Long-term results after TEVAR with ML stents for Thoracoabdominal AD

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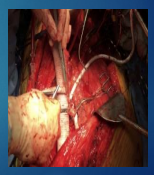
Surgical treatment- Type B Aortic Dissection

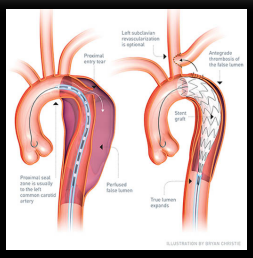
- While the gold standard treatment for Type A AD is open surgery, there is no consensus for the best treatment for TBAD or for residual thoracoabdominal dissections after surg ttt.

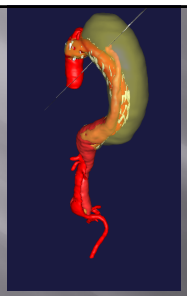
Recomandări pentru tratamentul disecției de aortă	Clasa*	Nivel*
La toți pacienții cu AD se recomandă tratament medical including antalgice și medicație pentru controlul tensiunii arteriale.	I	C
La pacienții cu AD tipul A se recomandă tratament chirurgical de urgență.	I	B
La pacienții cu AD tipul A și malperfuzie de organ se va lua în considerare o abordare terapeutică hibridă (ex. înlocuirea aortei ascendente și/sau a crosei aortei asociată cu procedură percutanată aortică sau la nivelul ramurilor arteriale emergente).	IIa	B
În AD tipul B necomplicată se recomandă întâmplarea terapiei medicamentoase.	I	C
În AD tipul B necomplicată se va considera TEVAR.	IIa	B
În AD tipul B complicată TEVAR este recomandată.	I	C
În AD tipul B complicată se poate lua în considerare tratamentul chirurgical.	IIb	C

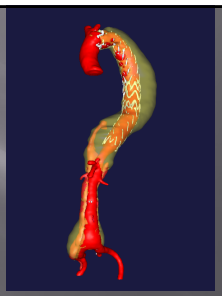
AAD = disecție acută de aortă, AD = disecție de aortă, TEVAR = reparare endovasculară a aortei toracice. *Clasa de recomandare; **Nivelul de evidență.



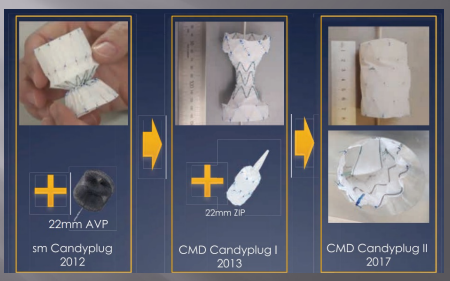
TEVAR for TBAD

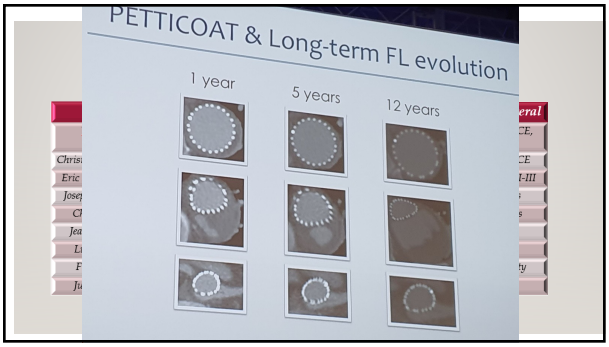


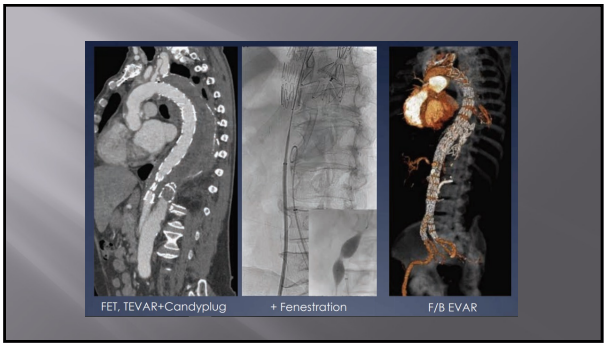




Aortic dilatation – common complication of TEVAR, 62.7% at 5y (IRAD)

