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SCUOLA DI INGEGNERIA INDUSTRIALE E DELL'INFORMAZIONE

Executive Summary of the Thesis

Computational and Experimental Study for the Static and Fatigue Analysis of Nickel–Titanium Stents

Laurea Magistrale in Biomedical Engineering - Ingegneria Biomedica

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1. Introduction

Peripheral stents made of nickel-titanium (NiTi) alloy are today a widely used solution for the treatment of obstructive pathologies in peripheral vessels. The use of this alloy is particularly advantageous due to its unique properties of superelasticity and shape memory. These properties are guaranteed by the structure of the alloy itself. In shape memory alloys, indeed, the crystal lattice is not unique, but can assume two different configurations: austenite and martensite. The two phases have different crystalline structures and are stable within distinct temperature ranges. In particular, superelasticity is convenient for endovascular devices, as it allows for minimally invasive procedures and ensures durable mechanical performance [1].

Despite these benefits, such devices also present structural challenges: their small dimensions limit their mechanical strength, making them vulnerable to fatigue failure. During their operational life, stents are subjected to millions of load cycles caused both by the pulsatility of blood flow and by physiological body movements. These cyclic stresses promote the nucleation and propagation of fatigue cracks in localized areas of the structure, which can compromise the integrity and lead to device failure. For this reason, a thorough study of the mechanical behavior of NiTi stents is essential to ensure their reliability, safety, and clinical effectiveness. Preclinical evaluation is traditionally based on experimental tests aimed at characterizing the mechanical performance of stents. However, such procedures are often costly and time-consuming. The integration of computational analyses to support experimental testing therefore represents an effective strategy to describe operating conditions in greater detail, identify critical points, and optimize stent design.

2. Methodology

2.1. Experimental Approach

As part of the present work, uniaxial tensile tests were performed on NiTi stent specimens - featuring a closed-cell geometry, *X-struts*, and electropolished surfaces - using a servohydraulic testing machine *MTS 858 Mini Bionix* (*Material Testing System*, Minneapolis, MN). The machine consists of a movable upper part and a fixed lower part, both equipped with grips to hold the specimens, with adjustable contact pressure. The clamping system ensures that

the lower grips hold the base of a cylindrical mounting device. The specimen is inserted in the mounting and fixed using two specially designed C-clamps. In the case of the stent, two additional cylindrical support devices were used to allow a secure grip on the upper part and prevent slippage during testing.
The specimen was placed inside a plexiglass chamber filled with demineralized water through a hydraulic circuit, to maintain a constant temperature of 37 ± 1°C. The chamber was attached to the lower grip using a sealing patch to avoid water leakage. Water circulation was ensured by a *Watson-Marlow* peristaltic pump operating in fully occlusive mode at 400 rpm, while a *Julabo* heater located downstream allowed water to return by gravity, maintaining thermal control. The water temperature was constantly monitored using a *HT-9815* thermocouple, ensuring stable environmental conditions throughout the tests.
All tests were displacement-controlled, providing force–displacement (F–s) curves as output from the MTS machine. Both static and fatigue tests were performed. For the static tests, specimens were tested at displacement levels of 1 mm and 1.5 mm, and the corresponding F–s curves were recorded.
For fatigue tests, the main measured quantities were the preload and maximum force for each cycle; the full force–displacement curve of each cycle was not recorded. Maximum force values were collected at predetermined intervals of 100 cycles until specimen failure or the end of the test.
The loading protocol consisted of:

1. **Preload phase:** displacement-controlled at 0.01 mm/s, followed by unloading to the mean displacement of the test to simulate stent crimping. The preload value was set to 0.55 mm.
2. **Sinusoidal cyclic loading:** initially at 5 Hz for 1000 cycles, then at 10 Hz until failure, applied from the mean displacement. The cycle amplitude was defined according to test conditions. During the test, the machine monitored the minimum ($u_{\min}$) and maximum ($u_{\max}$) displacements, representing the reduction of stent diameter due to arterial motion and the maximum recovery of the diameter, respectively.

Three fatigue tests were conducted with a mean displacement of $u_{\text{mean}} = 0.40$ mm and an amplitude of $u_a = 0.08$ mm, based on values reported in previous studies.

2.2. Computational Approach

The computational analysis was based on a detailed reconstruction of stent specimens using image acquisition. Images were captured with a *Canon EOS 6D* digital camera and analyzed with the software *ImageJ* to obtain accurate measurements. Five stent specimens, nominally identical, were measured to evaluate two types of variability:

- **Intra-stent variability**: mainly related to production tolerances and errors, causing differences in dimensions and shapes within the same stent.
- **Inter-stent variability**: due to differences in manufacturing processes, such as laser cutting direction and other production parameters.

