AN IMPROVEMENT IN THE ASSESSMENT OF MULTI-AXIAL FATIGUE BEHAVIOR OF NITINOL MEDICAL DEVICES

POLITECNICO MILANO 1863 — LaBS www.labsmech.polimi.it — MIT Massachusetts Institute of Technology — imes

Francesca Berti[1,2], Pei-Jiang Wang[2], Dario Allegretti[1], Carlo Guala[1], Francesco Migliavacca[1], Giancarlo Pennati[1], Gabriele Dubini[1], Elazer R Edelman[2] and Lorenza Petrini[3]

[1] LaBS, Chemistry, Materials and Chemical Engineering Department, Politecnico di Milano

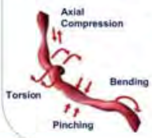
[2] Biomedical Engineering Center, Institute for Medical Engineering & Science, Massachusetts Institute of Technology, Cambridge, Massachusetts, USA

[3] Department of Civil and Environmental Engineering, Politecnico di Milano

INTRODUCTION

Occlusion of peripheral arteries

- ✓ Restore the original lumen area
- ✓ Give support to the vessel during healing



Cyclic loads e.g. leg movements

↓

Multi-axial & non-proportional state of stress and strain in the device

↓

Fatigue failure and other possible complications (e.g. in-stent-restenosis)

- ✓ Fatigue analysis is one of the requirements of regulatory bodies for the pre-clinical validation of stents
- ✓ In-vivo loading conditions are replicated in complex simulations

Predict in-vivo device fatigue behavior

Standard regulations **lack indications** for assessing:
- The **worst case scenario** for testing peripheral stents
- The most suitable **fatigue criterion** to be used for NiTinol

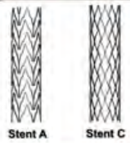
The commonly used fatigue **damage parameters** are the **first principal amplitude strain or the von Mises equivalent strain** vs the first principal mean one in a **constant life diagram** (Pelton et al. 2008, Runciman et al. 2011, Gokgol et al. 2015)

Recently, literature investigates **other approaches** more indicated for **multi-axial** and **non-proportional loads** (Auricchio et al. 2016, Marrey et al. 2018)

AIM: To analyse **different loading conditions** (combined axial, bending, torsion) to:
- Assess the **most dangerous** combination/loading action → **optimization** of the experimental campaign
- **Compare** the predictions of **different fatigue criteria** → selection of the **most suitable**

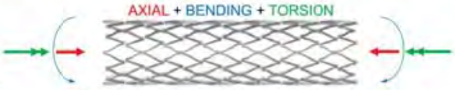
MATERIALS AND METHODS

Finite Element Models of two stents



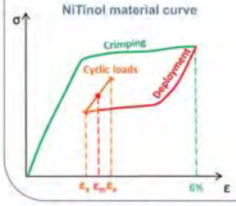
FE simulations of **different cyclic loading cases** applying **multi-axial BCs** after crimping and deployment ***

AXIAL + BENDING + TORSION



A=axial compression, B=bending, T=torsion, P=proportional, NP=non proportional, C=constant, I=counterphase

NiTinol material curve



Case 0 (P)		A, B, T	
Case 1 (NP)	A, B^C, T^C	A^C, B, T^C	A^C, B^C, T
Case 2 (NP)	A, B, T^C	A^C, B, T	A, B^C, T
Case 3 (NP)	A, B^I, T	A^I, B, T	A, B, T^I

***Crimping: 20% Axial + 4 mm radius Bending + 35°/cm Torsion

Deployment: 10% Axial + 7 mm radius Bending + 18°/cm Torsion

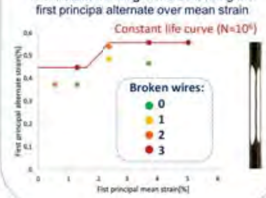
Cyclic load: 4% Axial + 20 mm radius Bending + 6°/cm Torsion

