Determining Clinical Feasibility and Usability of a Novel Endograft Explantation Tool

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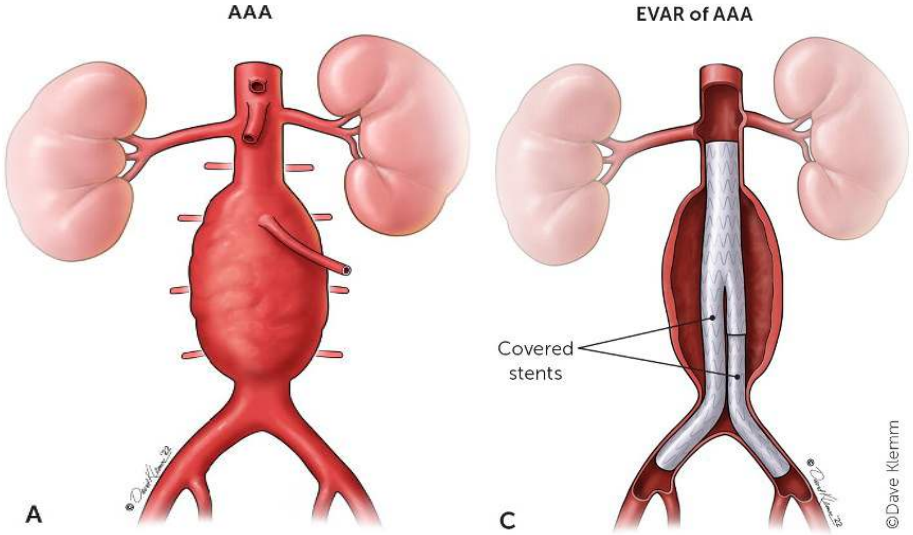
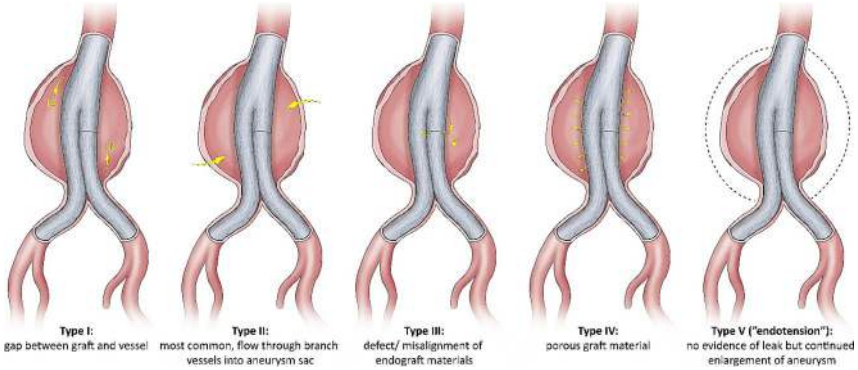
Endovascular Aneurysm Repair (EVAR)