Measured parameters included:

- Stent diameter (upper and lower parts);
- Radii of curvature of the struts;
- Height and width of the struts;
- Strut thickness, especially at the connection points (*links*);
- Overall length of the specimen.

Based on the measurements, mean values and standard deviations were computed to create a representative CAD model in *SolidWorks* (Dassault Systèmes, Vélizy-Villacoublay, France). In particular, multiple CAD models were generated to capture geometric variability observed in the real stents, as reported in Table 1. The CAD reconstruction allowed precise modeling of a single X-strut, its replication according to the repetitive unit pattern, and wrapping onto a cylindrical surface.

	CAD_1	CAD_2	CAD_3	CAD_4	CAD_{agg}	Specimens
D_{ext}	13	13	12.72	12.72	13	13.05 ± 0.17
s	0.3	0.2	0.3	0.2	0.3	0.24 ± 0.03
r_1	0.3	0.3	0.3	0.3	0.35	0.35 ± 0.02
r_2	0.28	0.28	0.28	0.28	0.28	0.28 ± 0.02

Table 1: Reference CAD dimensions and mean ± standard deviation of real specimens (mm).

Finite element simulations were performed in *Abaqus* (*Dassault Systèmes Simulia, Providence*, RI, USA), with mesh generation in *HyperMesh* to ensure proper discretization of the complex stent geometry. Material properties were assigned based on experimental characterization and data available from previous studies, and boundary conditions were set to replicate operating conditions. Several computational simulations were performed by applying the same displacements imposed in the experimental tests, with the aim of comparing the resulting force–displacement curves. In order to achieve the correct CAD gripping configuration in *Abaqus*, several sensitivity analyses were also carried out to evaluate the effect of different boundary conditions and ensure a realistic representation of the experimental setup.

Mesh discretization was performed on a quarter of the X-strut, exploiting symmetry along longitudinal and circumferential axes. This approach significantly reduced computational cost without compromising simulation accuracy. The quarter mesh was subsequently duplicated and mirrored to obtain the full model.

Four mesh densities were generated:

- **Coarse mesh**: 3 elements along the width and 2 along the thickness;
- **Medium mesh**: 6 elements along the width and 4 along the thickness;
- **Fine mesh**: 12 elements along the width and 8 along the thickness;
- **Very fine mesh**: 24 elements along the width and 16 along the thickness.

2.3. Experimental-Computational Comparison

The experimental test results were compared with numerical simulations to validate the computational models. To achieve a reliable match between simulations and experiments, several sensitivity analyses were conducted. Initially, these analyses focused on identifying the gripping configuration in *Abaqus* that best represented the real experimental setup.

Different mesh densities were also evaluated: the coarse 3x2 mesh was found to be insufficiently accurate, while the fine 12x8 and very fine 24x16 meshes provided similar results but required significantly more computational time. Therefore, the medium 6x4 mesh was selected as the optimal compromise between accuracy and efficiency.

In addition to gripping conditions and mesh, the

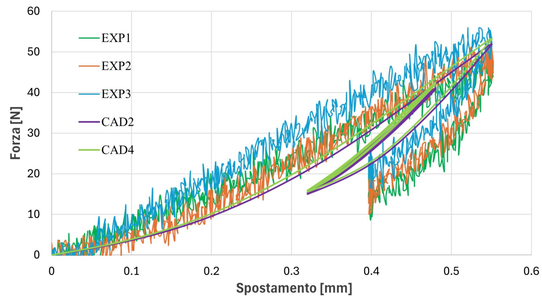


Figure 1: Comparison between computational and experimental fatigue tests.

CAD models differed in terms of dimensions. Simulations were performed to determine which CAD models most closely represented the real specimens. The two models CAD_2 and CAD_4 were identified as the most representative.

Once the appropriate gripping configuration, mesh, and representative CAD models were defined, the comparison between experimental and computational curves was carried out. This included both static tests and fatigue tests, considering *preload* values and force–displacement responses.

The result was a validated computational model capable of reliably reproducing the mechanical behavior of the real stent specimens.

3. Fatigue Criteria

Fatigue assessment in NiTi stents is challenging, as these devices are subjected to three-dimensional states of stress and strain, often non-proportional, due to both the complex geometry and the non-linear, asymmetric material behavior [2]. Even globally proportional loads can induce locally non-proportional responses.

