A Novel Anastomotic Device in the Treatment of Acute Type A Aortic Dissections

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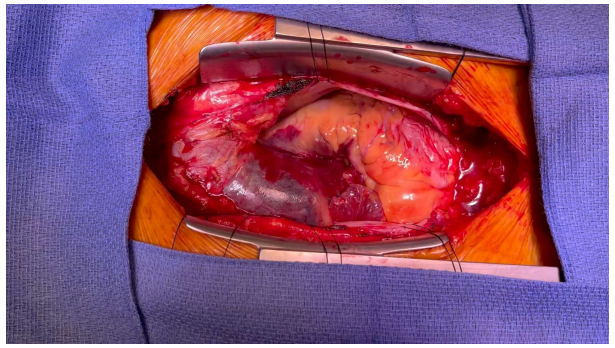
Disclosures

Share Holder Aortic Technolgies

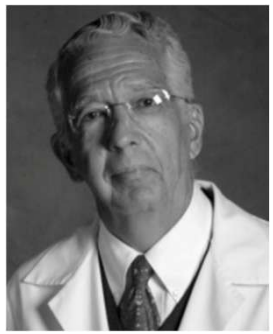
The Journey of treating acute Type A Dissections



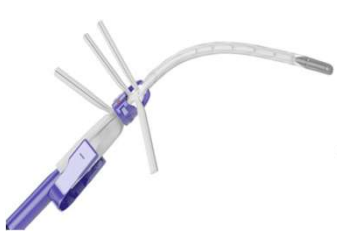
MORTALITY

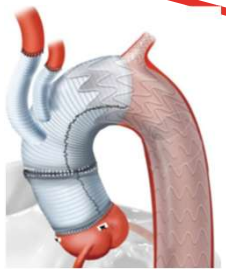
50 %

HCA



ACP/RCP

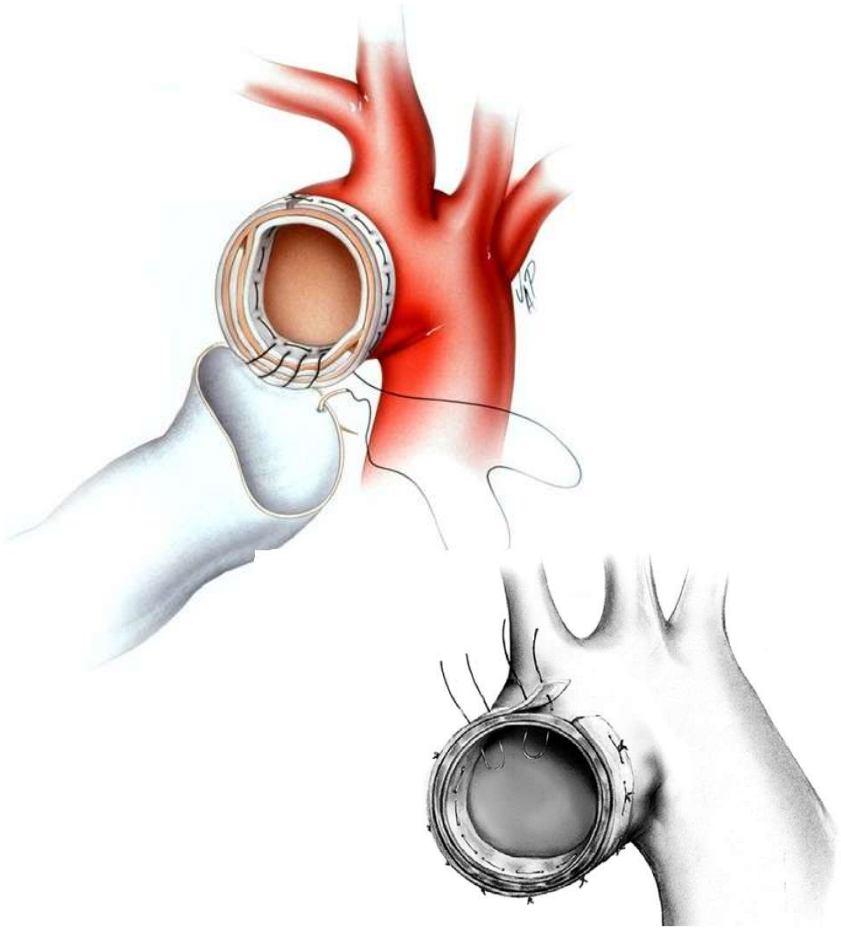


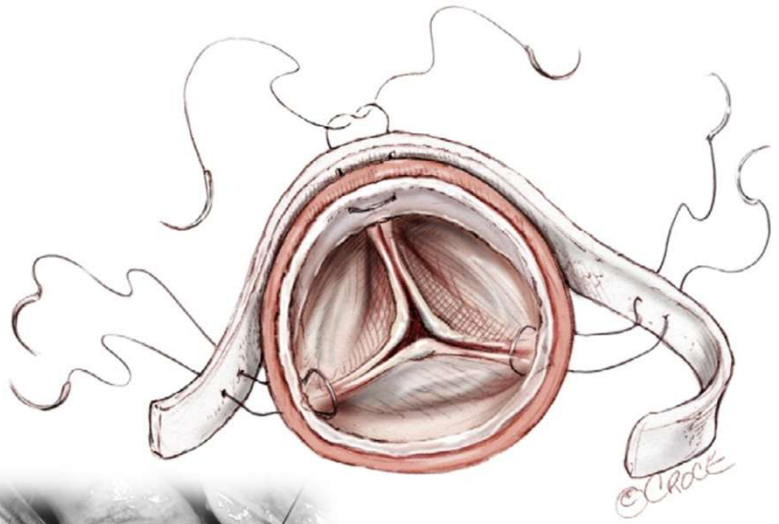


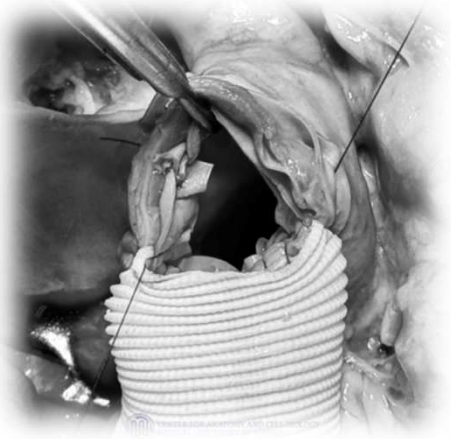
15 %

1963 1975 1986 2012 2023 2025

GOAL - Some Sort of Sandwich Technique







Felt or Pericardium

UNMET NEEDS AND CHALLENGES 2026

- Surgeons Experience (25% of USA Surgeon HCA)
- Dane (Distal Anastomotic New Entrance)

  Pane (Proximal Anastomotic New Entrance)

Surgeons Experience

National Outcomes in Acute Aortic Dissection: Influence of Surgeon and Institutional Volume on Operative Mortality