Types of Endoleaks



https://www.clinicalimaging.org/article/S0899-7071%2824%2900313-9/fulltext

https://www.aafp.org/pubs/afp/issues/2022/0800/abdominal-aortic-aneurysm.html

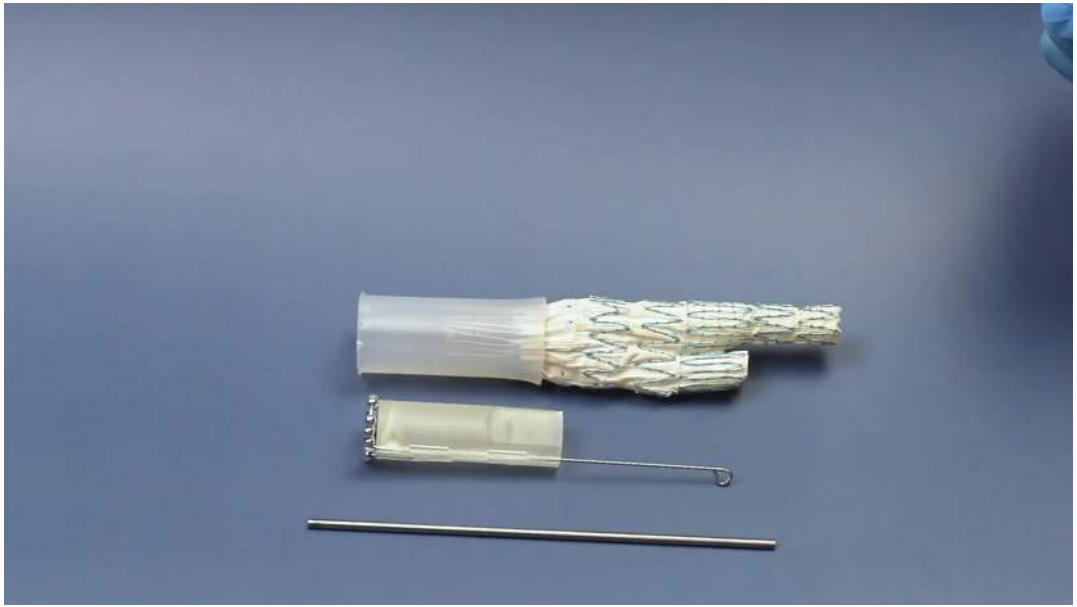
Indications for EVAR Explantation

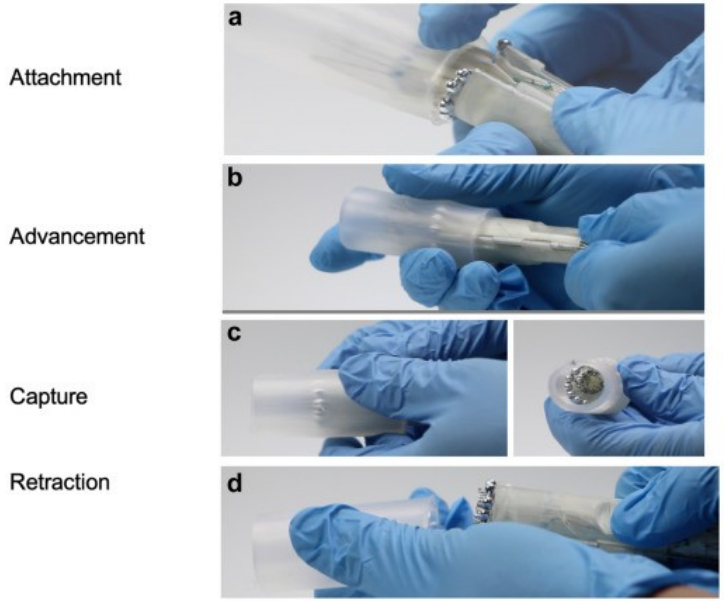
1. Endoleak
2. Infection
3. Sac Expansion

