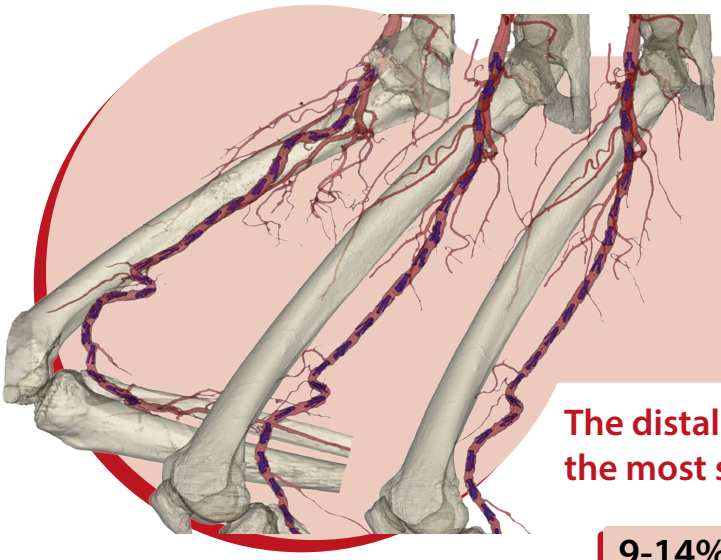
MIMICS[3D] Three-Year Subgroup Analysis

BioMimics[3D]

Why a Subgroup Analysis?

Stenting the distal SFA and proximal popliteal is traditionally associated with increased risk of reintervention and stent fracture.



BARE ARTERIES DURING KNEE-BENDING AND HIP FLEXION

	Mid-SFA	Distal SFA	Popliteal
70/20° (Shortening)	5%	14%	9%
90/90° (Shortening)	10%	23%	14%

The distal SFA and proximal popliteal segment demonstrated the most significant compression under flexion:[1]

9-14% compression while in walking position

14-23% compression during seated position

Cohort Lesion Characteristics[2]

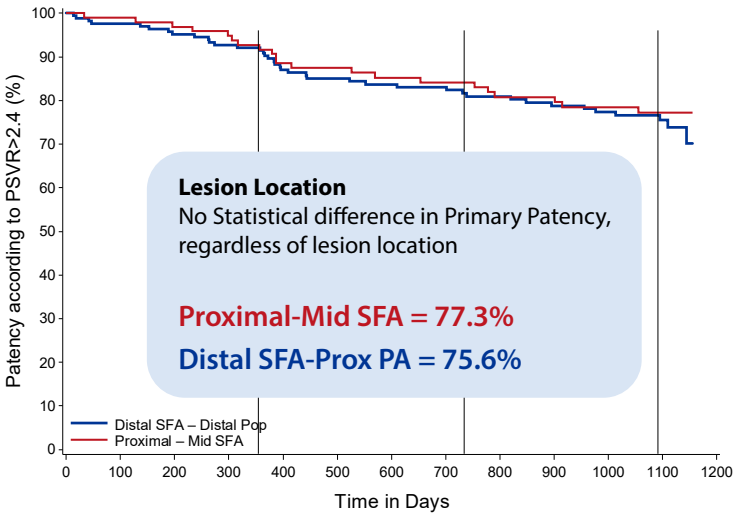
49.4% of lesions were **CTOs**

55.4% of lesions had **moderate to severe calcification**

7.98 cm **Avg. lesion length** in distal cohort

MIMICS3D Subgroup Analysis[2]

3-Year Primary Patency

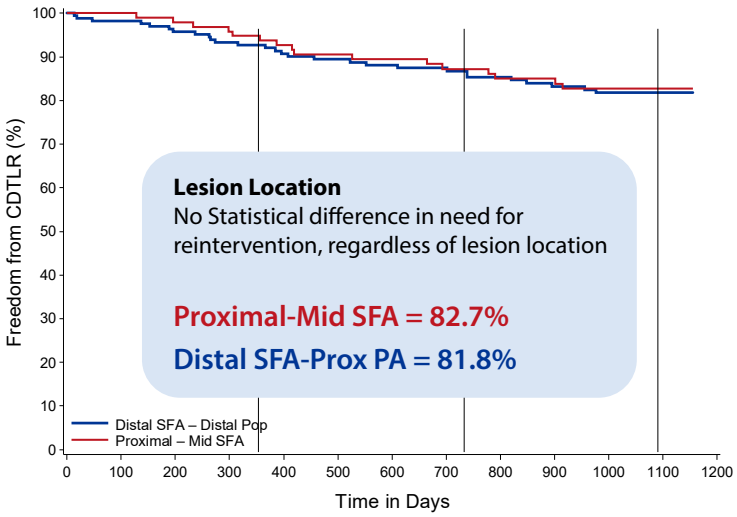


Lesion Location
No Statistical difference in Primary Patency, regardless of lesion location

Proximal-Mid SFA = 77.3%

Distal SFA-Prox PA = 75.6%

3-Year Freedom From CDTLR



Lesion Location
No Statistical difference in need for reintervention, regardless of lesion location

Proximal-Mid SFA = 82.7%

Distal SFA-Prox PA = 81.8%

Conclusions ▶

Conclusions[2]

Real world, prospective 500 patient registry with more complex patients and lesions demonstrating:

- 70.2% Freedom from Loss of Patency at 3 Years
- 78% Freedom from CDTLR at 3 Years
- Comparable outcomes to DES despite more challenging lesions

Subgroup analysis performed to determine differences in outcomes based on lesion location

- 35% of patients treated had lesions within distal SFA, extending to proximal P2
- 3 Year outcomes demonstrate:
  - No difference in Primary Patency between the cohorts
  - No difference in CDTLR between the cohorts
  - Low (<1.0%) stent fracture rate through 3-year follow-up in distal cohort

For additional information, please contact your local representative.