Experimental tests amplitude: P, P+3%, P+13%

NiTinol Fatigue Limit

The fatigue limit is obtained **experimentally** by varying *mean* and *amplitude* strain (10 Hz) on 3 wire dog-bone specimens with the **same dimensions and manufacturing treatments** of the stent struts (~200 μm)

A **constant life diagram** is built using the first principal alternate over mean strain



Comparison of different prediction fatigue criteria[1,2,3]

Criterion for proportional loadings based on equivalent strain

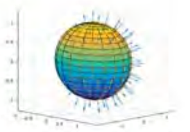
Von Mises Alternate Strain $$\varepsilon_a^{VM} = \frac{1}{(1+\nu)2\sqrt{2}} \cdot \sqrt{(\Delta\varepsilon_1 - \Delta\varepsilon_2)^2 + (\Delta\varepsilon_2 - \Delta\varepsilon_3)^2 + (\Delta\varepsilon_3 - \Delta\varepsilon_1)^2}$$

Criteria for non-proportional loadings based on the critical plane

Fatemi-Socie $$FS = \frac{\Delta\gamma_{max}}{2} \cdot \left(1 + K \cdot \frac{\sigma_{n,max}}{\sigma_y}\right)$$

Smith-Watson-Topper $$SWT = \sigma_{n,max} \cdot \frac{\Delta\varepsilon_{max}}{2}$$

Brown-Miller $$BM = \frac{\Delta\gamma_{max}}{2} + S\frac{\Delta\varepsilon_n}{2}$$

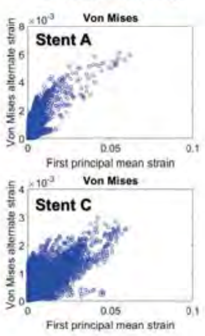


K,S are empirical constants

The Critical Plane in a polar coordinate system is where the stress responsible of the crack propagation takes the maximum value.

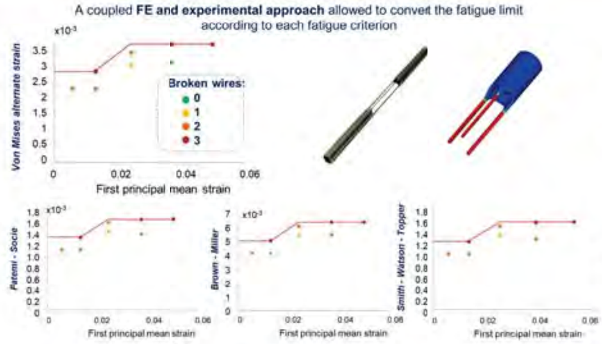
RESULTS

Effect of the design



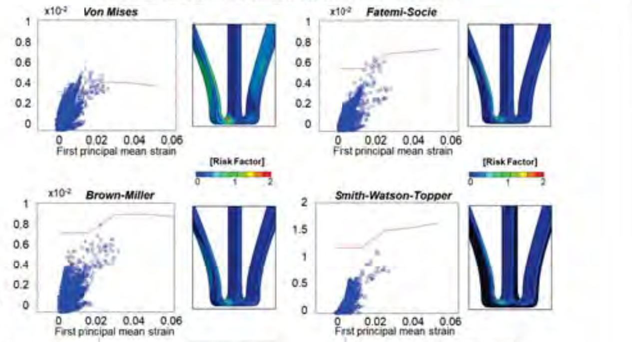
Fatigue limit according to each criterion