https://www.aafp.org/pubs/afp/issues/2022/0800/abdominal-aortic-aneurysm.html

EVAR Explantation Standard of care

EndoEx Method

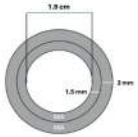


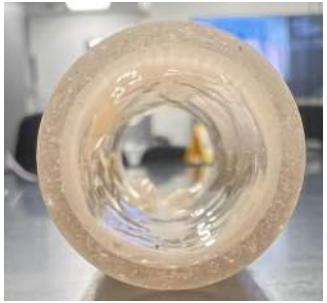


EndoEx vs Syringe Technique Evaluation

1. Development of An Accurate Aortic Model
2. Quantifying Safety and Effectiveness
3. Qualitative Evaluation

Aortic Model Development

Model	Model 1	Model 2	Model 3	Model 4
Picture				
Description	Single Layer Shore A 60 Hardness 2 mm thickness	Dual Layer Both Shore A 60 Hardness 2 mm thickness with 1.5 mm inner layer	Dual Layer Shore 60A inner layer with Shore 80A outer layer 2 mm thickness with 1.5 mm inner layer	Dual Layer Shore 40A inner layer with Shore 80A outer layer 1.5 mm thickness with 0.5 mm inner layer
Pros	Easy to produce Simple design	Bilayer construct separates the modeled intima and media from the outer adventitia	Differences in hardness better distinguishes between the modeled intima, media, and adventitial layers	Greater distinction in thickness and hardness between the aortic layers Overall thickness and inner diameter match that expected of a true aorta Thinned inner layer best replicated the intima layer
Cons	Failed to demonstrate any scraping or snowplowing Structural integrity does not match that of a human aorta	Although scraping was evident, limited snowplowing was seen upon testing the syringe technique Structural integrity does not match that of a human aorta	The thickness of the inner layer limits snowplowing from occurring and fails to truly replicate the aortic intima	Harder to produce many copies due to careful layering required for inner intimal layer



Final Aortic Model

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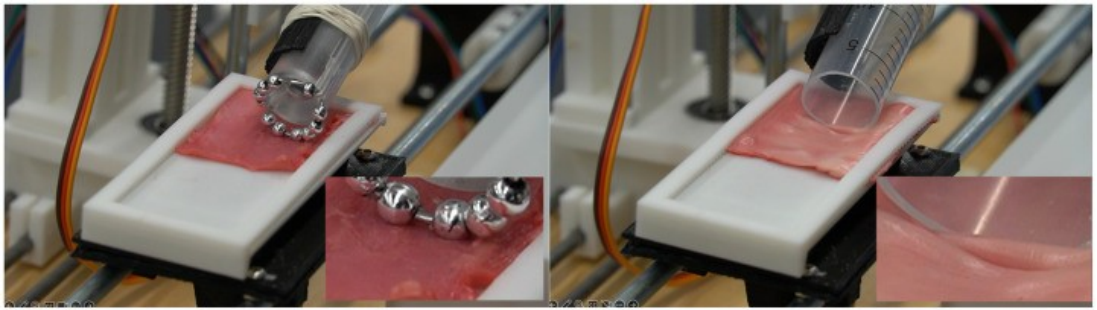
Quantitative Evaluation

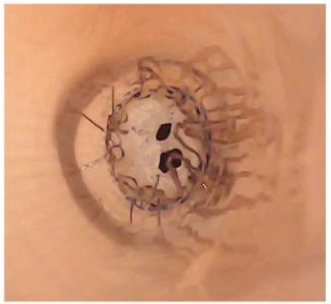
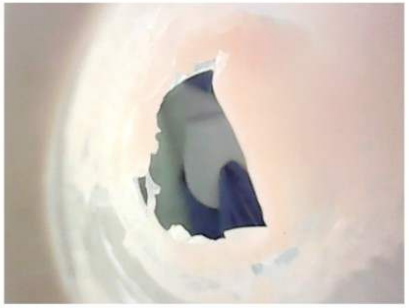
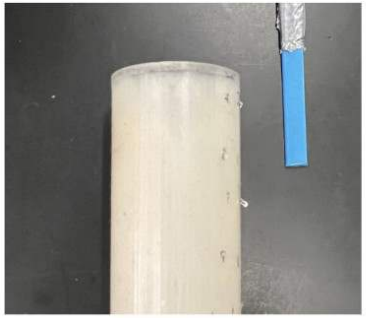
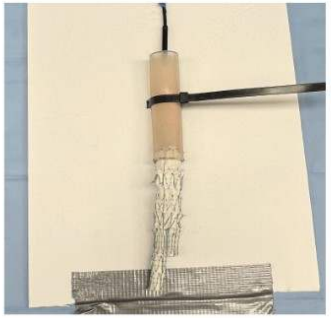
- **Area** scraped or snowplowed off
- **Time** to complete extraction



