A computational approach based on a multiaxial fatigue criterion combining phase transformation and shakedown response for the fatigue life assessment of Nitinol stents

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Abstract
Self-expanding stents made of Nitinol, a Nickel–Titanium shape memory alloy, are used in standard medical implants for the treatment of cardiovascular diseases. Despite the increasing success, clinical studies have reported stent failure after the deployment in the human body, thus undermining patient's safety and life. This study aims to fill the gap of reliable assessment of the fatigue life of Nitinol stents. We propose a global computational design method for preclinical validation of Nitinol stents, which can be extended to patient-specific computations. The proposed methodology is composed of a mechanical finite element analysis and a fatigue analysis. The latter analysis is based on a novel multiaxial fatigue criterion of the Dang Van type, combining the shakedown response of the stent and the complexity of phase transformation taking place within the material. The method is implemented in the case of a carotid artery stent. The implant configuration as well as the applied cyclic loading are shown to affect material phase evolution as well as stent lifetime. The comparison with the results obtained by applying a strain-based constant-life diagram approach allows to critically discuss both fatigue criteria and to provide useful recommendations about their applicability.

Keywords
Shape memory alloys, computational fatigue approach, cardiovascular stents, finite element analysis, Dang Van criterion, constant-life diagram

Introduction
Nowadays, cardiovascular diseases represent a significant cause of death, leading to high social and economical costs. Major incidence can be attributed to stroke that is caused by complex pathologic events, generally denoted as atherosclerosis.

Stents represent a standard treatment for atherosclerotic arteries, and interventions occur on coronary and peripheral vessels as carotid or superficial femoral arteries. Despite the continuing medical successes, clinical studies have reported evidences of stent fracture after their deployment inside the patient’s body, see, for example, Auricchio et al. (2016a) and Everett et al. (2016) and references therein. Regulatory bodies require a long-term endurance of the stent implants of, at least, 10 years of real-time use under physiological cyclic loading in order to avoid these undesired failures (U.S. Food and Drug Administration, 2010). Depending on the stent positioning inside the patient, such a requirement translates into $4 \times 10^8$, $2 \times 10^7$, and $1 \times 10^8$ cycles, respectively, for diastole–systole, musculoskeletal, and breathing cyclic loading, hence, into a high-cycle fatigue problem.

To satisfy long-term use requirements, it is first necessary to understand the causes of stent fractures. These are likely due to in vivo biomechanical cyclic solicitations associated to, for example, stent positioning and design or contact between the vessel, the atherosclerotic

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plaque, and the stent. In this context, stent material behavior under cyclic loading plays an important role to improve fatigue performances and to limit the incidence of failure.

This article focuses on stents made of Nitinol, a Nickel–Titanium shape memory alloy (SMA), since they are widely used in the biomedical field. Such an alloy possesses, in fact, a combination of properties that allow stents to accomplish both technical and biomechanical requirements, such as biocompatibility and self-deployment. Specifically, stent deployment is facilitated by the unique property of SMAs, known as pseudoelastici ty, which results from reversible diffusion-less solid–solid transformations between two phases, called, respectively, austenite and martensite.

The great complexity of Nitinol behavior under cyclic loading, however, makes the lifetime prediction of stents a challenge for academics, companies, and regulators (Bonsignore, 2017). Nitinol pseudoelastic behavior under cyclic loading is, in fact, very different from that of classical metals and it is mostly driven by the formation of stress-induced martensite, which is influenced by numerous factors such as loading conditions, material treatment and purity, as well as surface oxide damage (Alarcon et al., 2017; Hesami et al., 2018; Lim and McDowell, 1995; Mahtabi et al., 2015; Robertson et al., 2012). These factors make the transferability from standard shaped specimens and uniaxial loading to complex devices and multiaxial testing conditions anything but direct. Results from in vitro tests on Nitinol stents and subcomponents, performed according to international standards (ISO 25539-2:2012, 2012; U.S. Food and Drug Administration 2010), clearly highlight a high variability in the fatigue response (Kapnisis et al., 2013; Muller-Hulsbeck et al., 2010; Nikanorov et al., 2008; Pelton, 2011; Pelton et al., 2008; Runciman et al., 2011).