1. Smouse H, Nikanorov A, LaFlash D (2005) Endovasc Today 4:60–66
2. Data on File at Veryan Medical: MIMICS-3D database lock 07 Sept 2021

Contraindications, warnings, and precautions

CONTRAINDICATIONS

All customary contraindications for angioplasty must be considered when using the BioMimics 3D Vascular Stent System. There are additional contraindications:

- Patients whose lesions cannot be crossed with a wire and/or balloon catheter and cannot be dilated sufficiently to allow passage of the delivery system.
- Patients with known intolerance to antiplatelet and/or anticoagulation therapies.
- Patients who are judged to have a lesion that prevents proper placement or deployment of the stent.
- A lesion that is within an aneurysm or an aneurysm with a proximal or distal segment to the lesion.
- Patients with a known hypersensitivity to nickel, titanium or tantalum.

WARNINGS

General Warnings

- DO NOT use after the "use by" date specified on the label.
- DO NOT use if the sterile package is opened or damaged or any information provided is obscured.
- DO NOT use if the device is damaged or if the stent is partially deployed.
- DO NOT reuse the BioMimics 3D Stent Delivery System (SDS) – this may lead to infection, contamination and non-performance.
- DO NOT re-sterilize the BioMimics 3D Vascular Stent System.

Deployment Warnings

- DO NOT force passage if resistance is encountered at any time during delivery of the SDS. This may cause damage to the stent, the SDS, or vessel or may lead to partial deployment. If the stent cannot be deployed, remove the entire delivery system (a partially deployed stent may require surgical removal).
- DO NOT push or advance the SDS forward (distally) once stent deployment has commenced.
- DO NOT attempt to recapture a partially deployed stent using the stent delivery system.
- DO NOT force removal of the delivery system if resistance is encountered at any time during withdrawal (post stent deployment); instead hold the bifurcated Luer stationary and retract the inner shaft until the SDS tip contacts the outer sheath marker and withdraw the system as one unit. Applying excessive force could result in loss of delivery system components or damage to the stent, delivery system, or vessel.

PRECAUTIONS

- The SDS is not designed for use with power injection systems.
- Always use an introducer or guide sheath for the implant procedure, to protect the access site.
- Never post-dilate the stent using a balloon that is larger in diameter than the nominal (labeled) diameter of the stent.
- The minimally acceptable introducer or guide sheath size is printed on the package label. Do not attempt to pass the stent delivery system through a smaller size introducer or guide sheath than indicated on the label.
- Prior to deployment, ensure adeq uate distance between the proximal end of stent and the introducer/guide sheath to prevent deployment within introducer/ guide sheath.
- This device has not been tested in patients who are pregnant or patients who may be pregnant.
- Take caution when considering whether to use this device in a vessel in which there may be a residual stenosis of 50% diameter or larger in the target vessel after the planned intervention.
- In patients with poor kidney function, contrast agents may precipitate kidney failure.
- The stent is intended for use by physicians who have received appropriate training in endovascular intervention and placement of vascular stents.
- Failure to hold the Luer hub in a fixed position during stent deployment may result in partial or inaccurate deployment, incorrect deployed stent length or increased deployment forces.
- The reference vessel diameter should be measured accurately to reduce the possibility of stent migration or vessel damage due to incorrect sizing.
- The SDS is not intended for repositioning or recapturing a partially or completely deployed stent.
- If a second BioMimics 3D stent is required, deliver the most distal stent first to minimize the rish of stent dislodgement/damage or unsuccessful delivery of the second stent.
- If a second BioMimics 3D stent is placed in sequence and overlapped, the overlap should be less than 10mm. Overlapping more than two stents has not been evaluated.
- If the procedure requires additional non-BioMimics 3D stent placement, a nitinol stent should be selected. The risk of corrosion increases if stents of differing metals contact one another.
- Caution should be used when crossing the deployed stent with any ancillary devices.
- The BioMimics 3D SDS is not designed for guidewire exchanges. If a guidewire exchange is needed or desired, remove the delivery system first.
- Carefully inspect the sterile package and device prior to use to verify that neither has been damaged during shipment.
- The BioMimics 3D SDS is provided sterile for single use only and should be used by the end of the month of the "Use By" date printed on the package.
- After use the BioMimics 3D SDS is a potential biohazard. Handling and disposal should be in accordance with medical practice and local regulations.

The BioMimics 3D Vascular Stent System is FDA approved.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

PAM 309 Version 1.0

Veryan

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