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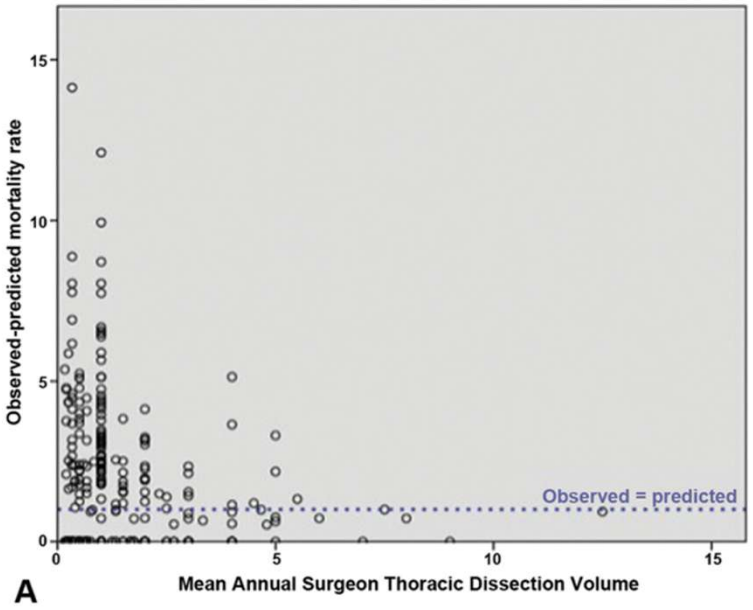
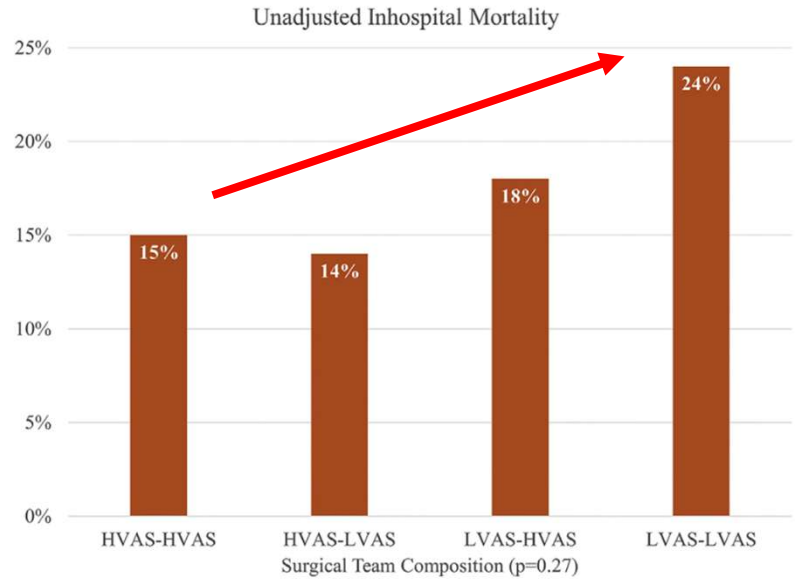


Acute Type A Dissection Repair by High-Volume Vs Low-Volume Surgeons at a High-Volume Aortic Center

Juan B. Umana-Pizano, MD, Alexander P. Nissen, MD, Harleen K. Sandhu, MD, MPH, Charles C. Miller, PhD, Andrei Loghin, BS, Hazim J. Safi, MD, Steven B. Eisenberg, MD, Anthony L. Estrera, MD, and Tom C. Nguyen, MD

Department of Cardiothoracic and Vascular Surgery, Memorial Hermann Hospital, McGovern Medical School, University of Texas Health Science Center at Houston, Houston; and Department of Surgery, San Antonio Military Medical Center, Fort Sam Houston, Texas



Vast majority of cardiac surgeons are performing < 3 cases /year

Surgeons Experience STS Database

18192 patients

Volume-failure-to-rescue relationship in acute type A aortic dissections: An analysis of The Society of Thoracic Surgeons Database

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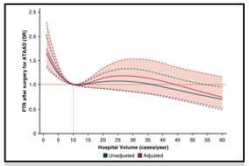
ABSTRACT

Objective: To determine the relationship between volume of cases and failure-to-rescue (FTR) rate after surgery for acute type A aortic dissection (ATAAD) across the United States.

Methods: The Society of Thoracic Surgeons adult cardiac surgery database was used to review outcomes of surgery after ATAAD between June 2017 and December 2021. Mixed-effect models and restricted cubic splines were used to determine the risk-adjusted relationships between ATAAD average volume and FTR rate. FTR calculation was based on deaths associated with the following complications: venous thromboembolism/deep venous thrombosis, stroke, renal failure, mechanical ventilation >48 hours, sepsis, gastrointestinal complications, cardiopulmonary resuscitation, and unplanned reoperation.

Results: In total, 18,192 patients underwent surgery for ATAAD in 832 centers. The included hospitals' median volume was 2.2 cases/year (interquartile range [IQR], 0.9-5.8). Quartiles' distribution was 615 centers in the first (1.3 cases/year, IQR, 0.4-2.9); 123 centers in the second (8 cases/year, IQR, 6.7-10.2); 66 centers in the third (15.6 cases/year, IQR, 14.2-18); and 28 centers in the fourth quartile (29.3 cases/year, IQR, 28.8-46.0). Fourth-quartile hospitals performed more extensive procedures. Overall complication, mortality, and FTR rates were 52.6%, 14.2%, and 21.7%, respectively. Risk-adjusted analysis demonstrated increased odds of FTR when the average volume was fewer than 10 cases per year.

Conclusions: Although high-volume centers performed more complex procedures than low-volume centers, their operative mortality was lower, perhaps reflecting their ability to rescue patients and mitigate complications. An average of fewer than 10 cases per year at an institution is associated with increased odds of failure to rescue patients after ATAAD repair. (J Thorac Cardiovasc Surg 2024;168:1416-25)



Restricted cubic splines: ORs for FTR according to the average ATAAD cases per year.

CENTRAL MESSAGE

Low-volume centers treating patients with ATAAD are associated with greater failure-to-rescue rates.

PERSPECTIVE

Although multiple factors determine the successful outcome of patients being operated on with ATAAD, this analysis suggests that the greater mortality rates historically observed in low-volume centers are a function of potentially reduced capacity to rescue patients after a complication. These results add to the evidence about the impact of macrosystem factors on health services quality.

See Discussion on Page 1426.