As an example, accelerated testing, performed by Kapnisis et al. (2013), showed that the degree of arterial curvature, combined with stents’ overlapping, enhances the incidence and degree of wear and fatigue fracture. Nikanorov et al. (2008) tested six stents for superficial femoral arteries in elastic silicone tubes up to $1 \times 10^7$ cycles of chronic deformation without evidencing failure. Muller-Hulsbeck et al. (2010) tested different stent designs for superficial femoral artery through mechanical fatigue tests in bending, compression, and torsion in the fully expanded configuration, up to $6.5 \times 10^5$ cycles or up to fracture. The stents investigated by Muller-Hulsbeck et al. (2010) showed differences in the incidence of high-strain zones, and the design played an important role in the appearance of fracture. Pelton et al. (2008), Pelton (2011), and Runciman et al. (2011) performed displacement-controlled fatigue tests on stent-like specimens under pulsatile loading conditions. Contrary to standard steels, Nitinol fatigue life was observed to increase with increasing mean strain in the deformation range of 2%–4%.

The number of experimental data available from the literature is, however, limited for several reasons: fatigue testing is expensive and requires time; the reproducibility of in vivo conditions is often difficult; the small size of the components increases the difficulties in testing and monitoring mechanical parameters; data are often limited due to confidential reasons; and the role of microstructural phase evolution on fatigue damage may be difficult to quantify.

As a consequence, numerical approaches offer a way to fill gaps and limits associated with the experimental field. As an example, the U.S. Food and Drug Administration (2010) recommends the use of mechanical and fatigue analyses to locate critical points on the stent, to establish the number of cycles the stent can withstand, and to optimize the design. Computational models are able to take into account multiple conditions in the evaluation of the stent mechanical response, for example, by changing loading and boundary conditions, material properties, geometrical quantities, or implanted configurations, as well as to give useful information about the distribution of martensitic phase during cycling (Wang et al., 2017).

When performing a stent numerical fatigue analysis, three main aspects have to be considered: (1) the parameters of the constitutive material model and of the fatigue criterion have to be calibrated on the set of experimental data performed on the same type of SMA; (2) the role of SMA microstructural phase evolution on cyclic mechanical behavior has to be taken into account; and (3) an appropriate fatigue failure criterion for SMAs has to be selected.

Regarding the latter aspect, the strain-based constant-life diagram approach is the most commonly used criterion due to its simplicity (Ackermann and Capek, 2012; Allegretti et al., 2018; Dordoni et al., 2014; Everett et al., 2016; Kumar et al., 2013; Meoli et al., 2014; Pelton et al., 2008; Petrini et al., 2016). Such a uniaxial approach defines a safety threshold in terms of mean strain and strain amplitude for a given SMA material and a specific number of cycles. Despite its simplicity, its uniaxial nature makes difficult the extension to multiaxial (and non-proportional) loading conditions, as in the case of stents, and neglects stress-induced martensite formation, which is a key parameter affecting Nitinol fatigue (Bonsignore, 2017). A recent comparison between four strain-based models is provided in Allegretti et al. (2018).

To cope with the discussed features of SMA cyclic behavior, the concept of shakedown is often used to describe the stress–strain response of structures or materials under cyclic loading. However, in contrast to elastoplastic materials, for which shakedown refers to a state in which plastic strains stabilize after a finite number of loading cycles, and therefore elastic or alternating plastic deformation may take place, the response of pseudoelastic SMAs depends on the formation of stress-induced martensite volume fraction, the transformation...
and reorientation strain values, and/or the occurrence of transformation-induced plasticity in the fully martensitic state (Feng and Sun, 2007). Accordingly, several material responses can be identified, for example, elastic shakedown, alternating phase transformation, alternating plasticity, or ratcheting (see Auricchio et al. (2016b) and Gu et al. (2016) and references therein for a detailed discussion). Within these physical boundaries, only the elastic shakedown response, corresponding to a stabilized cyclic evolution of the martensite volume fraction, can be reasonably expected to result in high-cycle fatigue life (Racek et al., 2015). Given the different possible fatigue conditions, in a computational approach, it becomes necessary to verify whether Nitinol stents will shakedown elastically or not, in order to obtain an infinite lifetime, that is, resulting in high-cycle fatigue life.