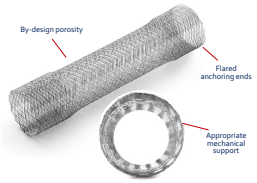






Device

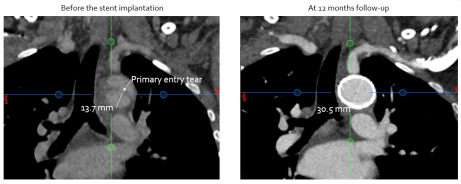
- MFM® multilayer stent, now called Allay™ Aortic Stent
- Open-mesh self-expanding stent technology designed to:
  - Provide extensive coverage of the dissected aorta
  - Reopening of the true lumen
  - Maintaining side branch patency even when overlapped



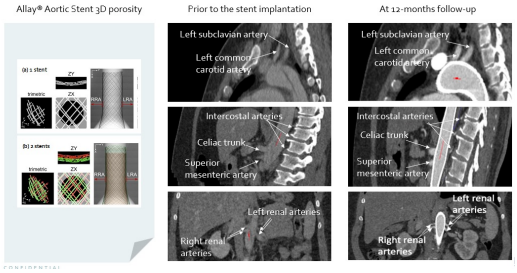
* The MFM® is an investigational device in aortic dissection

MLS - Mechanism of action

Mechanism of action: reopening the true lumen



Mechanism of action: maintaining side branch perfusion

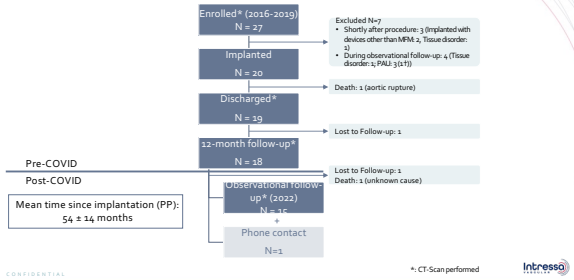


Results – MLS in TBAD

DRAGON Study (NCT03033771)

- Design: Prospective, multicenter, international, single-arm study
- Objective: Investigate the long-term safety and performance of multilayer stents in patients with TBAD
- Data Collection: After baseline assessment, patients were implanted with multilayer stents over the length of the **ENTIRE DISSECTED AORTA**
  After hospital discharge, patients attended follow-up visits at 1, 6 and 12 months, and annually thereafter (currently up to 6 years). During these visits, clinical evaluations and CT-scans were performed
- Analyses: Statistical analyses were performed independently from the Sponsor, including CT-Scan assessments by a US imaging core lab, based on pre-defined plans

Population – Patient Flow



*: CT-Scan performed

Results – Procedure (PP)

A mean of 2.5 aortic stents were implanted per patient, covering a total of 135 aortic branches (out of 152, 89%):

- 42 supra-aortic arteries
- 55 visceral arteries
- 38 renal arteries

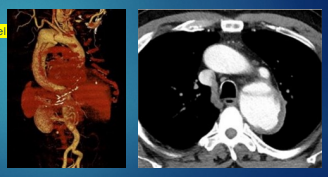
The stents covered the aortic segment from where lumbar and intercostal originate in 100% of the patients

Procedure was performed using standard endovascular techniques and resulted in high success rates:

- Technical success: 95%
  (1 incomplete stent opening without consequence nor AE)
- Procedural success: 90%
  (as above + 1 death)

Case report

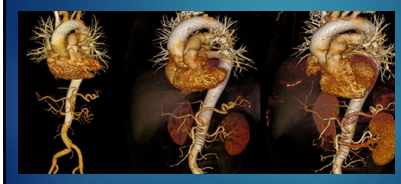
- 56-y/o hypertensive patient with complicated TBAD required TEVAR
- CTA: increase in false lumen with aneurysm formation distal from LSA to distal from RA, later expanding over the arch
- Max. true lumen compression at Th5 level

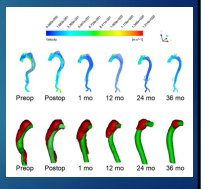


Aortic Remodeling After Total Endovascular Aortic Repair With Multilayer Stents: Computational Fluid Dynamics Analysis of Aortic Remodeling Over 3 Years of Follow-up