Tracking hospital outcomes using risk-adjusted mortality has been the cornerstone for benchmarking health care quality and empowering patients with information when deciding where to obtain health services. However, given its limited dimensionality, efforts have been directed toward other ways to measure outcomes more comprehensively. Failure to rescue (FTR) is a measure of quality that describes the ability of a team or institution to diagnose, treat, and mitigate complications before death.[1] FTR implies that death can be averted in some circumstances when

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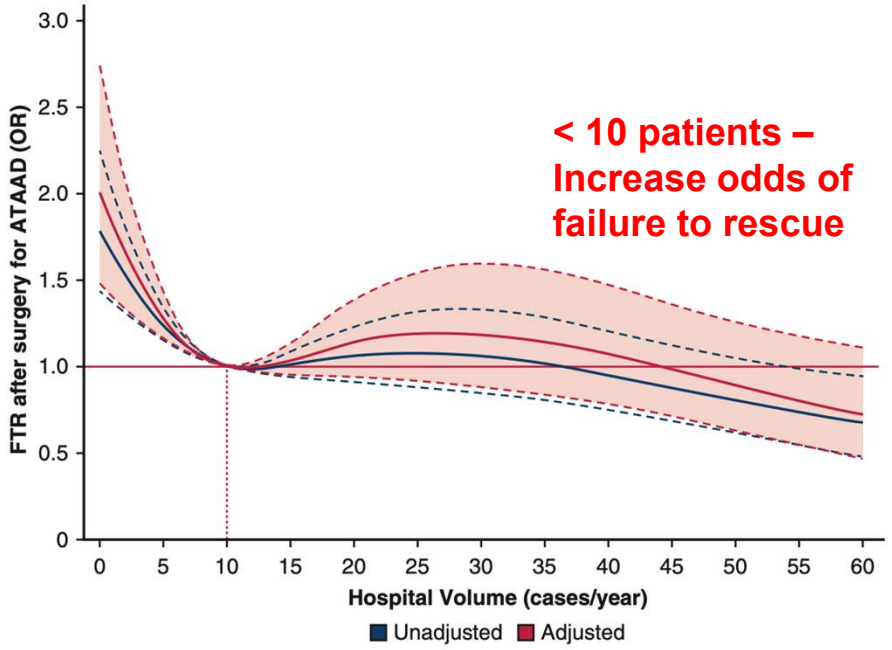


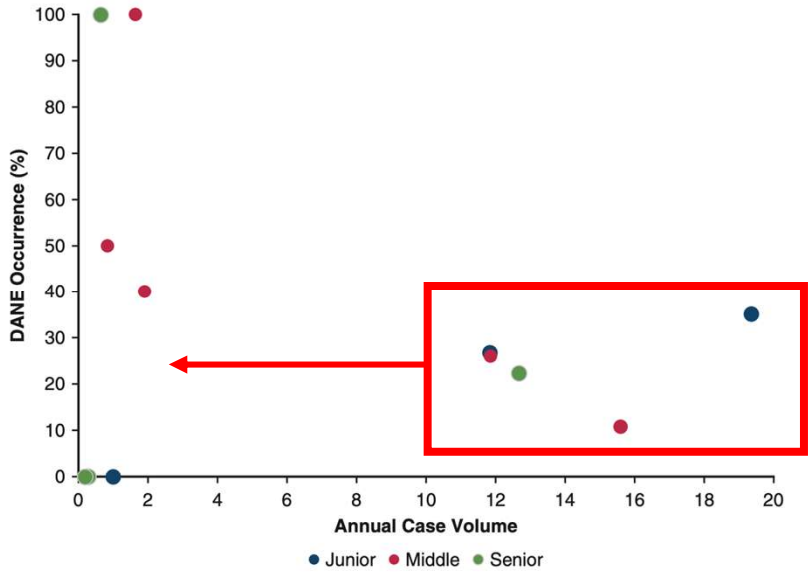
< 10 patients – Increase odds of failure to rescue

Conclusions: Although high-volume centers performed more complex procedures than low-volume centers, their operative mortality was lower, perhaps reflecting their ability to rescue patients and mitigate complications. An average of fewer than 10 cases per year at an institution is associated with increased odds of failure to rescue patients after ATAAD repair. (J Thorac Cardiovasc Surg 2024;168:1416-25)

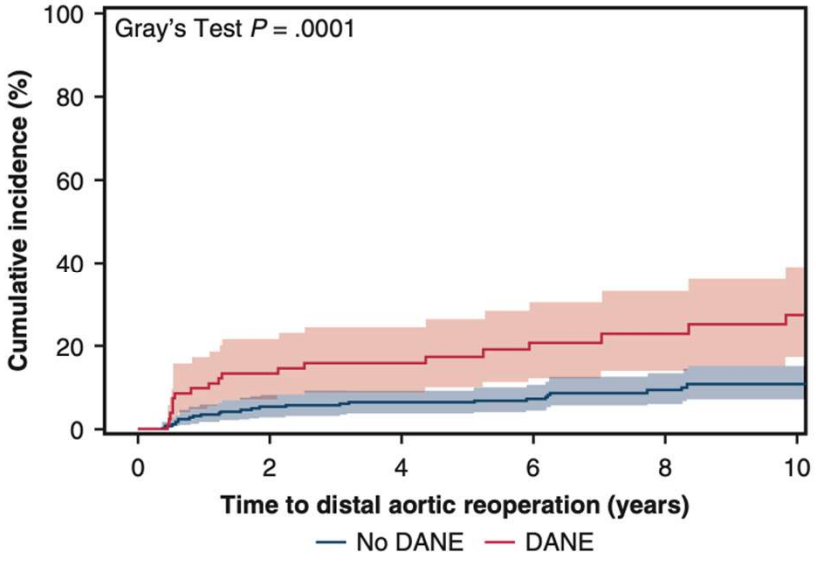
DANE

Distal anastomosis new entry tear in acute type A aortic dissection: A risk factor for distal aortic reoperation

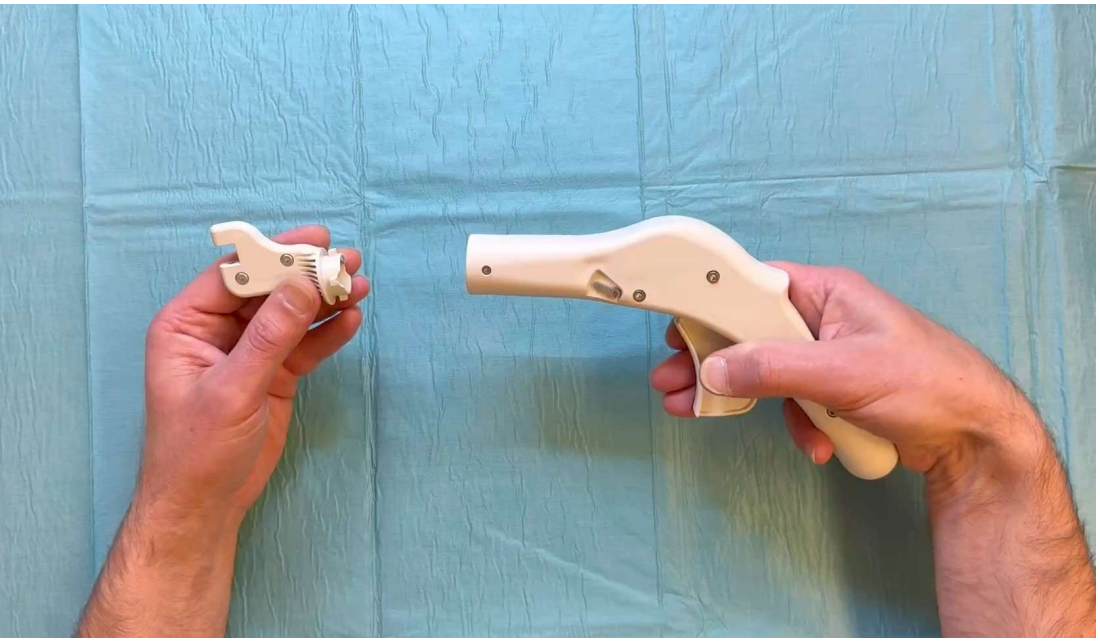
Rana-Armaghan Ahmad, BS,[a] Prabhvir Marway, MD,[b] Carlos Alberto Campello Jorge, MD,[b] Katelyn Monaghan, BS,[a] Divyaam Satija, BS,[a] Carol Ling, MS,[a] Shinichi Fukuhara, MD,[a] Himanshu Patel, MD,[a] G. Michael Deeb, MD,[a] Nicholas Burris, MD,[b] and Bo Yang, MD, PhD[a]