Shakedown theorems and analyses (Peigney, 2010) have been recently proposed for SMAs, and based on such contributions, a criterion of the Dang Van type for SMAs has been proposed by the authors (Auricchio et al., 2016b). The proposed criterion addresses the fatigue analysis of SMA under elastic shakedown and has the advantage of being multiaxial and of taking into account the complexity of the phase transformation between austenite and martensite. However, to the author’s knowledge, there is a lack of computational works facing the fatigue analysis of Nitinol stents based on these recent shakedown concepts, and no discussion concerning the applicability, advantages, and disadvantages of these fatigue methodologies is available.

Motivated by the above considerations, this article aims to propose a computational approach for the fatigue analysis of Nitinol stents under cyclic loading based on the Dang Van–type criterion for SMAs. The investigation is conducted in the framework of a global computational approach to fatigue, which is a methodology widely known and accepted for the analysis of metals. It consists in the following two steps:

1. A structural analysis, for example, based on the finite element (FE) method, to compute the mechanical response of the implant under investigation. The implant is defined in terms of stent design, pre- and post-implant configuration, and material properties. The analysis is set up to simulate all the deployment steps, that is, stent crimping, deployment, and the in vivo cyclic loading. The stabilized behavior of the stent after cycling, that is, its shakedown response, is computed at the end of the analysis.
2. A fatigue analysis to compute the onset of failure in the stent. This step consists in adopting a fatigue criterion, for example, stress, strain, or energy based, depending on the expected shakedown response.

Specifically, we analyze a standard carotid artery stent design, interacting with a plaque and a vessel subjected to diastolic–systolic and bending cycling, and we perform the fatigue analysis taking into account the three main aspects listed above. We apply the Dang Van–type criterion for SMAs, and we discuss the results in terms of stent shakedown response, stress-induced martensite evolution, and their role on fatigue life. The comparison with the results obtained by applying a strain-based constant-life diagram approach has the purpose of critically evaluating both methodologies.

This article is organized as follows. Section “Model problem” presents the model problem under investigation. Section “Loading and boundary conditions” describes the analysis set-up in terms of applied loading conditions. Section “Mechanical analysis” and section “Fatigue analysis” show the results of the mechanical and fatigue analysis, respectively. Section “Conclusions” provides conclusions and future perspectives.

Model problem

This section describes the three-dimensional model under investigation. It consists of the stent, the surrounding vessel, a symmetric atherosclerotic plaque, and a catheter. The particular choice of model configuration does not restrain the generality of the present method and has been chosen as a representative case. The meshing and mechanical analyses are performed with the FE method, using the software Abaqus/Standard (Simulia; Dassault Systemes, Providence, RI, USA).

Stent design

We adopt a model resembling a portion of a closed-cell carotid stent, known as XACT stent (Abbott, Abbott Park, IL, USA). The geometry is based on the values reported in Auricchio et al. (2010). The stent model has an outer diameter of 8.01 mm, a length of 10.20 mm, a strut thickness of approximately 0.182 mm, and a strut width between 0.09 and 0.114 mm. Such dimensions are comparable with those of the specimens used for parameters’ calibration, as detailed in the following sections. The mesh of the stent is presented in Figure 1, and it is defined by means of 54,432 three-dimensional linear hexahedral FEs (C3D8), corresponding to 89,820 nodes; the FE size ranges between 0.008 and 0.173 mm, with mesh refinement close to the curvature zones. A further mesh refinement cause a significant increase in computational time without providing a noticeable improvement in the results. We recall that, since the grain size is approximately 75–100 nm and two orders of magnitude smaller than the critical flaw size (15–50 μm), as measured in Pelton (2011) and Pelton et al. (2008), stress-concentration effects arising from grain deformations are negligible.
Stent material

The stent is assumed to be made of Nitinol. We employ the three-dimensional phenomenological model proposed in Souza et al. (1998) to describe material constitutive behavior. The model is able to describe the main macroscopic properties typical of SMAs, that is, pseudoelasticity and shape memory effect, and it is implemented within Abaqus/Standard through a UMAT subroutine. Model parameters are reported in Table 1. They have been calibrated in Auricchio et al. (2016b) on a uniaxial stress–strain curve at 37°C (Pelton, 2011), related to micro-dogbone specimens, extracted from stent-like devices, with 6 mm gauge length, 0.3 mm gauge width, and 0.15 mm gauge thickness. The design and manufacturing conditions led to an austenite finish transformation ($A_f$) temperature of 20°C, that is, comparable to the $A_f$ temperature of Nitinol stents. It is worth highlighting that the same experimental data have been used to calibrate the fatigue criteria parameters.

