EVALUATION OF DIFFERENT MULTI-AXIAL FATIGUE CRITERIA FOR THE DURABILITY ASSESSMENT OF ENDOVASCULAR DEVICES

POLITECNICO MILANO 1863

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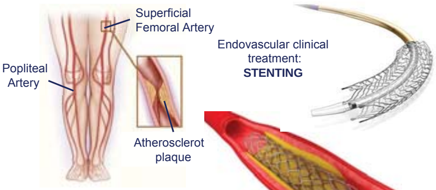
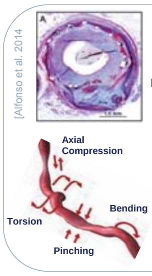
INTRODUCTION

Occlusion of peripheral arteries



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



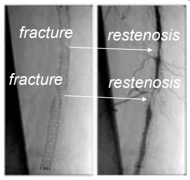
Cyclic loads
e.g. leg movements

↓

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

↓

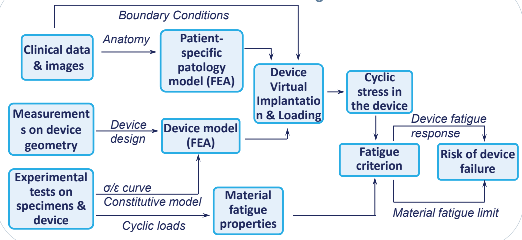
Fatigue failure and other possible complications (e.g. in-stent-restenosis)



[Scheinert et al. 2005]

- ✓ **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**

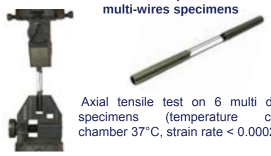
Predict in-vivo device fatigue behavior



MATERIALS AND METHODS

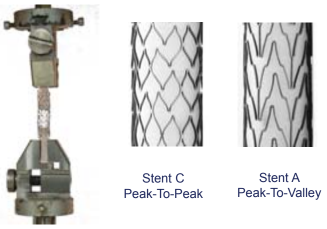
Experimental tests

Identification of material parameters on material multi-wires specimens



Axial tensile test on 6 multi dog-bone specimens (temperature controlled chamber 37°C, strain rate < 0.0002 sec^{-1})

Identification of devices static response



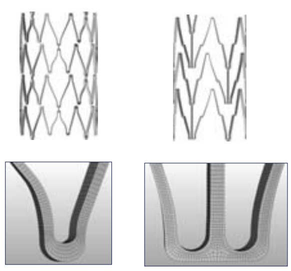
The stents are tested under traction and compression axial loadings (temperature controlled chamber at 37°C, strain rate < 0.0002 sec^{-1})

Finite Element models

Finite element analysis of the specimen geometry to obtain the set of parameters for the SMA constitutive **ANSYS** material

ANSYS

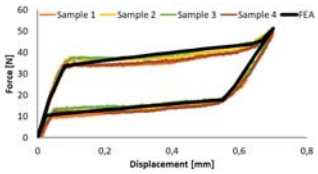
FE Stent C model **FE Stent A model**

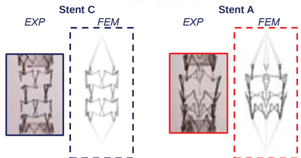


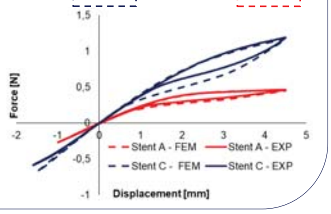
203600
8-node cubic elements

196890
8-node cubic elements

Numerical validation







Comparison of different prediction fatigue criteria[1,2]

Criterion for proportional loadings based on equivalent strain

Von Mises Alternate Strain

$$\varepsilon_a^{VM} = \frac{1}{(1+\eta)\sqrt{2}} \cdot \sqrt{(E_a^{xx}-E_a^{yy})^2 + (E_a^{yy}-E_a^{zz})^2 + (E_a^{zz}-E_a^{xx})^2}$$

Criteria for non-proportional loadings based on the critical plane

Fatemi-Socie

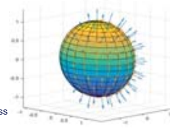
$$FS = \frac{\gamma_a^{max}}{2} \cdot \left(1 + K \cdot \frac{\sigma_{n,max}}{\sigma_y}\right)$$