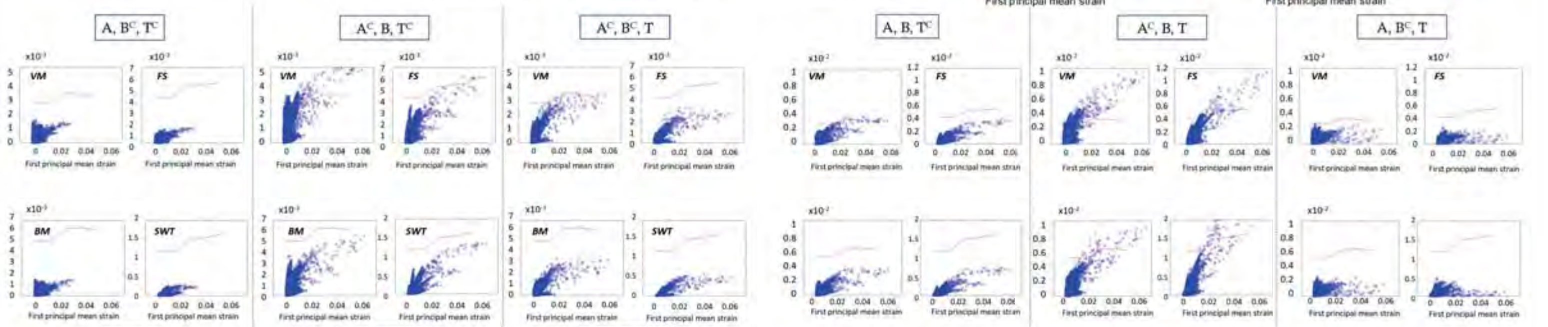
A coupled **FE and experimental approach** allowed to convert the fatigue limit according to each fatigue criterion

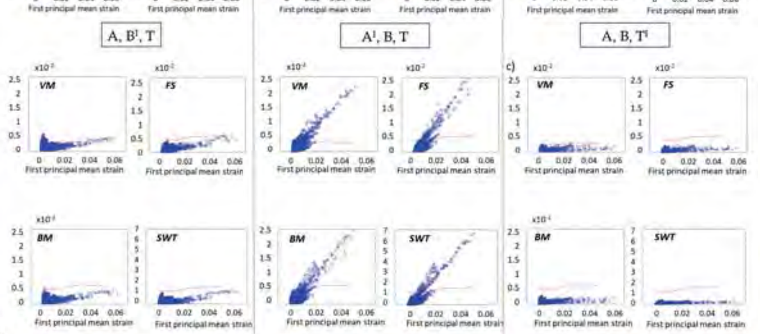


Stent A – Case 0, A B T

All the criteria predict the **same most critical** area of the stent



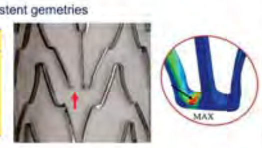




Preliminary FEA vs experimental campaign – Case 0

The model **predicts** the experimental fracture location in both the stent geometries

Stent A - FEA					EXP
Case	VM	FS (k=1)	BM (S=1)	SWT	
P	Fail	Fail	Safe	Safe	S-S
P+13%	Fail	Fail	Fail	Fail	F-F-F
P+3%	Fail	Fail	Fail	Border-safe	S-F-S-S



Sten C - FEA					EXP
Case	VM	FS (k=1)	BM (S=1)	SWT	
P	Fail	Fail	Safe	Safe	S-S
P+13%	Fail	Fail	Fail	Fail	F-F-F
P+3%	Fail	Fail	Fail	Border-safe	S-S

CONCLUSIONS

✓ A **counterphase axial** load results the **most critical** loading case

✓ **Brown-Miller** and **Smith-Watson-Topper** criteria seem to give the most accurate fatigue prediction whereas Von Mises equivalent strain and Fatemi-Socie criteria seems overestimate the risk of failure

- The methodology should be applied to more devices in different loading conditions.
- Others fatigue criteria (e.g. Dang Van) should be considered
- The fatigue limit curve is assessed through axial tests
- K and S are taken from literature

Contact address:
francesca.berti@polimi.it

References:
[1] Pelton et al. Rotary bending fatigue characteristics of medical-grade Nitinol wires. J Mech Behav Biomed Mater (2013)
[2] Mahtabi et al. Mean strain effects on the fatigue behavior of superelastic Nitinol alloys. An experimental investigation. Procedia Eng (2015)
[3] Allegretti et al. Fatigue Assessment of Nickel–Titanium Peripheral Stents: Comparison of Multi-Axial Fatigue Models. Shape Memory and Superelasticity (2018)