Artery, plaque, and catheter

We model the artery as a thick-walled pipe of length of 12 mm, internal diameter of 6 mm, and thickness of 0.7 mm (see Figure 2(a)) as reported in Auricchio et al. (2010). We use 11,520 three-dimensional linear hexahedral hybrid FE nodes, corresponding to 15,520 nodes. We model the symmetric plaque as a cylinder with a length of 4 mm and an internal diameter of 4.8 mm, corresponding to a reduced level of stenosis of 20% (see Figure 2(a)). We use 3840 elements (C3D8H) corresponding to 5280 nodes. To describe the mechanical behavior of both artery and plaque, we use the hyperelastic isotropic material model proposed in Lally et al. (2005).

The catheter has an initial diameter of 8.4 mm and is used to force the radial deformation of the stent during the simulation. It is discretized by means of 3510 three-dimensional quadrilateral surface elements with reduced integration (SFM3D4R), corresponding to 3600 nodes.

We recall that some simplifications are introduced in the described FE model to reduce the computational cost. Specifically, the artery is modeled as a straight cylinder, the plaque is modeled as a cylinder, the anisotropy in both vessel and plaque tissues is neglected, and only a small portion of stent is considered. However, our results do not restrain the generality of the presented methodology.

Loading and boundary conditions

This section illustrates the stenting simulation which is splitted into three steps: the first one accounts for the stent crimping, the second one addresses the stent
deployment, and the third one considers the subsequent physiological cyclic loading (i.e., fatigue loading). The cyclic loading reproduces the in vivo diastolic–systolic pressure. To evaluate the effect of other loading conditions, arising from physiological movements and morphological characteristics of the vessels, the stent model is also subjected to cyclic bending in the fully expanded configuration. To this purpose, we perform a small-strain and large-rotation analysis at a temperature of 37°C to allow for the pseudoelastic recovery of the SMA.

**Stent crimping**

We impose a uniform radial displacement of 3.2 mm to the catheter to crimp the stent. During this step, the nodes lying at the proximal end of the stent are fixed in circumferential and longitudinal direction, while only the contact between the outer stent surface and the inner catheter surface is activated. According to the discussion reported in Dordoni et al. (2014), we use a friction coefficient of 0.01 at the interface between the stent and the catheter. The final implant configuration after crimping is shown in Figure 2(a).

**Stent deployment**

We gradually release the catheter boundary conditions to allow its re-expansion and stent deployment. We activate the contact between the outer surface of the stent and the inner surface of the vessel and we adopt a friction coefficient of 0.01 between the two surfaces. We fix all the nodes lying at the distal and proximal vessel ends in circumferential and longitudinal directions during the whole analysis. The final configuration after deployment is reported in Figure 2(b).

**Physiological cyclic loading**

We consider two cyclic loading cases as described in the following.

1. **Diastolic–systolic pressure.** After the stent deployment described in section “Stent deployment,” an internal cyclic pressure is applied on the inner wall of the atherosclerotic vessel to simulate the diastolic–systolic condition, as schematically shown in Figure 2(c). The pressure varies between a maximum value of 120 mmHg and a minimum value of 80 mmHg, and the contact between the outer surface of the stent and the inner surface of the vessel is activated. The cycling is repeated until a stabilized response of the stent is reached, that is, until a stabilized evolution of the martensite volume fraction is obtained in all the integration points of the mesh. For the specific loading under investigation, such a stabilized response is reached after 10 cycles.