Case report

- Uneventful follow-up, proper tension control





Aortic Remodeling After Total Endovascular Aortic Repair With Multilayer Stents: Computational Fluid Dynamics Analysis of Aortic Remodeling Over 3 Years of Follow-up

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Aortic Remodeling After Total Endovascular Aortic Repair With Multilayer Stents: Computational Fluid Dynamics Analysis of Aortic Remodeling Over 3 Years of Follow-up

Costache VS, Yeung KK, Solomon C, Popa R, Melnic T, Sandu M, Bucurenciu C, Candea G, Santa A, Costache A.
JEVT. 2018 Dec. PMID: 30354915

Case Report

Aortic Remodeling After Total Endovascular Aortic Repair With Multilayer Stents: Computational Fluid Dynamics Analysis of Aortic Remodeling Over 3 Years of Follow-up

Victor S. Costache, MD, PhD[1], Kak K. Yeung, MD, PhD[2], Crina Solomon, MD, MSc[1], Radu Popa, MD[1], Tatiana Melnic, MD[1], Mihai Sandu[1], Cristian Bucurenciu[1], Gabriela Candea[1], Adrian Santa, MD[1], and Andreea Costache, MD[1]

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TEVAR with MLS at 8 years !!!

PETTICOAT & Long-term FL evolution

1 year 5 years 12 years

DRAGON Europe Study – Long-term results

90% Est. 5-year survival[1]	0% Neurological complications, no end-organ ischemia[2]	0% Aortic-related reintervention	0% Aortic rupture
95% Technical success	0% Stent failure[3]	79% Of the patients had stable or decreased transaortic diameter[4]	98% Maintenance of distal flow in branches[5]

1: Mean survival time of 69 months; 2: A mean of 2.3 aortic stents were implanted per patient, covering a total of 145 branches including 48 supra-aortic, 57 visceral and 40 renal arteries, 2 cases of loss of distal flow observed radiologically were not linked to any symptom of end-organ perfusion, 3: As related to stent migration, kinking, or loss of integrity; 4: Change in max transaortic diameter <5 mm over follow-up period; 5: 2 onsets of branch patency loss over 118 branches patent at baseline, as observed by independent core lab

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Intressa THERAPY

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One-Year Single-Center Results of the Multilayer Flow Modulator Stents for the Treatment of Type B Aortic Dissection.

Costache VS, Meekel JP, Costache A, Melnic T, Bucurenciu C, Chitic A, Candea G, Solomon C, Yeung KK.
JEVT. 2020 Sep. PMID: 32873130

Clinical Investigation

One-Year Single-Center Results of the Multilayer Flow Modulator Stents for the Treatment of Type B Aortic Dissection

Victor S. Costache, MD, PhD[1,2], Jorn P. Meekel, MD[1,3,4,5], Andreea Costache, MD[1,2], Tatiana Melnic, MD[1,2], Cristian Bucurenciu, MSc[1], Anca Chitic, MD[1,2], Gabriela Candea, PhD[1], Crina Solomon, MD, MSc[1], and Kak K. Yeung, MD, PhD[1,2,3,6]

NextCardio

In our series up to of 8 years follow-up, the MLS still proved to be a safe, feasible and effective alternative for treating complex aortic dissections

