EndoEx: Verification and Validation of a Novel EVAR Explantation Tool

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Objectives

- Endovascular Aortic Repair (EVAR) reduces mortality and morbidity compared to open repair. However, it is associated with long term complication including graft infection (10%) and endoleaks (68%)[1]
- Failed management of complications leads to increased morbidity and mortality.
- This study outlines a novel device that can perform explantation which reduce morbidity and mortality associated with this technique.

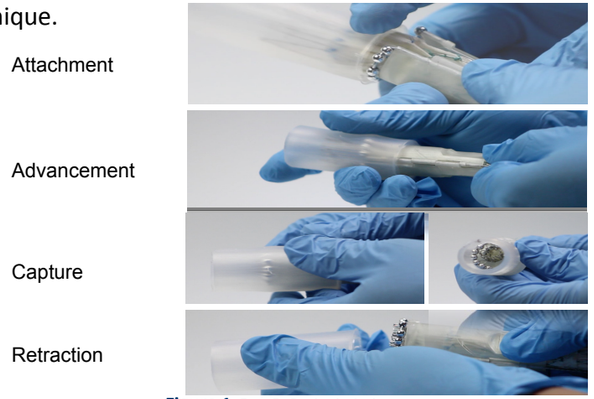

Figure 1. EndoEx Device in Action

Methods

- Tested the effectiveness of the device on agarose gel and pig aorta tissue both of which were used to simulate endothelium in human aorta tissue
- Surface area calculations by ImageJ compare the shaved area of the EndoEx device versus the syringe
- Reviewed the mean difference in area shaved, with standard error calculations and conducted a t-test to compare the device to the syringe (current industry standard)

Experiment

Gel Testing

Agarose gels were developed to model endothelial damage due to shear forces during endograft explantation from removal tools.

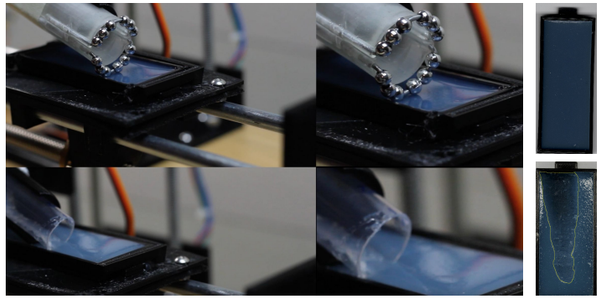

Figure 2. EndoEx (top row) and Syringe (bottom row) Agarose Gel Testing. Example of damage circled of surface area lost (right).

Pig Aorta Testing

Porcine abdominal aorta samples were implemented in place of gels for simulation.

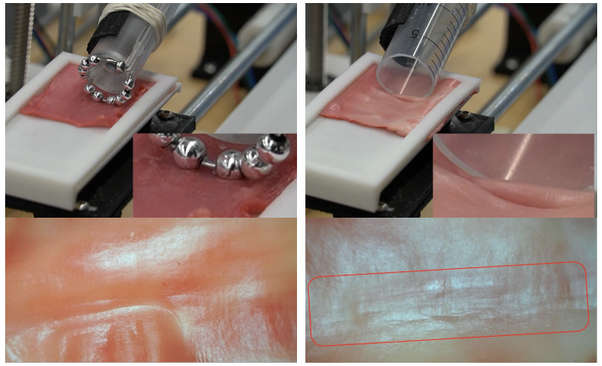

Figure 3. Porcine Tissue Test. EndoEx device testing and microscopic examination of damage (left). Syringe testing and microscopic examination of damage (right).

Results

The agar testing yielded a p-value of 5.6E-6, which indicates our device drastically reduced the amount of shavings compared to the syringe. Preliminary results in porcine aorta testing showed similar outcomes in regards to endothelial shaving.

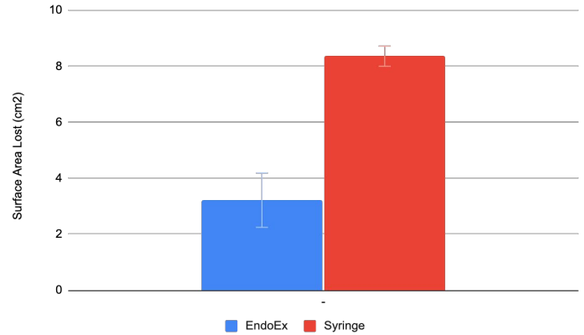

Figure 4. This figure compares the mean and standard error of EndoEx versus syringe in surface area shaved

Conclusion

Clinical Significance

- EndoEx reduced endothelial shaving (dissection into visceral aortic branch) as compared to the syringe method
- This device addressed the risk of catastrophic bleeding due to suprarenal fixation hooks tearing the aorta and reduction of mesenteric ischemia and/or renal failure due to dissection caused by syringe technique

Conclusions

- Benchtop gel and preliminary animal tissue testing support the efficacy of this device in endograft removal.
- EndoEx's limited shaving could be due to reusing the device between trials and the rotating balls getting stuck in later trials.

REFERENCES

1. de Boer, M., Qasabian, R., Dubenec, S. & Shiraev, T. The failing endograft-A systematic review of aortic graft explants and associated outcomes. *Vascular*, 17085381221082370 (2022).

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