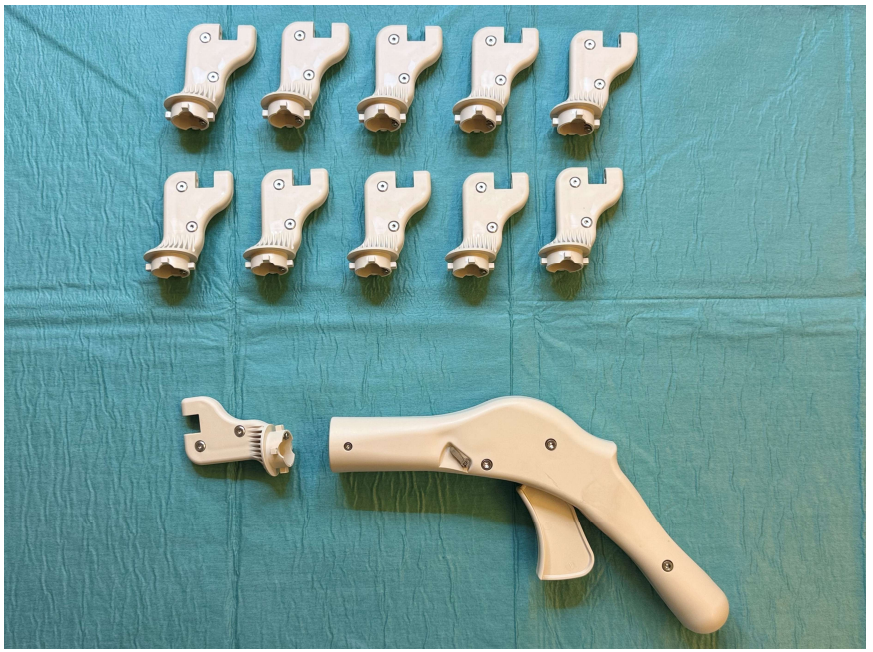


Reoperation



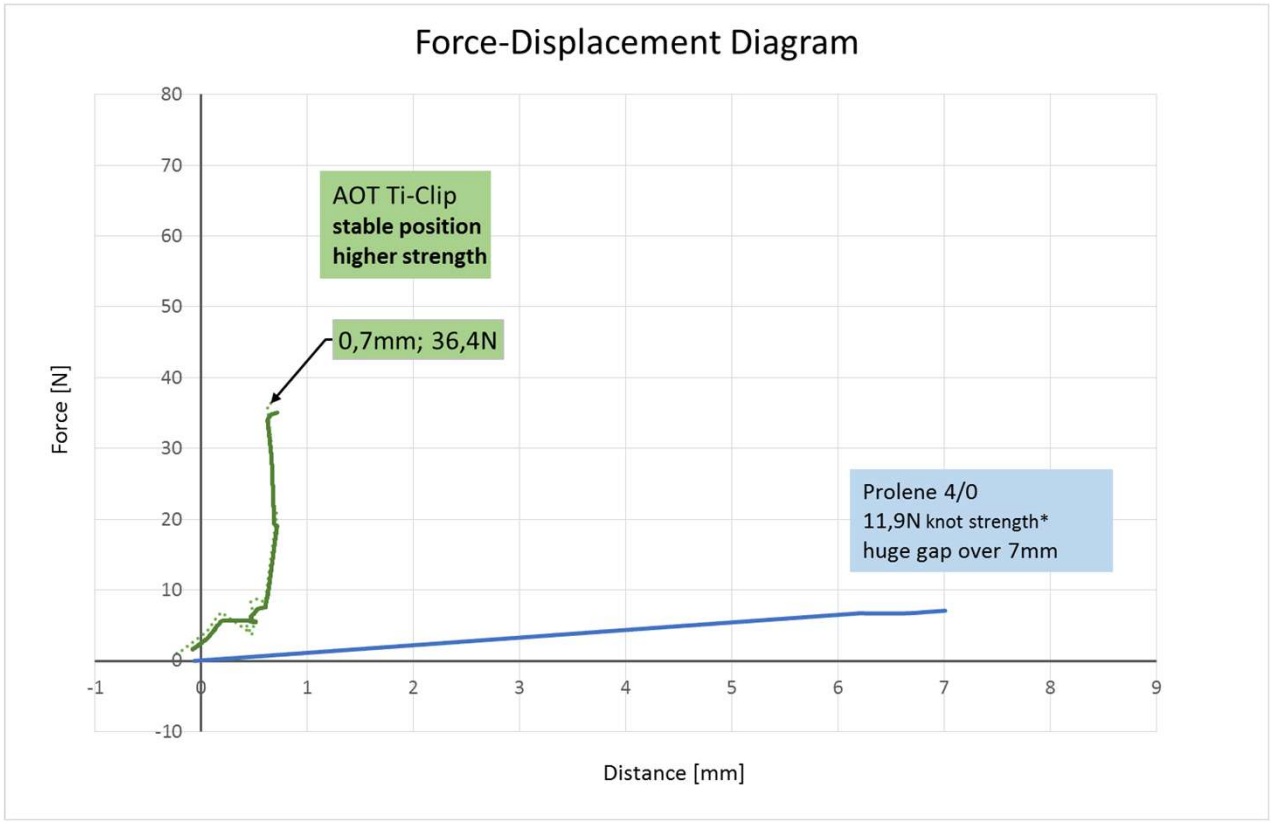
STAR DEVICE
Stapling Tool for Aortic Reinforcement

