Computational finite element analysis as a tool to predict in-vivo peripheral stent fatigue behaviour

POLITECNICO DI MILANO

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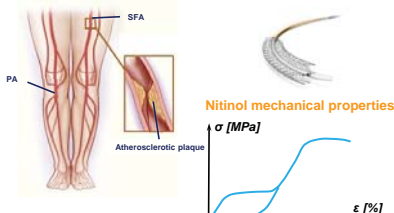
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Introduction

Peripheral artery disease (PAD)

Clinical treatment with Nitinol stent

SFA
PA
Atherosclerotic plaque

Nitinol mechanical properties

σ [MPa]
ε [%]

Open problem

Straight leg   *Flexed leg*

[Jonker, 2009]

Cyclic Multiaxial loads

Axial Compression
Bending
Torsion
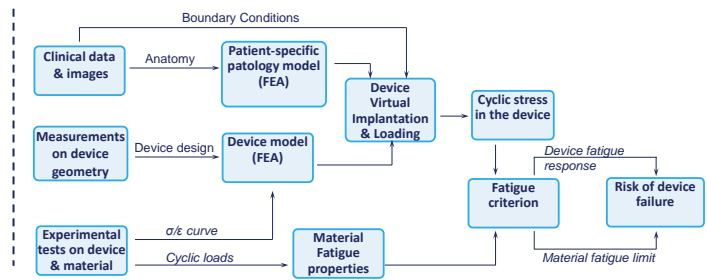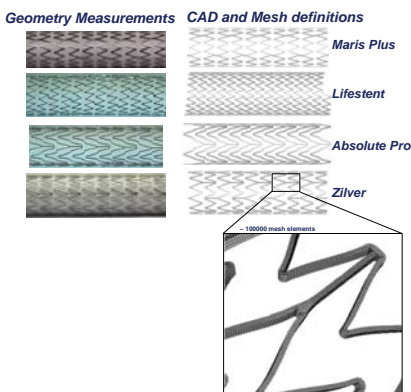Pinching
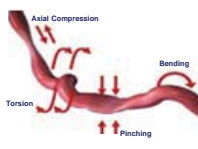
Nitinol stent success is undermined by **long-term fatigue failure**

Stent fracture may leads to in-stent restenosis

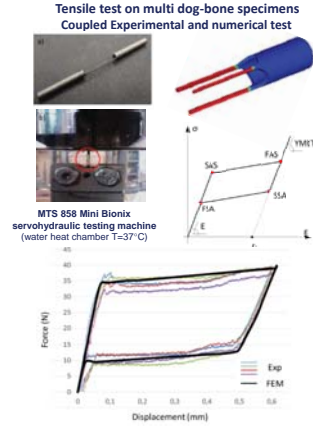### Predict in-vivo device fatigue behaviour

Boundary Conditions

| Clinical data & images | Anatomy | Patient-specific patology model (FEA) |
| Measurements on device geometry | Device design | Device model (FEA) |

Device Virtual Implantation & Loading → Cyclic stress in the device

Experimental tests on device & material — σ/ε curve → Material Fatigue properties

Cyclic loads

Fatigue criterion → Risk of device failure

Device fatigue response
Material fatigue limit

Stent Finite Element Model: What Do We Need?

3D accurate geometry reproduction

Geometry Measurements   CAD and Mesh definitions

Maris Plus
Lifestent
Absolute Pro
Zilver

~ 100000 mesh elements

Mechanical parameters evaluation

Tensile test on multi dog-bone specimens
Coupled Experimental and numerical test

MTS 858 Mini Bionix servohydraulic testing machine (water heat chamber T=37°C)

Force (N)
Displacement (mm)
Exp — FEM

Validation of the model static behaviour

Coupled Experimental and numerical test

Axial tensile test (80%)   Axial compression test (-20%)

Force (N)
Displacement (mm)
EXP — FEM
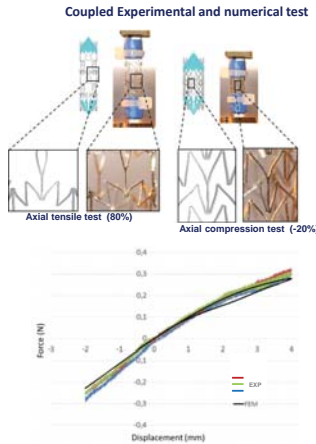
Fatigue characterization

Tensile test on multi dog-bone specimens

Crimping
Cyclic loads
Deployment

Constant life diagram for NiTi specimens for N=107

Von Mises alternate strain [%]
First principal mean strain[%]