2. **Bending.** To investigate the effect of the deployment of the stent in a curved vessel, an additional analysis is performed. Such an analysis...
The stent is first crimped, as described in section “Stent crimping” and then fully expanded (without constraints due to the vessel and the presence of plaque). Then, the stent is preliminary bent by rotating its end sections at a fixed angle, using a multi-point constraint (MPC) boundary condition. Finally, cycling is applied by rotating the end sections between two angles, as schematically shown in Figure 2(d). The values of the rotation angles are chosen according to those reported in clinical studies (Gomez-Lara et al., 2010, 2011). Specifically, a preliminary angle of 0.04125 rad/s is applied to simulate the deployment of the stent into a curved vessel; then, a maximum angle and a minimum angle, respectively, of $\pm 0.0165$ and $-0.0165$ rad/s are considered for cyclic bending. The cycling is repeated until a stabilized response of the stent is obtained. For the specific loading under investigation, such a stabilized response is obtained after five cycles. No internal cyclic pressure is applied on the inner wall of the atherosclerotic vessel during cyclic bending.

### Mechanical analysis

This section presents the results of the mechanical analysis conducted to investigate the shakedown response of the stent and to compute the quantities of interest for the fatigue analysis.

Tables 2 and 3 report the mechanical quantities as well as the martensite volume fraction, respectively, for the two loading cases, that is, cyclic diastolic–systolic pressure and bending (see section “Physiological cyclic loading”). The martensite volume fraction $z$ is here defined as $z = \frac{\|e^m\|}{\|e_L\|}$, according to the notation adopted for the SMA constitutive model (see Table 1). Indeed, $z$ varies between 0 (fully austenite) and 1 (fully martensite).

In the diastolic–systolic pressure case, the quantities are reported at crimping, maximum expansion (deployment), diastole, and systole. The von Mises equivalent stress reaches the maximum value at crimping and presents values four times lower at the subsequent steps. The pressure stress also reaches its maximum value at crimping and presents almost constant values during systole and diastole. The distributions of the von Mises equivalent and pressure stresses along the stent strut are shown in Figure 3. The highest values are visible mainly in the radial arc of the main strut, and the distribution is almost the same during fatigue loading at systole and diastole.

### Table 2. Quantities obtained from the mechanical analysis simulating stent crimping, deployment, and cyclic diastolic–systolic pressure.

<table>
<thead>
<tr>
<th>Step</th>
<th>Value</th>
<th>Mises stress (MPa)</th>
<th>Pressure (MPa)</th>
<th>Maximum principal strain (−)</th>
<th>Minimum principal strain (−)</th>
<th>$z$ (−)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crimping</td>
<td>Max</td>
<td>1708.70</td>
<td>448.905</td>
<td>0.13</td>
<td>$2.09 \times 10^{-4}$</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Min</td>
<td>11.28</td>
<td>−224.57</td>
<td>$2.29 \times 10^{-4}$</td>
<td>−0.20</td>
<td>0</td>
</tr>
<tr>
<td>Deploy</td>
<td>Max</td>
<td>496.60</td>
<td>187.40</td>
<td>0.073</td>
<td>$1.50 \times 10^{-5}$</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Min</td>
<td>0.78</td>
<td>−122.99</td>
<td>$1.62 \times 10^{-5}$</td>
<td>−0.11</td>
<td>0</td>
</tr>
<tr>
<td>Diastole</td>
<td>Max</td>
<td>492.05</td>
<td>190.95</td>
<td>0.073</td>
<td>$1.26 \times 10^{-5}$</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Min</td>
<td>0.69</td>
<td>−123.26</td>
<td>$1.56 \times 10^{-5}$</td>
<td>−0.10</td>
<td>0</td>
</tr>
<tr>
<td>Systole</td>
<td>Max</td>
<td>482.12</td>
<td>187.08</td>
<td>0.073</td>
<td>$1.27 \times 10^{-5}$</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Min</td>
<td>0.73</td>
<td>−123.04</td>
<td>$1.68 \times 10^{-5}$</td>
<td>−0.10</td>
<td>0</td>
</tr>
</tbody>
</table>

### Table 3. Quantities obtained from the mechanical analysis simulating stent crimping, free expansion, prebending, and cyclic bending.