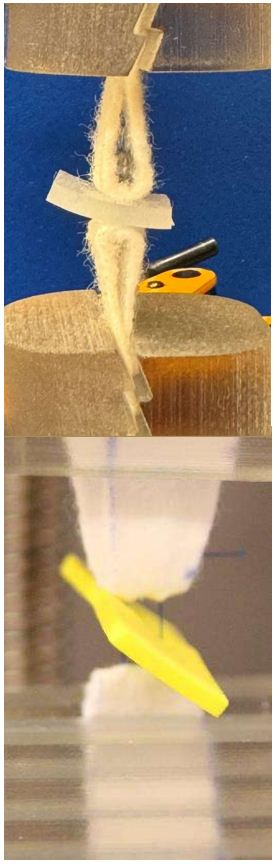




SET OF 2 HANDLES and
8-12 NEEDLE HEADS

MECHANISM OF DANE PREVENTION

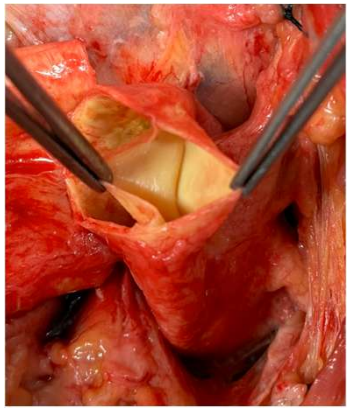


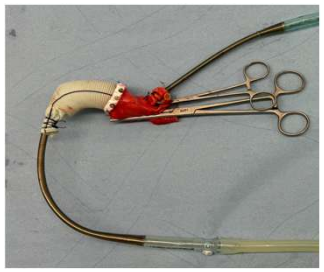


The STAR-rivet is 5-times stronger than Prolene 4/0 and stays stable in position

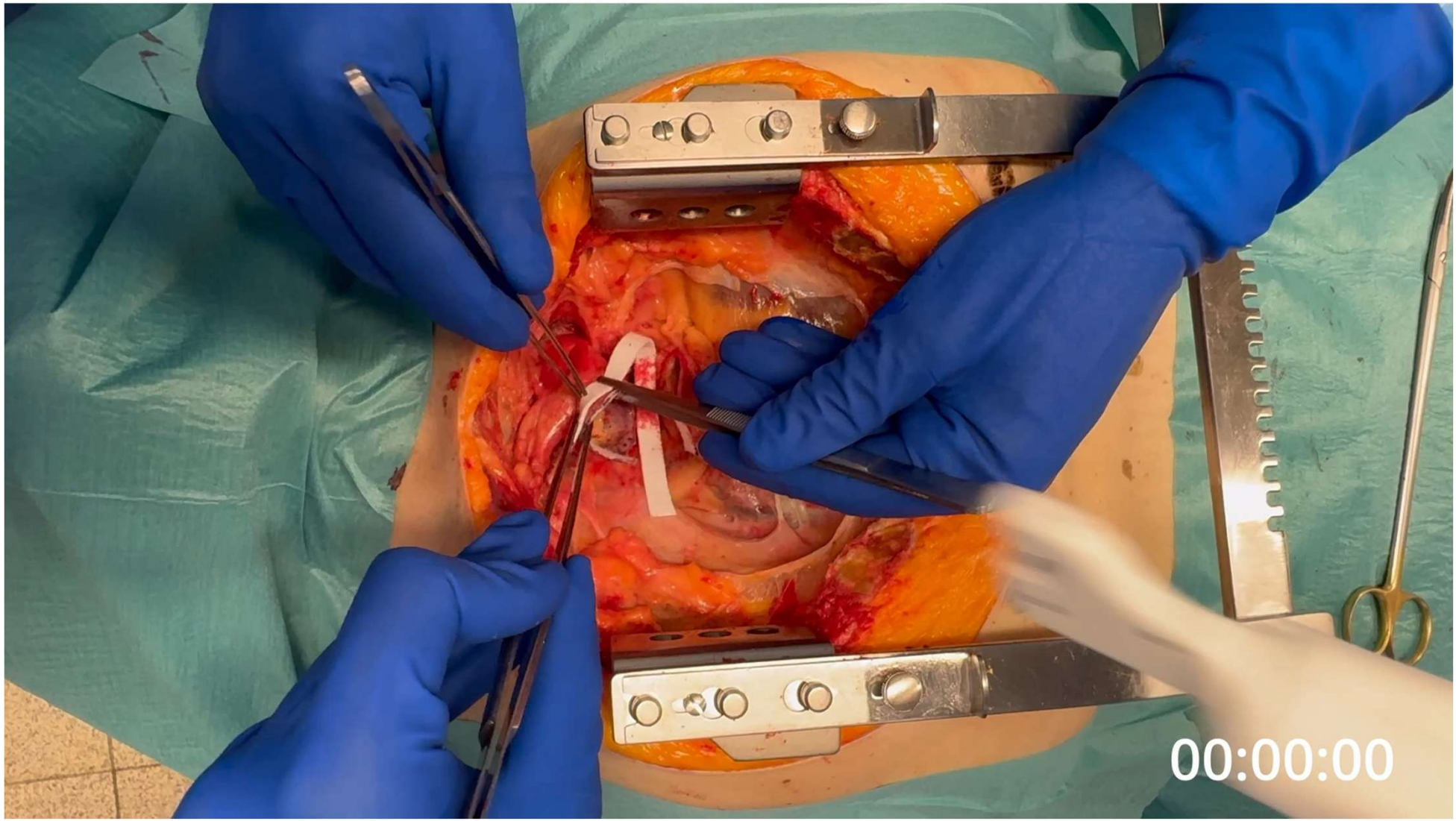
CADAVER STUDY

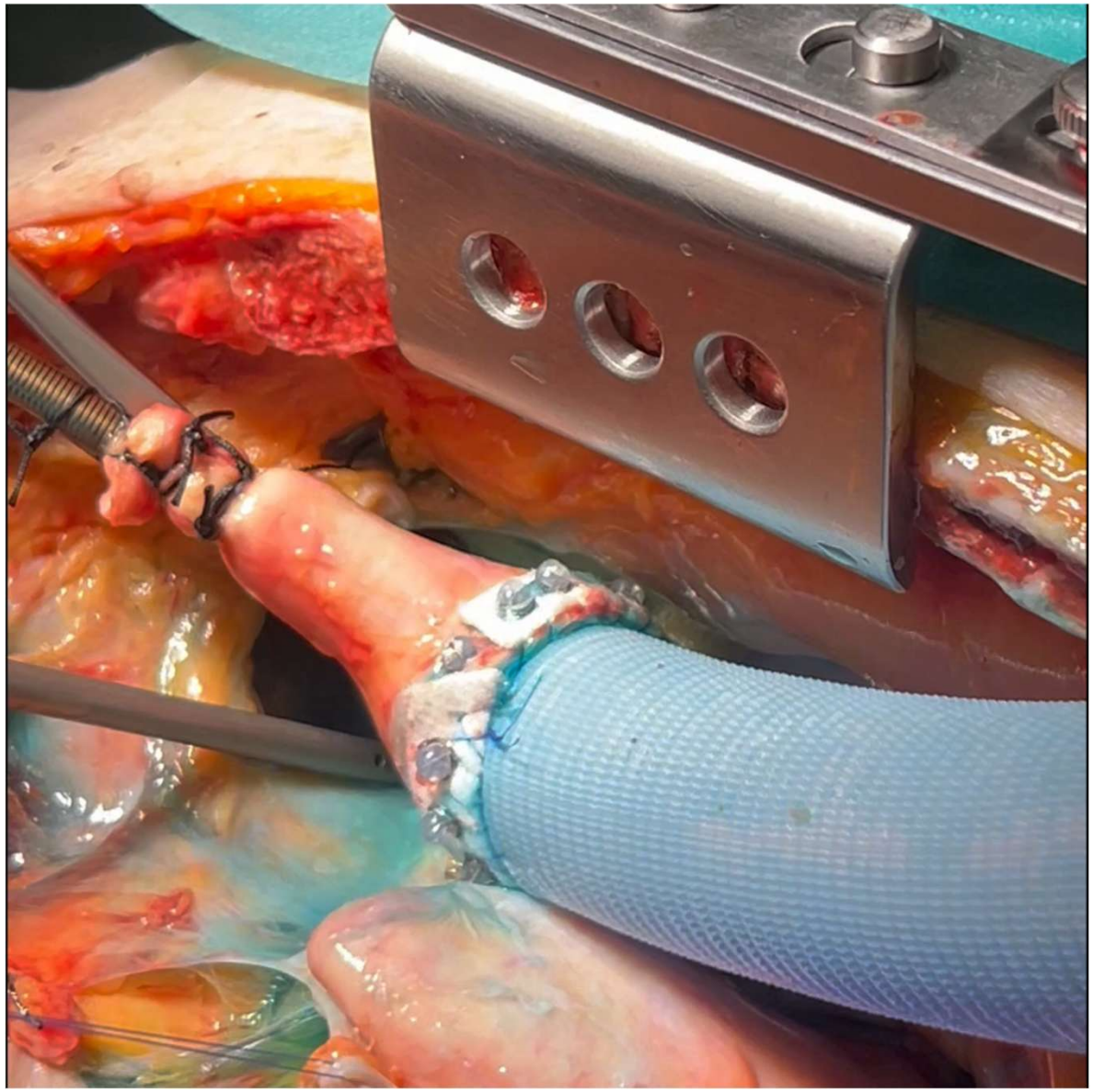
- 10 cadavers
- Iatrogenic creation of a 15 mm dissection (180°)
- 5 received sandwich with stapler – 5 conventional suture
- End-to-end anastomosis with Vascutek prosthesis
- Explantation of specimen
- Attachment to pressure pump for 5 minutes (160/90mmHg)
- Measurement of
  - Time for sandwich
  - Fluid loss
  - DANE
  - Progression of dissection





