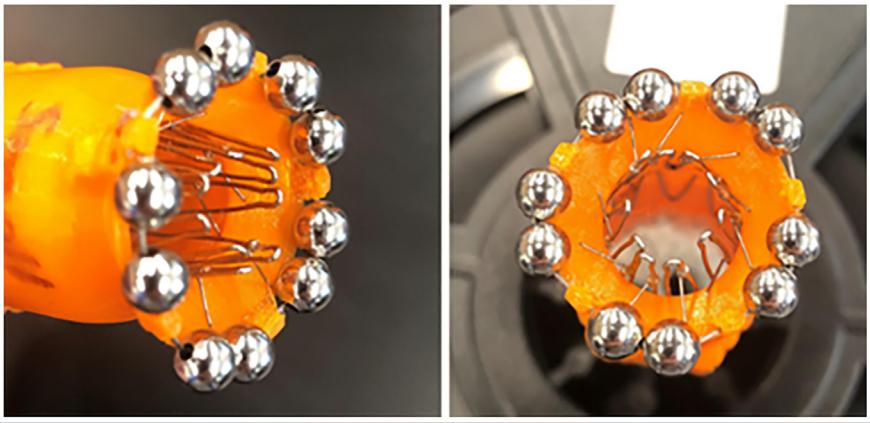

Fig 5. Close up views of proximal leading edge with metallic beads.

Graft diameter in benchtop models was able to be decreased quickly from 25 mm to 7 mm. With our prototype selected, we continued to adjust the device to be more suitable for real-world use. To further mitigate endothelial damage, stainless steel beads were added at the apex of the device to decrease shear stress and the possibility of dissection. To increase ease of use, a hinge mechanism was developed, allowing for easy closure around the graft without interference from metal struts in the graft body. Three-dimensional printing was transitioned from the less precise extrusion polylactic acid/thermoplastic polyurethane printers to higher-fidelity and biocompatible resin SLA printers to produce the final prototype. The final prototype was 60 mm long with a 10-mm external radius, and a 5.02-mm internal radius at the narrowest part of the taper. The narrowest point of the 51° taper was placed 4.7 mm from the proximal edge of the device. A curved expanding funnel then leads from the bottleneck of the taper toward the distal end of the device; this larger segment of the device is intended to hold the sheathed graft after fixating struts have been removed from the vessel wall (Fig 3).

The overall taper design mechanism is similar to the current improvised cut syringe technique to remove aortic grafts. This device is a cylinder with a quickly tapering diameter at the proximal end into which the EVAR graft is initially inserted. As the device is pushed up the graft, the taper design exerts an inward radial force, collapsing the graft (Fig 4). This gradual closure with smooth geometry allows for ease of use and requires less force than the fixed diameter syringe technique. Furthermore, this design also features beveled/curved edges at the proximal end that interfaces with the aorta minimizing endothelial friction and damage.

After the initial proof of concept was developed and benchtop testing proved that this prototype could meet the design requirements, iterative design was our primary objective for slight improvements in ergonomics, speed, and risk reduction. One limitation of the initial prototype was that it required two-handed manipulation to use. Thus, the first design addition was a distal knurled