NO PARAPLEGIA OR STROKE

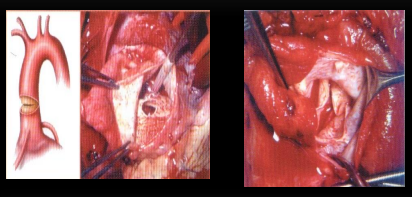
NO LOSS OF BRANCH PATENCY

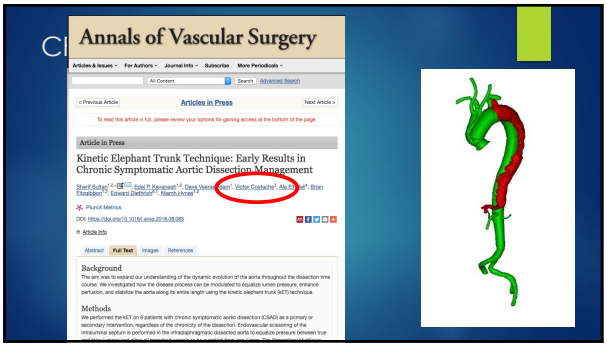
NO RUPTURE

NO DEVICE FAILURE

Results – MLS in Type A AD

TYPE A AORTIC DISSECTION – REPLACEMENT OF THE ASCENDING AORTA



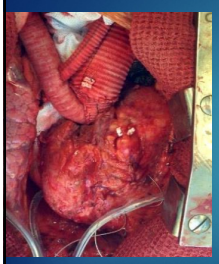


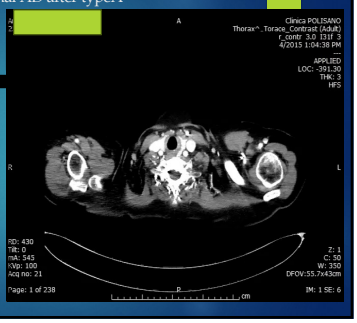
Type A

56-years-old, female

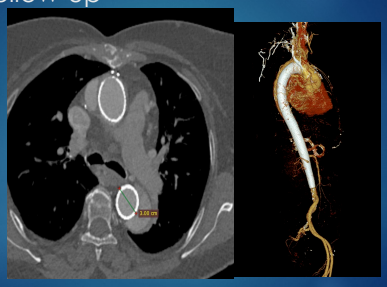
- Type A aortic dissection (01.2015)
- Ascending aorta and aortic arch replacement with Dacron nr.28 (01.2015)
- Redo of ascending (04.2015, Bentall)
- Hypertension grade III with high-risk

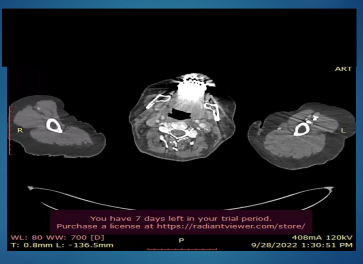
TEVAR for residual thoracoabdominal AD after typeA





7 years follow-up





MLS - PERSPECTIVES

PERSPECTIVES – Composite KET

GS, 47 years

- Type B Aortic Dissection - complicated
- Uncontrolled Hypertension
- Left Renal Ischemia; Renal Insufficiency
- Claudication less then 20 m (malpefusion)
- Obesity

Endovascular Procedure

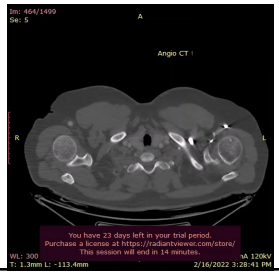
- Medtronic Valiant Thoracic Stentgraft 34 mm
- INTRESSA MLS (6) 25/180, 25/150, 35/120 mm
- Carotid-Subclavian Bypass with 7 mm Dacron

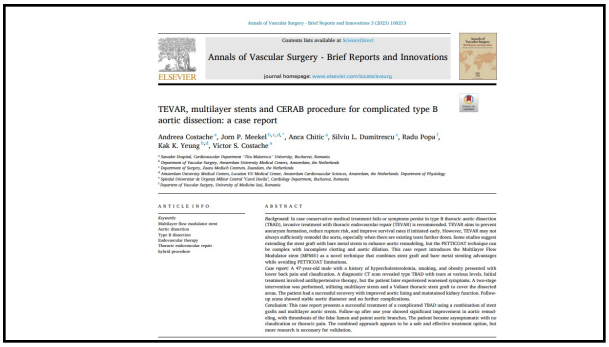
Endovascular Procedure

Endovascular Procedure

6 MONTHS F U Post-op CT

COMPOSITE KET at 2 years !!!!