Procedure on Human Cadaver





Results Human Cadaver

All needles were deployed successfully

Mean time for the sandwich technique was 2:26 ± 00:42min device vs. 07:00±00:54min suture (p=0.008)

Fluid loss device 320±44.7ml vs. suture 398±212.8ml (p=n.s.)

NO DANE in the device group vs. two DANEs in the suture group

Suture group had 3 cases of false lumen perfusion vs. none in the device group

ADULT

Novel anastomotic device for the sandwich technique in type A aortic dissections: A human cadaver study

Emilio Osorio-Jaramillo, MD,[a] Jasmine El-Nashar, MD,[a,b] Ewald Unger, BE,[c] Paata Pruidze, MD,[b] Stefan Geyer, MD,[b] Thomas Poschner, MD,[a] Wilhelm Schreiner, BSc,[c] Wolfgang J. Weninger, MD,[b] Daniel Zimpfer, MD,[a] and Marek P. Ehrlich, MD[a]

ABSTRACT

Objective: To assess a new aortic anastomotic device for the repair of acute type A aortic dissection (ATAAD) designed to facilitate and expedite ATAAD repair, potentially minimizing the occurrence of distal anastomotic new entry (DANE) and progression of the disease.

Methods: Ten repairs were conducted in an iatrogenically induced ATAAD model using fresh human cadavers and the felt sandwich technique. Five were repaired with conventional 4-0 polypropylene, and 5 were repaired with the new device. With the device, pins were stapled circumferentially through the sandwich and fixed outside with a cap. The sandwich anastomosis was timed. The aortic arch and vascular prosthesis were explanted and connected to a pressure pump filled with glycerol/H_2O solution pressurized at 170/90 mm Hg over 5 minutes. Fluid loss was measured. The anastomoses were checked for DANE, false lumen perfusion (FLP), and dissection progression.

Results: Fifty-four pins (100%) were successfully deployed, with a median of 11 pins (interquartile range [IQR], 10-11.5) per cadaver. Sandwich median time was significantly shorter with the stapler (02:22 [IQR, 01:49-03:05] min/sec vs 06:40 [IQR, 06:23-07:47] min:sec; $P = .008$). The time for end-to-end anastomosis with the vascular prosthesis ($P = .31$), as well as measured fluid loss ($P = 1.00$), were similar in the 2 groups. The suture group showed DANE in 2 specimens, FLP in 3 specimens, and dissection progression in 1 specimen, whereas the stapler group showed none of these conditions. Microscopy showed tearing at stitch channels in all sutured samples and no tears in the stapler group ($P = .008$).

Conclusions: The new aortic anastomotic device was safe and faster than the conventional technique and may produce more homogeneous and stronger sealing, potentially reducing DANE through less tissue trauma. Further studies in humans are needed to confirm the potential benefits of this novel device. (J Thorac Cardiovasc Surg 2026;171:349-56)

Steps of the experiment.

CENTRAL MESSAGE

A novel aortic anastomotic device, designed to expedite and improve outcomes of acute type A aortic dissection repairs, was evaluated in a preliminary human cadaver study.

PERSPECTIVE

This novel aortic anastomotic device aims to expedite, facilitate, and improve the quality of acute type A aortic dissection repairs. Results from this preliminary proof-of-concept study suggest that it is simple and fast to use, but in vivo validation is needed.

Acute type A aortic dissection (ATAAD) repair remains a challenging procedure that necessitates circulatory arrest and reapposition of the dissected aortic layers.[1] Among various surgical techniques, a frequently used method is the so-called "sandwich" technique.[2] This approach uses either felt or pericardium to reinforce and readjust the dissected aortic wall layers, followed by the implantation of a vascular prosthesis to restore blood flow into the true lumen.

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The prototype development of the device tested in this study was supported in part by the Medical University of Vienna, the AWS (Promotional Bank of the Austrian Federal Government), and Aortic Technologies GmbH.

The Medical University of Vienna Ethics Review Board granted approval (no. EK1997/2024). The study was conducted in accordance with the principles of the Declaration of Helsinki. All individuals authorized the donation of their bodies providing written informed consent during their lifetime.

Read at the 105th Annual Meeting of The American Association for Thoracic Surgery, Seattle, Washington May 2-5, 2025.