Therefore, after defining representative CAD models and performing numerical simulations, the aim of the analysis is to convert the three-dimensional tensorial information obtained from the simulation into a scalar damage index, which can be compared with limit curves obtained from uniaxial tests. In the study, four fatigue criteria were employed to evaluate fatigue indices (*Fatigue Index*, FI) and compare them with experimental limit lines, highlighting how different mechanical quantities can provide different predictions of failure.

The Von Mises (VM) criterion uses the equivalent alternating strain as the fatigue index, computed from the variations of the principal strains

$(\Delta\varepsilon_1, \Delta\varepsilon_2, \Delta\varepsilon_3)$ [2]:

$$\mathrm{VM} = \frac{1}{2\sqrt{2(1+\nu)}} \begin{bmatrix} (\Delta\varepsilon_1 - \Delta\varepsilon_2)^2 \\ + (\Delta\varepsilon_2 - \Delta\varepsilon_3)^2 \\ + (\Delta\varepsilon_3 - \Delta\varepsilon_1)^2 \end{bmatrix}^{1/2} \tag{1}$$

where ν is the Poisson ratio. This criterion is simple to implement but can be overly conservative under multiaxial and non-proportional loading. To overcome these limitations, criteria based on the critical plane concept are used, identifying the material plane where a mechanical quantity reaches its maximum during the loading cycle [1].
The Fatemi–Socie (FS) criterion accounts for the maximum shear strain and the maximum normal stress on the critical plane:

$$\mathrm{FS} = \frac{\Delta\gamma_{\max}}{2}\left(1 + k\frac{\sigma_{n,\max}}{G\Delta\gamma}\right) \tag{2}$$

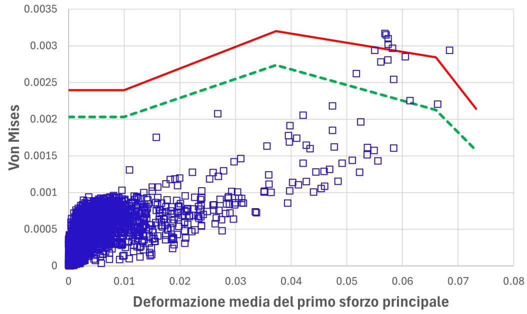
where $\Delta\gamma_{\max}/2$ is the maximum shear strain, $\sigma_{n,\max}$ is the maximum normal stress, G is the shear modulus, and k is an empirical factor.
The Brown–Miller (BM) criterion combines shear and normal strains:

$$\mathrm{BM} = \frac{\Delta\gamma_{\max}}{2} + S\frac{\Delta\varepsilon_n}{2} \tag{3}$$

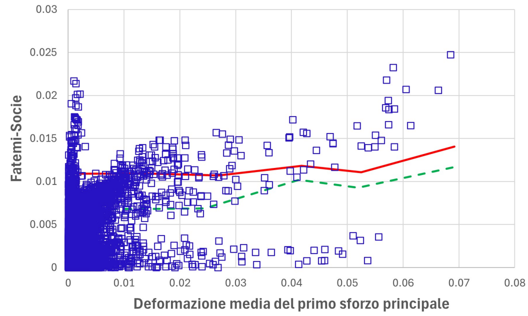
Finally, the Smith–Watson–Topper (SWT) criterion defines the fatigue index as the product of the maximum normal stress and the amplitude of normal strain:

$$\mathrm{SWT} = \sigma_{n,\max} \cdot \frac{\Delta\varepsilon_n}{2} \tag{4}$$

From the numerical simulations in *Abaqus*, stress and strain tensors were extracted at the element centroids of the stent structure. The MATLAB code was applied to the preload simulations performed on CAD_2 and CAD_4 models, with the corresponding F–s curves reported in Figure 1. The script then computed the fatigue indices for each criterion, generating *constant-life diagrams* where each element corresponds to a representative point.
Experimental limit curves were obtained from uniaxial tests and compared with the FI distribution, identifying critical conditions (points above the failure curve) and safe regions.