Fracture probability
● 0%
● 33%
● 67%
● 100%
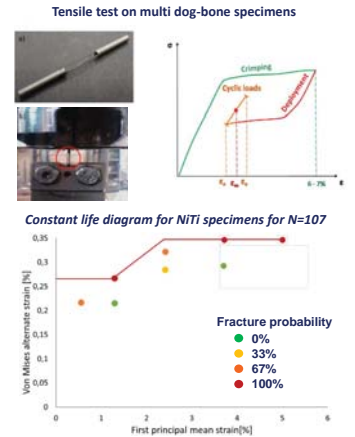
In-Vitro Fatigue Predictivity Validation: FE Analysis vs. Experimental Cyclic Test

Peripheral nitinol stents are subjected to cyclic multiaxial loading

bending/torsion/tension

Fatigue analysis highlights high risk of stent failure

Von Mises alternate strain
5.491e-03
4.942e-03
4.393e-03
3.844e-03
3.295e-03
2.746e-03
2.196e-03
1.647e-03
1.098e-03
5.491e-04
0.000e+00

Von Mises alternate strain
First principal mean strain

Experimental test on the stent under the same loads confirm the model predictivity in occurrence and location of the fracture
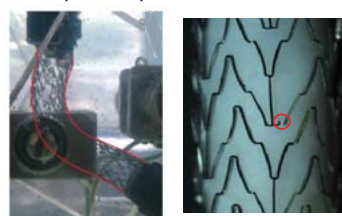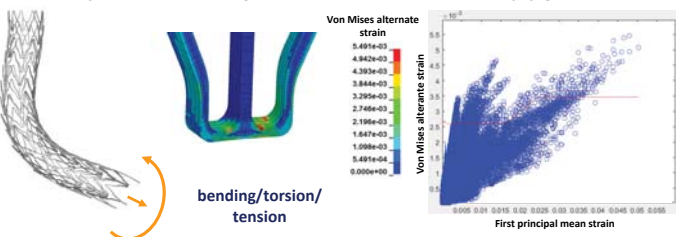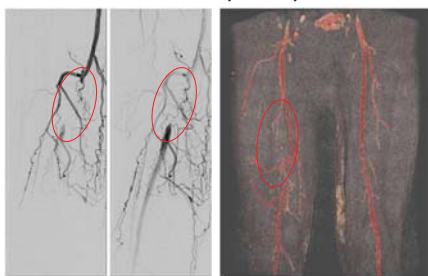
✓ **A model device-specific is mandatory to obtain reliable fatigue predictivity**
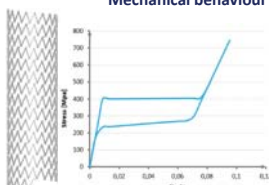
Model Application: A patient specific case study

Clinical data & images

Total occlusion of the superficial femoral artery clinically treated with a stent Lifestent
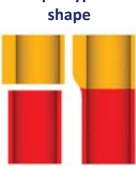
Angiographic images before treatment

Volume rendering of the thighs

Specific stent model

Mechanical behaviour

Stress [Mpa]
Strain

Specific boundary conditions

Placque type and shape

Loading conditions
Compression + Bending
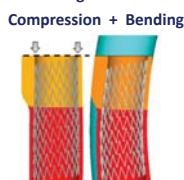
Comparative analysis between the stent FE model and the clinical follow-up

18 months follow-up

• stenotic vessel
• healthy vessel
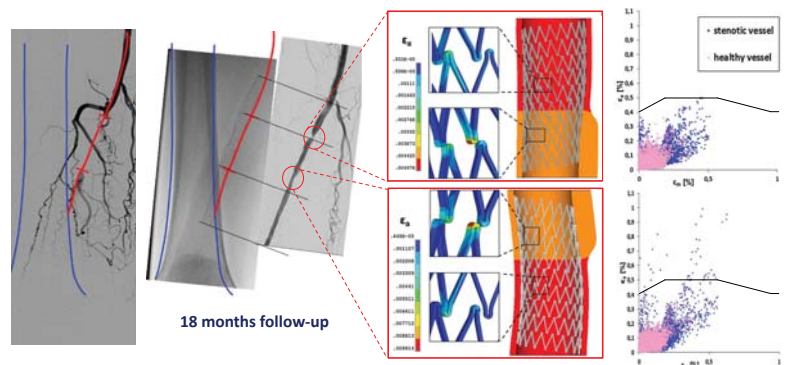
✓ **The model predicts an high risk of failure for the specific case according to the follow-up that evidences 2 stent fractures**

Clinical Application

Postoperative
Design patient-specific follow-up

Preoperative
Help physicians to choose the most appropriate stent for specific lesion