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0022-5223

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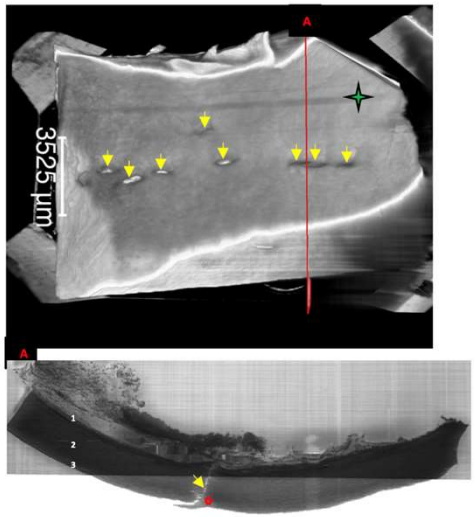
Published JTCVS

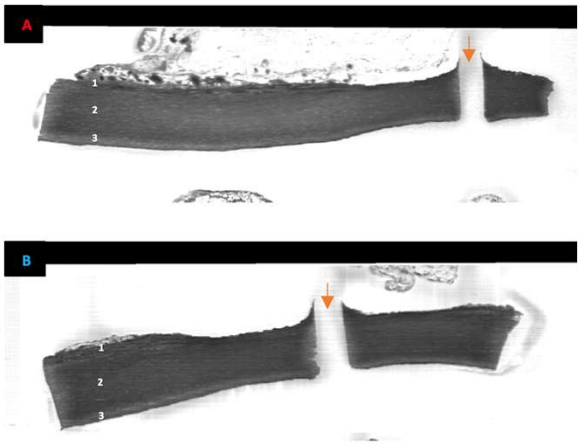
Two Major Benefits of the Device

- 80 – 90 % Reduction of surgical time

- Prevention of DANE and PANE

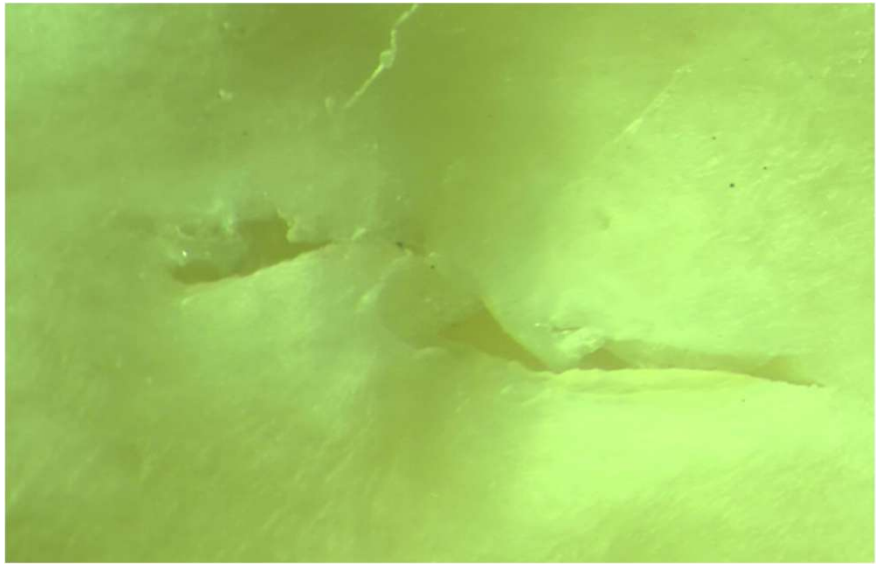


Micro tears at every suture hole

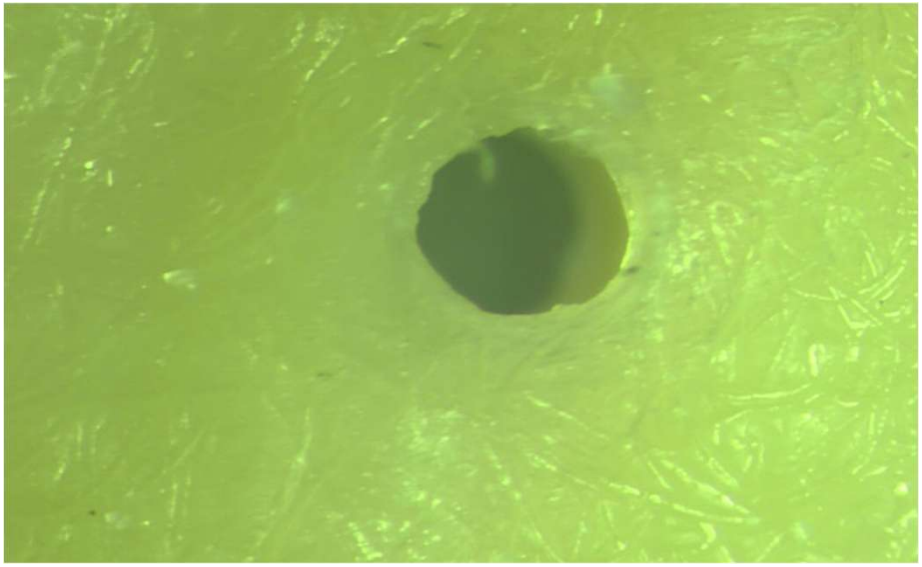


Straight channel with less traumatic properties

Electromicroscopy



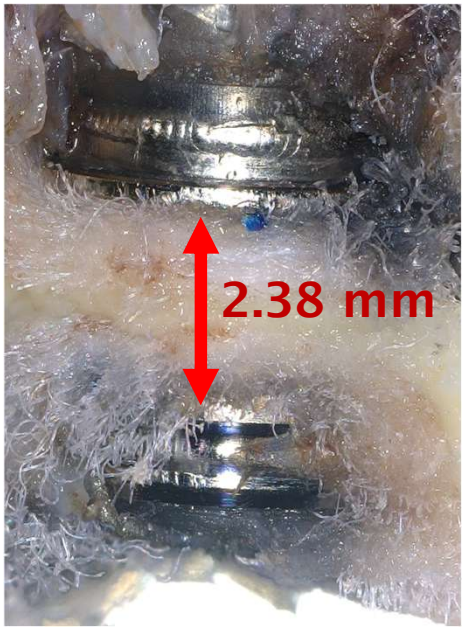
Micro tears at every suture hole



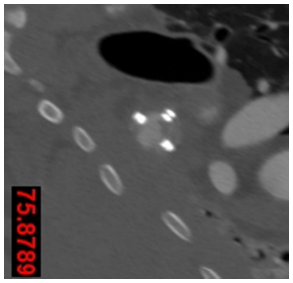
Straight chanel

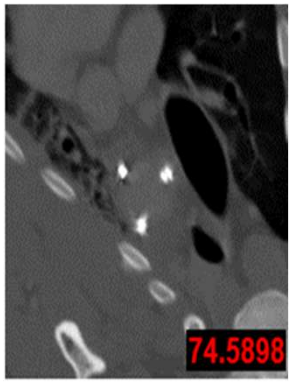
Chronic Animal Model – Seven animals with 3 month survival