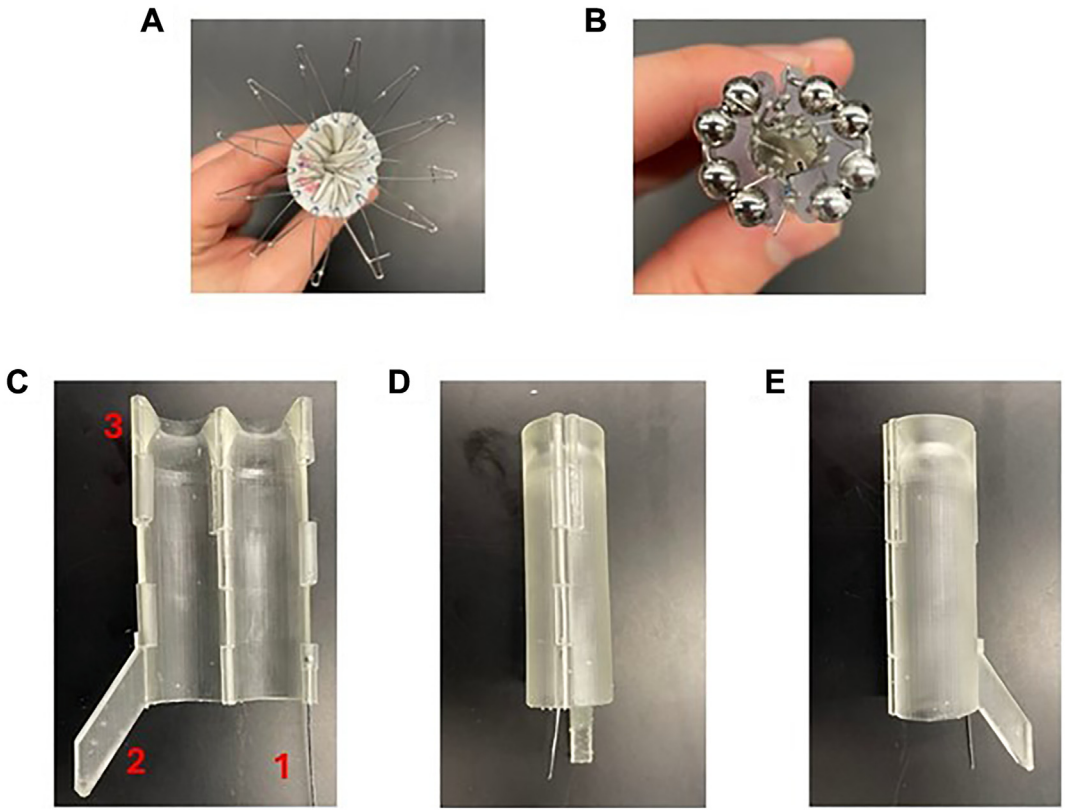

Fig 6. **(A)** Pinching of an endograft device causes fixating struts to expand radially, complicating explantation. **(B)** Leading edge metal beads facilitate movement along the collapsing endograft. **(C)** A partially disassembled prototype mockup featuring (1) the metal pin acting as the key for device closure, (2) the distal device handle, and (3) the tapered interior diameter that assists in graft closure. **(D** and **E)** Additional views of the closed prototype mockup.

grip for one-handed manipulation of the device; this element allowed for faster and more controlled device deployment. Stainless steel beads were incorporated to further decrease shear stress from the rigid edges of the original prototype (Fig 5). Another functional inefficiency noted by surgeon feedback was the catching of graft struts by the device upon initial placement onto the exposed graft. We addressed this by redesigning the device as a two-part cylinder that opened and closed lengthwise. The closing mechanism used a specialized ball-end rod so that secures the device components together. This allowed for a smooth initial placement of the device onto the exposed graft and eliminated the possibility of catching graft struts (Fig 6).

The prototype so far described holds many advantages over the traditional modified syringe technique. The most important advantage is the decrease in endothelial damage to the vessel when moving the device along the body of the graft; such endothelial damage can have devastating consequences for patients as discussed elsewhere in this article. The capability to open longitudinally also simplifies the initial application of the device to the graft body, while the lumenal taper to a significantly smaller radius allows for a stronger radial collapsing force of progressive nature around the graft, ensuring full strut closure every time and removal of hooks from the vessel walls each time (Supplementary Video, online only).

DISCUSSION

Our main objective of producing a safe EVAR explantation tool was accomplished by proving effectiveness and feasibility through benchtop testing and surgeon feedback. Our device is able to fulfill a complication-fraught surgery that currently uses an improvised technique. No device currently exists for this procedure. Our device is still undergoing iterative development for further optimization. Future validation of the aortic endograft explantation device should focus on objectively quantifying the difference in endothelial damage between the modified syringe technique and our explantation tool. We plan to use histological cross-section data to demonstrate superiority of our device. Additional points of interest are touched upon for price, manufacturing, and adoption.

After creating a prototype, a breakdown of the end device cost was calculated. First, the cost of each individual

part required was determined; this included plastic filament, beads, and rods. These costs summed to approximately $9.45 per prototype. The cost of a technician to assemble the device was then added, because expertise will be required to fully assemble the prototype at scale. This labor cost was approximately $6.67, resulting in a total net cost per device of $16.12. Notably, it is clear that the vast majority of the prototype's cost is derived from the rolling beads; bead purchase and SLA printer assembly comprise 94% of the entire cost of the device, assuming that the assembly is done by hand.

When compared with the current standard of care syringe method, our design is technically superior to the syringe method in speed, reliability, and reproducibility. The primary disadvantage of our design is cost. Because a syringe is widely available in the operating room, the syringe technique is effectively costless. However, the time spent in creating a usable syringe removal tool needs to be accounted for in the overall assessment. The cost of our prototype is marginal compared with the labor time required from the surgeon to create a usable syringe. With the syringe method, the surgeon must spend time improvising the device. This time cost does not factor in the separate cost to maintain the operating room per minute, which can start at $15 per minute in the operating room. Overall, although our design requires an initial dollar investment, the end cost is far less than the cost of the time spent by the surgeon creating the syringe device.

CONCLUSIONS

Our study has shown that the current standard of care for endograft explantation is inefficient with potential for lethal complications at several steps, necessitating novel technology.[7,8] There are no current commercial devices that can reliably explant the aortic endograft. We described the biodesign process for a device that decreases the risks of endograft explantation. Our prototype, using a taper design with rolling beads and two detachable halves, is a viable solution that is on balance cost and time effective. The device is currently protected under a provisional patent serial number 63/427,138 and is on track for compassionate use at Houston Methodist Hospital. Our future work will involve continual improvement of the prototype with testing in cadaveric and animal models. Outcomes of compassionate use in patients will be recorded and reported once enough data have been collected to verify efficacy.

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DISCLOSURES

None.

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