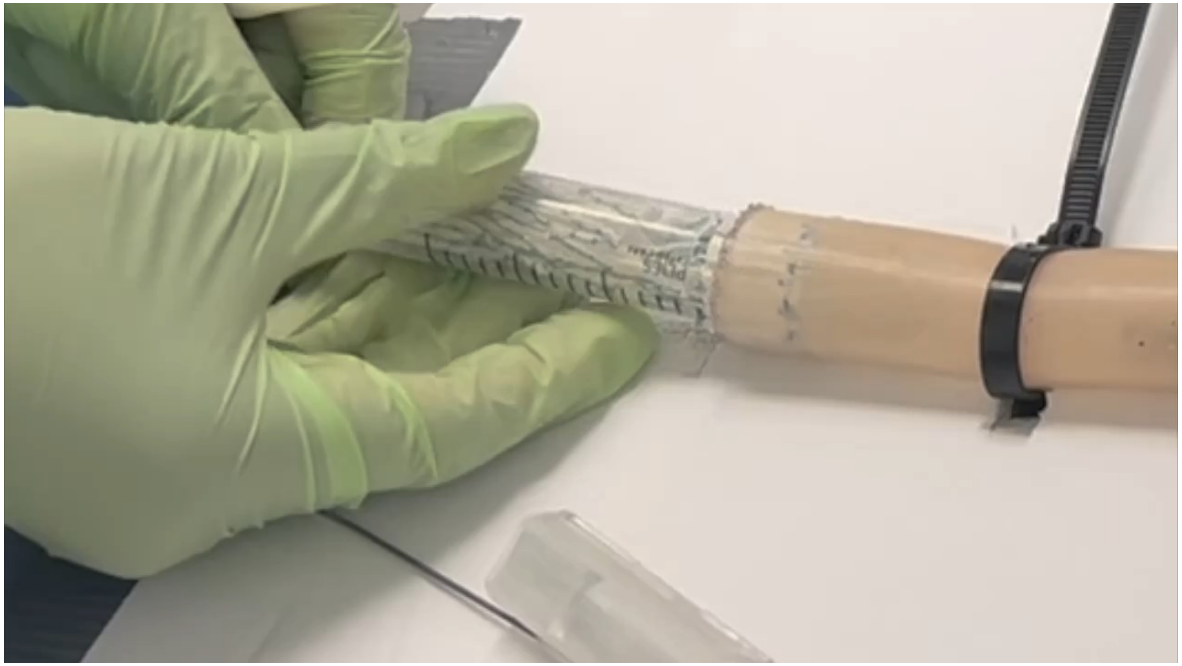
Qualitative Evaluation

- Survey adapted from the **NASA Task Load Index (TLX)** and **Systems Usability Survey (SUS)**
- Assessment of:
  - Ergonomics
  - Procedural Control
  - Perceived Safety

Experimental Setup

	Prior to Explantation	EVAR Deployment	Syringe Technique	EndoEx Technique
Internal Scope Image				
Model External Appearance				