3 months Survival Post mortem examination, CT Scan and Histology

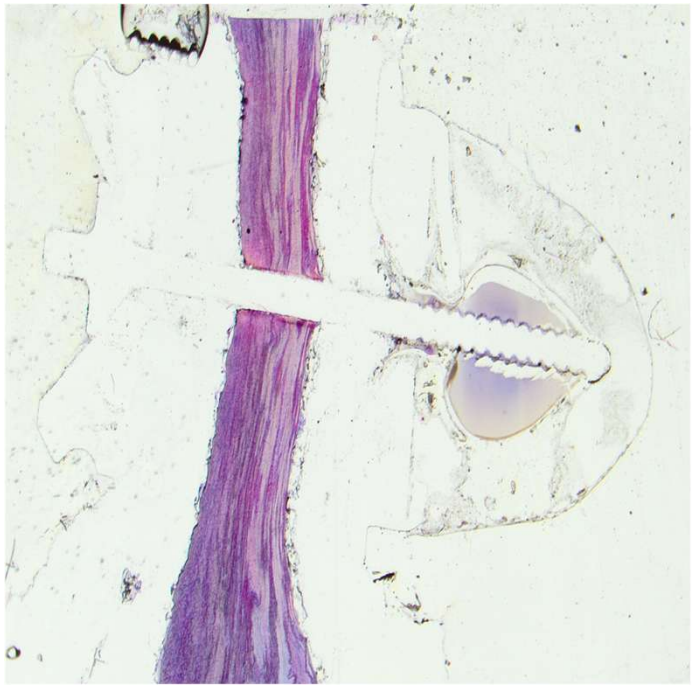


No dislodgement



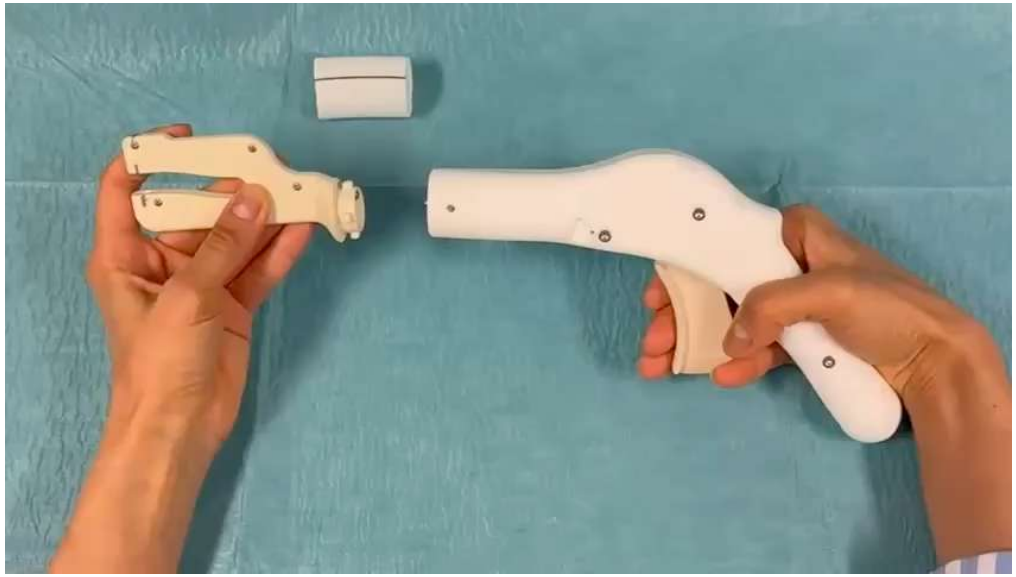


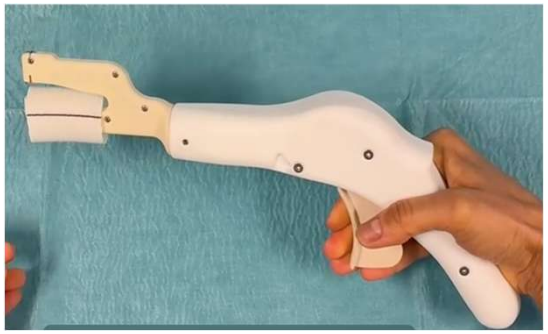
CT scan

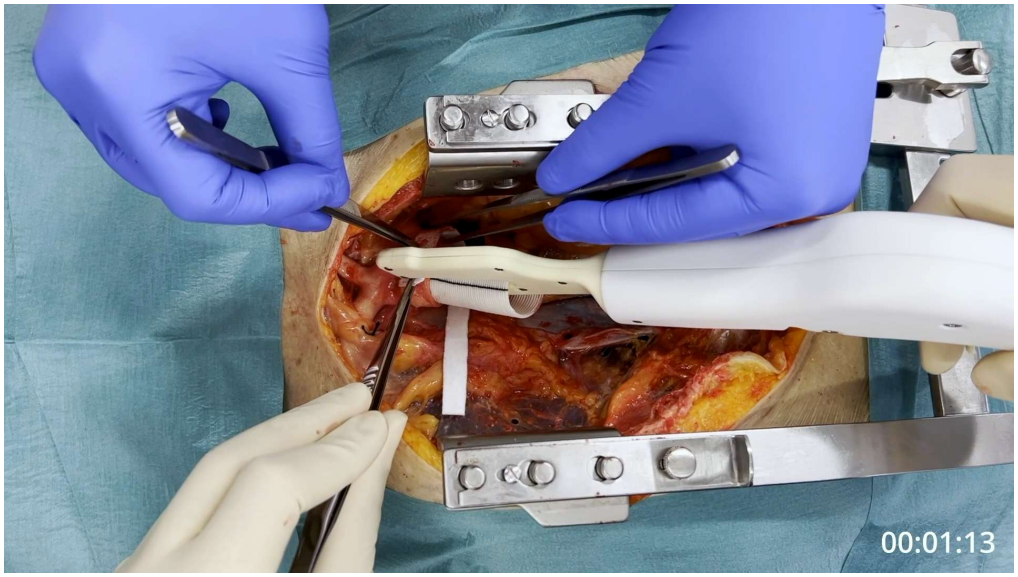


No signs
of inflammation or necrosis

Long-Head – End to End Anastomosis







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ORIGINAL ARTICLE

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CONVENTIONAL AORTIC SURGERY

A Novel Aortic End-to-End Anastomotic Stapler Device—Results of a Human Cadaver Study

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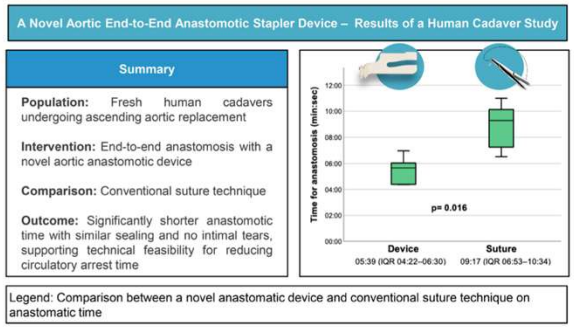
Graphical abstract



Published EJCTS

Meeting presentation: The abstract of this manuscript has been read at the 39th EACTS Annual Meeting, Copenhagen, Denmark, October

CONCLUSION

- STAR is a safe, simple and effective device in readapting felt and aortic wall in acute type A aortic dissections
- It reduces significantly surgical time in achiving the distal/proximal sandwich technique
- It reduced in an experimental setting Dane and dissection propagation by homogenous distribution of forces of the rivets
- It might become an additional helpful tool in the treatment of acute type A aortic dissection after FDA approval

Joseph Bavaria

Might become the Cor Knot for Aortic Surgery
EACTS 2025

THANK YOU


THE BEST WAY TO PREDICT THE
FUTURE IS TO INVENT IT.
Alan Kay / @InspiringThinkn