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TEVAR, multilayer stents and CERAB procedure for complicated type B aortic dissection: a case report

Andreea Costache [a], Jorn P. Meekel [b,c,d], Anca Chitic [e], Silviu L. Dumitrescu [f], Radu Popa [f], Kak K. Yeung [b,d], Victor S. Costache [g]

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ARTICLE INFO

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Type B dissection
Type A dissection
Endovascular therapy
Thoracic endovascular repair
hybrid procedure

ABSTRACT

Background: In case conservative medical treatment fails or symptoms persist in type B thoracic aortic dissection (TBAD), invasive treatment with thoracic endovascular repair (TEVAR) is recommended. TEVAR aims to prevent aneurysm formation, reduce rupture risk, and improve survival rates if initiated early. However, TEVAR may not always sufficiently remodel the aorta, especially when there are existing tears further down. Some studies suggest that the addition of a multilayer flow modulator stents to enhance aortic remodeling, but the PETTICOAT technique can be complex with incomplete closing axial aortic dilation. This case report introduces the Multilayer Flow Modulator stent (MFMS) as a novel technique that combines stent graft and bare metal stenting advantages while avoiding PETTICOAT limitations.

Case report: A 47-year-old male with a history of hypercholesterolemia, smoking, and obesity presented with lower back pain and claudication. A diagnostic CT scan revealed type TBAD with tears at various levels. Initial treatment involved antihypertensive therapy, but the patient later experienced worsened symptoms. A two-stage intervention was performed, utilizing multilayer stents and a Valiant thoracic stent graft to cover the dissected areas. The patient had a successful recovery with improved aortic lining and maintained kidney function. Follow-up CT scans showed a 10 mm decrease in aortic diameter after 6 months.

Conclusion: This case report presents a successful treatment of a complicated TBAD using a combination of stent grafts and multilayer aortic stents. Follow-up after one year showed significant improvement in aortic remodeling, with thrombosis of the false lumen and patent aortic branches. The patient became asymptomatic with no claudication or thoracic pain. The combined approach appears to be a safe and effective treatment option, but more research is necessary for validation.

CONCLUSIONS

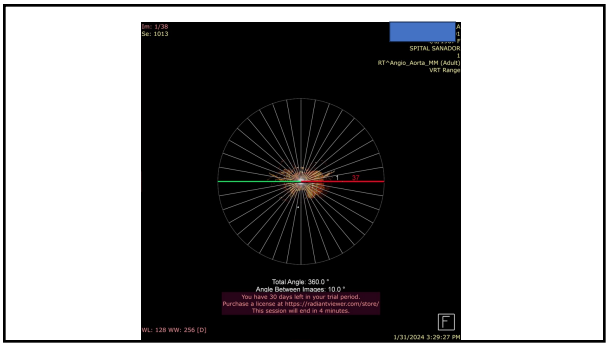
Long term clinical and CFD data confirm the durability of this new form of endovascular treatment for both complicated TBAD and residual AD after type A surgical repair

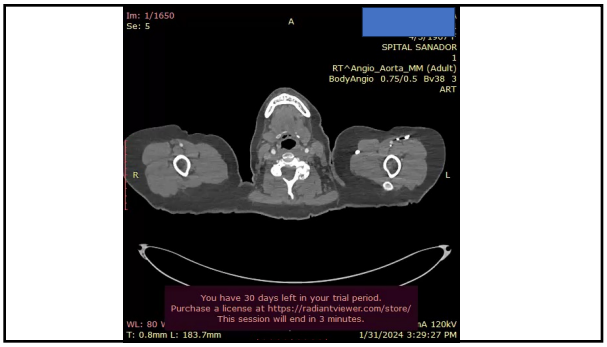
Faster aortic remodeling is achieved when combining MLS with stent grafts or FET hybrid grafts

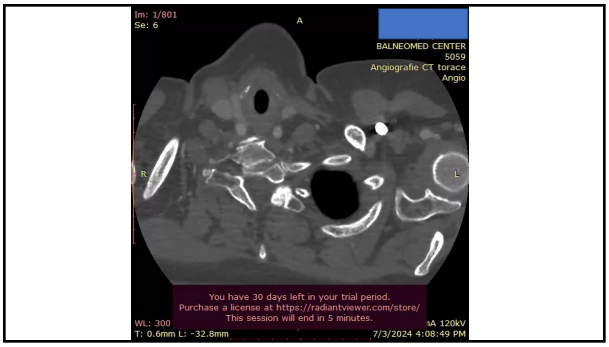
Further studies are needed to confirm the role of these new generation flow-modulating devices in the management of aortic dissection.

Thank you!