Syringe Technique

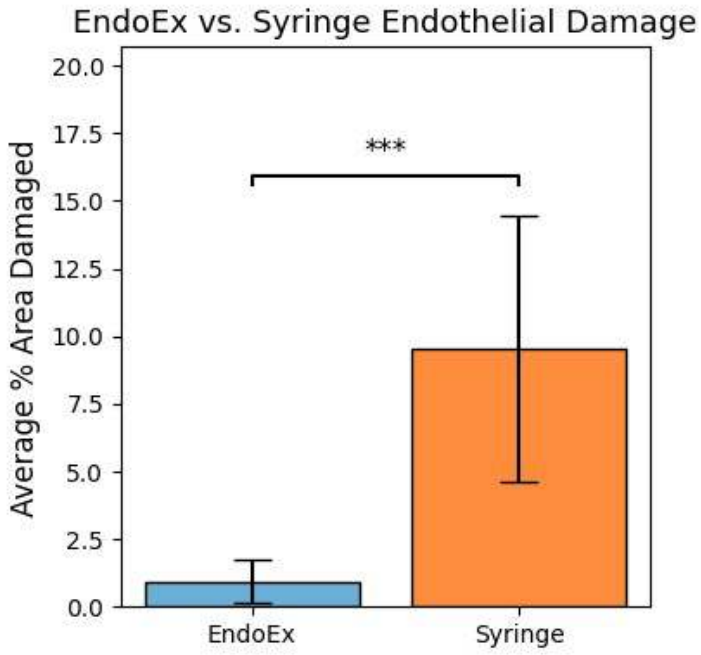


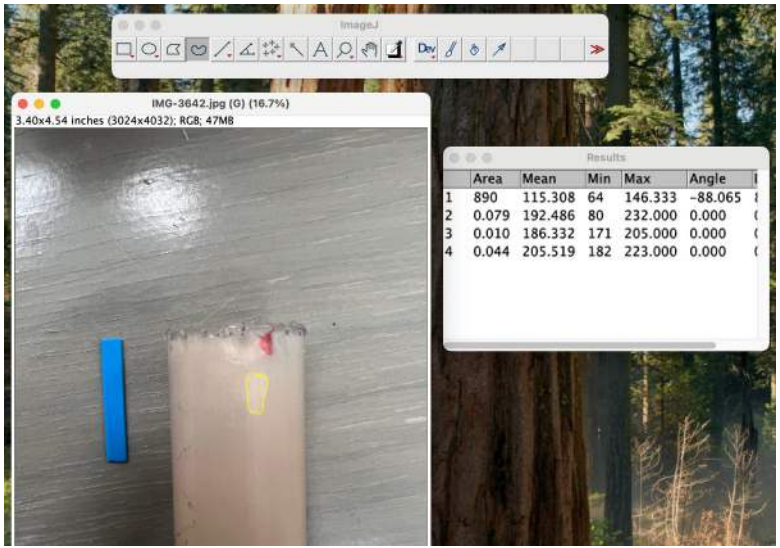
Video speed has been increased

EndoEx Technique

Video speed has been increased

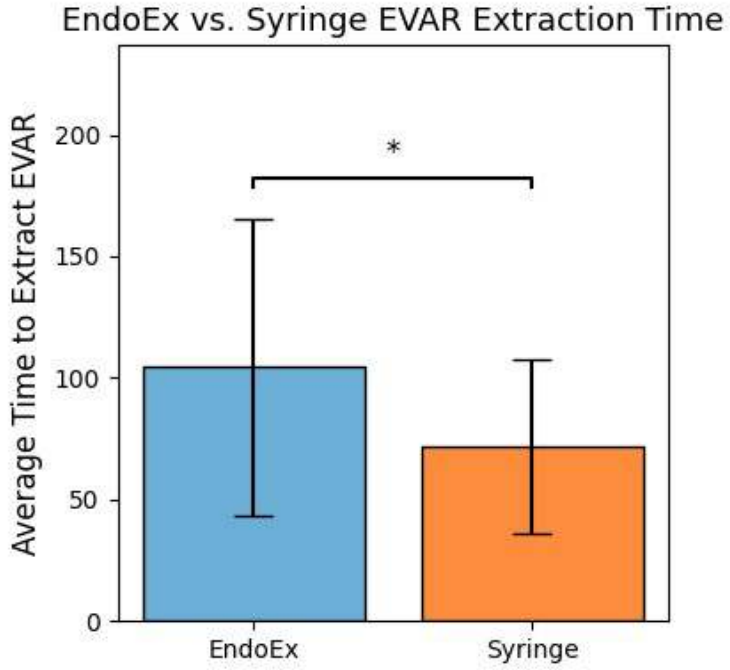
Major Findings: Quantitative Metrics





The blue line represents a 1-inch reference object used for scale.