(a)



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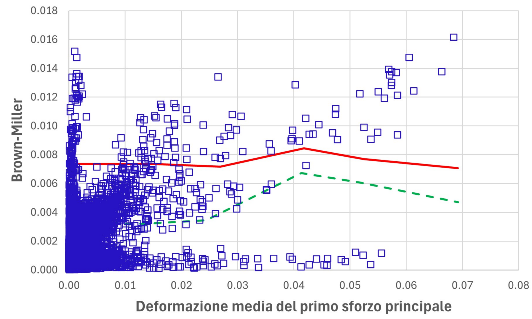

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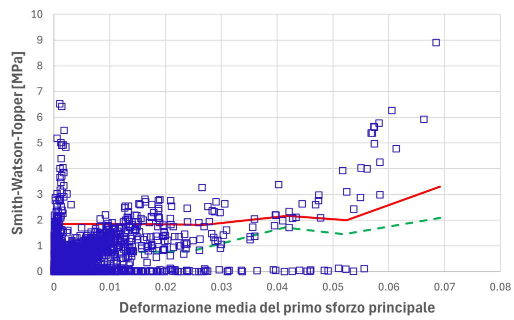

(d)

Figure 2: Results of different fatigue criteria for CAD_2 : the point clouds are compared with the fracture and safety curves obtained by interpolating the fatigue test results on custom multi-wire specimens.

4. Results

The experimental campaigns allowed the analysis of force–displacement diagrams obtained under different loading conditions, both static and fatigue, providing a detailed characterization of stent behavior *in vitro*, although limited to uniaxial loading.
The main objective of this study was to compare experimental and numerical results, aiming to identify a computational model capable of predicting the behavior of NiTi stents with closed-cell geometry and electropolished surfaces. CAD modeling in *SolidWorks*, followed by finite element simulations in *Abaqus*, enabled a direct comparison between computational and laboratory data. This approach led to the identification of computational models that satisfactorily reproduce the experimental observations.
Regarding fatigue curve comparisons (Figure 1), the simulations for CAD_2 and CAD_4 adequately reproduce the average trend of the experimental tests, especially during the initial loading phase. A slight underestimation of stiffness is observed in the central part of the curve for CAD_4, whereas CAD_2 shows a closer match. Both models converge toward the experimental values at the final displacement. Differences are likely due to simplifications in boundary conditions, material modeling, and the absence of certain non-linearities present in the experimental setup.
Fatigue analysis, based on fatigue criteria, was performed using a MATLAB code, which allowed calculation of the percentages of elements above the failure line (elements at risk of fracture), below the safe line (elements without risk), and between the two lines. The normalized risk factor (RF), defined as the ratio between each element's fatigue index and the corresponding value of the material limit curve at the same strain, was also computed. An RF greater than 1 identifies potentially critical conditions. Maximum RF values were used as a reference for classification.
Literature results [3] indicate that critical-plane-based criteria, particularly BM and SWT, provide more reliable predictions under realistic multiaxial loading (axial compression, torsion, bending) than the Von Mises criterion, despite different assumptions regarding crack nucleation. This trend is confirmed in the present analysis for CAD_2 and CAD_4.
Constant-life diagrams show that FS, BM, and SWT indices are consistent with experimental results, whereas Von Mises provides more conservative or less accurate predictions. While VM can be used for preliminary fatigue safety assessment, it is not precise enough for detailed cyclic load analyses. In addition, it should be emphasized that the FS and BM indices depend on the empirical constants k and S, which were assumed equal to one in the absence of experimental data; predictions could vary if different values were available.

5. Conclusions

This work demonstrated that properly calibrated computational models of NiTi stents can reliably reproduce the average experimental behavior, providing a valuable tool for predicting device performance. Fatigue analysis using critical-plane-based criteria (FS, BM, SWT) showed good agreement with experimental results, whereas the Von Mises criterion may offer less accurate predictions.
For further developments, the following improvements are suggested:

- Increase the number of specimens analyzed, including samples of different configurations, to enable statistical processing of results for both static and fatigue characterization.
- Introduce tests under non-proportional loading conditions, such as bending, torsion, and compression, to better replicate physiological stresses.
- Consider additional critical-plane-based fatigue criteria and appropriately characterize the influence of empirical parameters k and S through experimental tests under bending and torsion [2].
- Refine the MATLAB code used for critical-plane calculation and fatigue criteria application. Currently, the software is designed for post-processing results from 3D hexahedral element simulations; optimizing the code could significantly reduce computation time and improve efficiency.
- Develop faster numerical simulations to allow testing of multiple configurations in shorter time. This could be achieved by using lighter yet accurate meshes or

by streamlining and optimizing the post-processing code.

Overall, these improvements would increase the reliability and efficiency of computational predictions and support more effective design and evaluation of NiTi stents.

References

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