Smith-Watson-Topper

$$SWT = \sigma_{n,max} \cdot \varepsilon_{max}^{a}$$

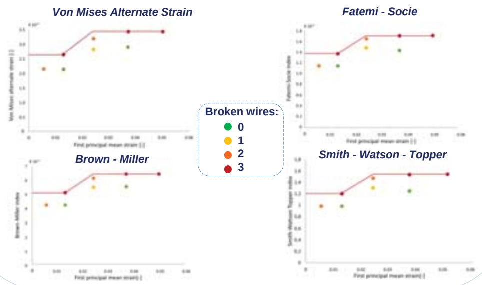
Brown-Miller

$$BM = \gamma_a^{max} + S\varepsilon_{max}^{a}$$



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

Material fatigue limit according to each fatigue criterion



RESULTS

Stent C

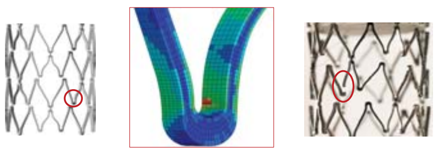
	Loading [mm]		Fatigue Criteria Prediction				Experimental Outcome
	Mean	Amplitude	VM	F-S	B-M	S-W-T	
(1)	2.25	0.25	P	P	P	P	-
(2)	2.3	0.3	B-F	P	P	P	-
(3)	2.425	0.425	F	F	P	P	2 exp (P-P)
(4)	2.5	0.5	F	F	B-F	B-P	3 exp (F-P-F)
(5)	2.525	0.525	F	F	F	B-F	2 exp (F-F)
(6)	2.6	0.6	F	F	F	F	2 exp (F-F)

B-M and S-W-T approaches seem to be more reliable in predicting experimental fatigue failure.

Stent A

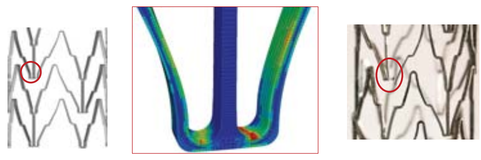
Loading [mm]		Fatigue Criteria Prediction				Experimental Outcome
Mean	Amplitude	VM	F-S	B-M	S-W-T	
1.65	0.15	P	P	P	P	-
1.75	0.25	B-F	P	P	P	-
1.85	0.35	F	B-F	P	P	2 exp (P-P)
1.9	0.4	F	F	P	P	3 exp (F-P-F)
1.95	0.45	F	F	B-F	B-F	2 exp (F-F)

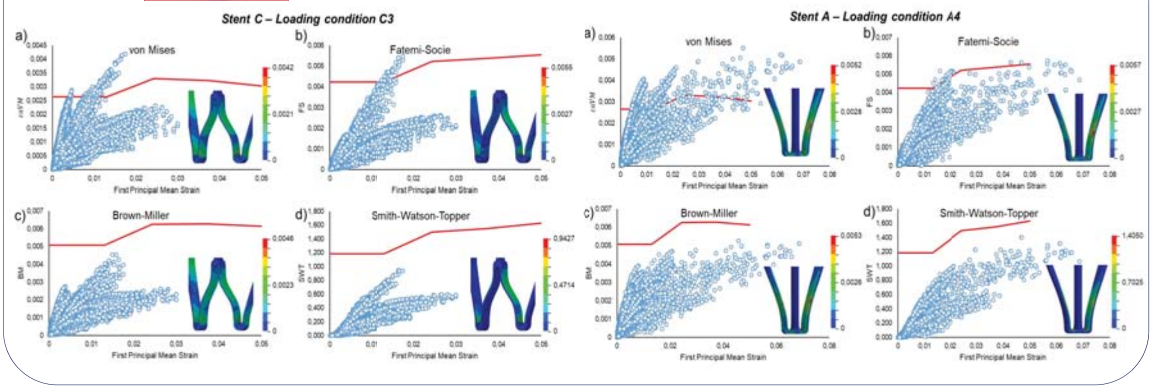
P=PASSED F=FAILED B-S=BORDERLINE PASSED B-F= BORDERLINE FAILED



Localization of the fracture

The model prediction agrees with the experimental failure

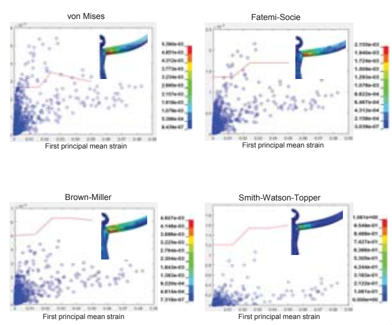




Extension on a different case study: NiTi stent frame of Aortic valve analysis

TAVI: Transcatheter Aortic Valve Implantation

In durability tests, the valve is implanted in a silicone compartment and subjected to cyclic blood pressure[3].



CONCLUSIONS

Possible applications:

- **INDUSTRY**
  Design & Optimization
- **ACADEMIA**
  Upgrade in the State of the Art
- **CLINICS**
  Postoperative follow-up
  Preoperative planning

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

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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 effect s on the fatigue behavior of superelastic Nitinol alloys. An experimental investigation. Procedia Eng (2015)
[3] Petrini et al. Simplified multistage computational approach to assess the fatigue behavior of a NiTi Transcatheter aortic valve during in vitro tests: a proof-of-concept study. J Med Device (2017)