Major Findings: Quantitative Metrics



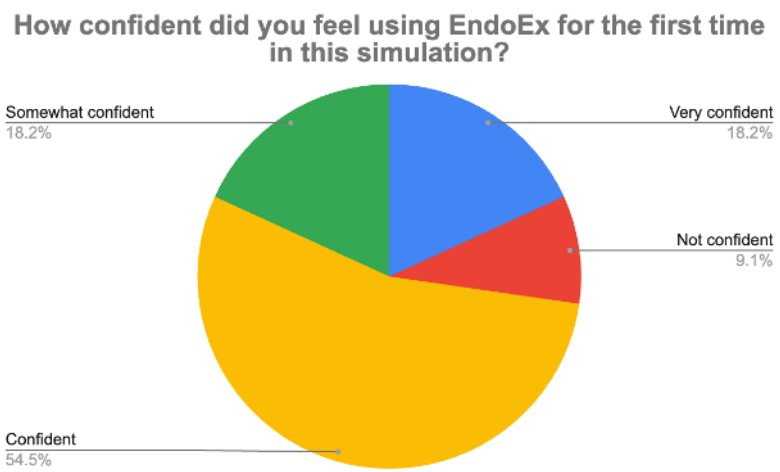
There are a **greater number of steps** involved in using the EndoEx device which likely resulted in an increase in time required to perform the extraction.

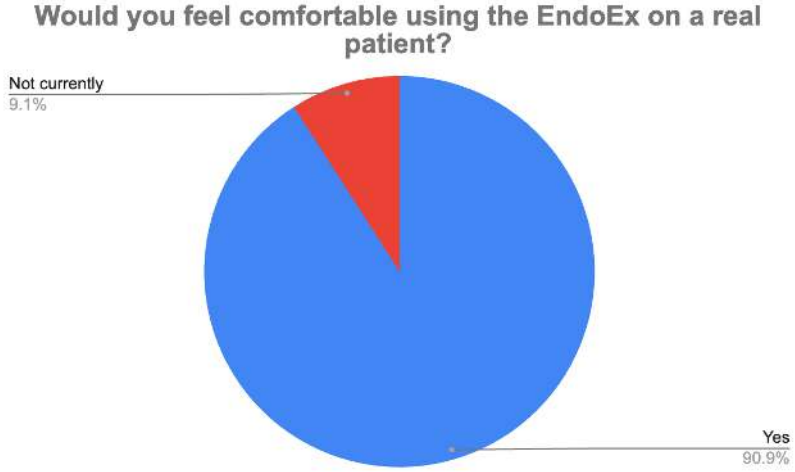
EndoEx Technique: 104.50 ± 60.90 seconds
Syringe Technique: 71.70 ± 35.92

Major Findings: Survey Metrics

Survey-Based Usability Metrics Scaled From 1 (Worst) to 10 (Best)			
Feature	EndoEx	Syringe	p-value
Ease of device introduction and positioning:	7.09 ± 3.14	4.09 ± 2.43	$p < 0.05$
Ergonomics and hand feel:	7.00 ± 3.1	4.36 ± 2.16	$p < 0.05$
Visibility of operative field while using EndoEx:	7.36 ± 3.04	4.55 ± 2.50	$p < 0.05$
Intuitiveness of device function (without prior extensive explanation):	7.09 ± 3.02	4.55 ± 2.61	$p < 0.05$
Stability and control during explantation maneuvers:	7.00 ± 3.13	4.73 ± 2.57	$p < 0.05$
Safety perception (risk of vessel injury or graft fragmentation):	6.55 ± 3.27	3.64 ± 2.69	$p < 0.05$
Overall Usability Scores	7.02 ± 3.12	4.32 ± 2.49	$p < 0.001$

Major Findings: EndoEx Survey Metrics





Conclusions

- The EndoEx significantly reduced the **snowplowing effect and endothelial scraping.**
- Participants in the study felt increased procedural **stability**, **ergonomics**, and overall **usability** with the EndoEx device.
- Although the extraction time was slightly longer with the EndoEx device, this is attributable to the **greater number of steps required for use.**