KET saving FET





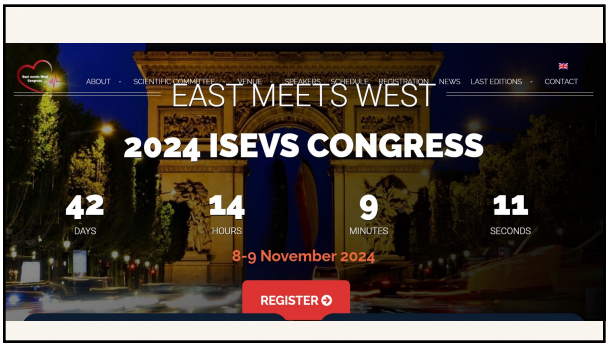


CONCLUZII

TEVAR cu ML stents este o procedura endovasculara rapida si cu o curba de invatare scurta asociata cu un traumatism operatoriu minim si fara complicatiile associate cu ttt chirurgical sau endovascular clasic (paraplegie, progresie anevrismala, insuficienta renala etc)

Datele clinic, imagistice si CFD confirma durabilitatea pe termen lung a rezultatelor obtinute

Studille clinic ulterioare vor confirma rolul acestor dispositive modulatoare de flux (izolat sau in combinatie cu FET sau stent graft) in tratamentul disectiei aortice



CONCLUSIONS

TEVAR with ML stents is associated with minimal operative trauma, also with a short endovascular intervention and reduced hospitalization period.

Long term clinical and CFD data confirm the durability of this new form of endovascular treatment

Further studies are needed to confirm the role of these new generation flow-modulating devices in the management of aortic dissection.

Long-Term Safety Outcomes of Patients with Type B Aortic Dissection Treated with Multilayer Stents: Results from a Prospective Multicenter Pilot Study

COSTACHE V[1], COSTACHE A[1], CHITIC A[1], STANKOV Z[2], PETROV P.
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Clinical article

- Single-center series of patients with type B aortic dissection treated with the MFM
- 23 patients (median age 53 years; 20 men)
- Complicated type B aortic dissections
- Primary endpoints:
  - Rupture or dissection-related death
  - Overall mortality
- Secondary outcomes:
  - Technical success
  - Adverse events
  - Aortic remodeling

One-Year Single-Center Results of the Multilayer Flow Modulator Stents for the Treatment of Type B Aortic Dissection.

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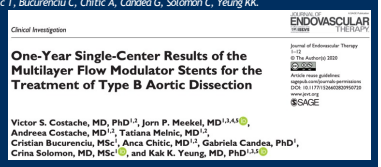
Clinical Investigation

One-Year Single-Center Results of the Multilayer Flow Modulator Stents for the Treatment of Type B Aortic Dissection

Victor S. Costache, MD, PhD[1,3], Jorn P. Meekel, MD[1,3,4,5], Andreea Costache, MD[1,2], Tatiana Melnic, MD[1,2], Cristian Bucurenciu, MSc[1], Anca Chitic, MD[1,2], Gabriela Candea, PhD[1], Crina Solomon, MD, MSc[1], and Kak K. Yeung, MD, PhD[1,3,5]

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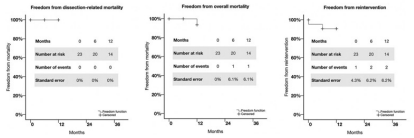
Clinical article

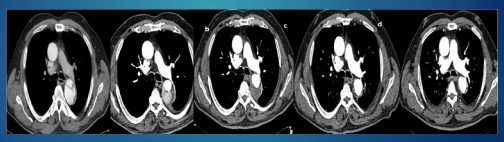
- Initial technical success was 91.3%.
- At 12 months:
  - 100% for freedom from rupture or aortic-related death
  - 95.7% for freedom from overall mortality
  - 91.3% for freedom from reintervention



One-Year Single-Center Results of the Multilayer Flow Modulator Stents for the Treatment of Type B Aortic Dissection.

Results - Summary

87.5% estimated 5-year survival	High technical and procedural success	No neurological complications, no end-organ ischemia, preserved aortic branch perfusion	No aortic-related reintervention	No device migration, kinking, or loss of integrity



preop | postop | 12 months | 24 months | 36 months