<table>
<thead>
<tr>
<th>Step</th>
<th>Value</th>
<th>Mises stress (MPa)</th>
<th>Pressure (MPa)</th>
<th>Maximum principal strain (−)</th>
<th>Minimum principal strain (−)</th>
<th>$z$ (−)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crimping</td>
<td>Max</td>
<td>1667.52</td>
<td>465.48</td>
<td>0.13</td>
<td>$-2.0 \times 10^{-4}$</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Min</td>
<td>10.76</td>
<td>−230.05</td>
<td>0</td>
<td>−0.20</td>
<td>0</td>
</tr>
<tr>
<td>Free expansion</td>
<td>Max</td>
<td>44.68</td>
<td>364.55</td>
<td>$8.0 \times 10^{-5}$</td>
<td>$-10^{-5}$</td>
<td>$10^{-4}$</td>
</tr>
<tr>
<td></td>
<td>Min</td>
<td>0.0289</td>
<td>−4.68</td>
<td>$-10^{-5}$</td>
<td>$8 \times 10^{-4}$</td>
<td>0</td>
</tr>
<tr>
<td>Prebending</td>
<td>Max</td>
<td>879.99</td>
<td>340.95</td>
<td>0.11</td>
<td>$-0.14$</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Min</td>
<td>5.13</td>
<td>−316.28</td>
<td>$10^{-4}$</td>
<td>$-10^{-4}$</td>
<td>0</td>
</tr>
<tr>
<td>Max bending angle</td>
<td>Max</td>
<td>483.08</td>
<td>203.87</td>
<td>0.07</td>
<td>$-10^{-5}$</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Min</td>
<td>2.20</td>
<td>−199.95</td>
<td>$10^{-5}$</td>
<td>$-0.09$</td>
<td>0</td>
</tr>
<tr>
<td>Min bending angle</td>
<td>Max</td>
<td>874.32</td>
<td>339.33</td>
<td>0.11</td>
<td>$-10^{-4}$</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Min</td>
<td>5.13</td>
<td>−316.01</td>
<td>$10^{-4}$</td>
<td>$-0.14$</td>
<td>0</td>
</tr>
</tbody>
</table>
These distributions can be directly correlated to the formation of stress-induced martensite $z$. Figure 4 shows the martensite volume fraction $z$ versus time diagram, where several curves, related to different integration points of the stent mesh, are represented. It is clear that the martensite fraction stabilizes on a limit value in all the integration points of the mesh, thus demonstrating the existence of a stabilized cycle under elastic shakedown for the stent after diastole–systole cyclic loading. The distribution of $z$ along the stent after stabilization is also shown in Figure 4. Full martensitic transformation (i.e. $z = 1$) is visible mainly in the radial arc of the main strut, according to the distribution of stresses.

In the cyclic bending case, the mechanical quantities are reported at stent crimping, free expansion, pre-bending, and maximum and minimum bending angles. The von Mises equivalent stress reaches the maximum value at crimping, but presents halved values at pre-bending and minimum bending angle, and it is four times lower at maximum bending angle. The values are extremely low at free expansion, if compared with the diastolic–systolic pressure case, due to the absence of any constraint due to the plaque and the vessel as well as of the applied internal pressure. These low values cause no formation of martensite (see Table 3). Similar considerations can be made for the pressure stress. The distributions of the von Mises equivalent stress and the pressure stress along the stent strut are shown in Figure 5 at the maximum and minimum bending angles. Different from the diastolic–systolic pressure case, highest von Mises stresses are visible and concentrated mainly in the bridge elements. Accordingly, full martensitic transformation (i.e. $z = 1$) after stabilization is visible mainly in the bridge elements (see Figure 6). Again, a stabilized cycle under elastic shakedown exists for the stent after cyclic bending.

It is worth highlighting that the SMA material model employed in this article neglects plasticity in the fully martensite state. Such a simplification is, however, appropriate; in fact, since the highest value of maximum principal strain experienced in the stent is 13% (Tables 2 and 3), and since SMA elastic limit is approximately 8%–9% strain, a small percentage of plastic deformation is experienced by the considered alloy, but the impact on the overall strain distribution is minimal.

**Fatigue analysis**

This section reports on the adopted approaches in the fatigue analysis. First, we introduce the fatigue criteria used, and then, we present the results of their application to the specific case under investigation. The examined approaches are discussed in terms of (1) assumptions and characteristics, (2) experimental fatigue data needed for the calibration, (3) difficulty of implementation, and (4) applicability to stents.
Figure 4. Cyclic diastolic–systolic pressure case. Martensite volume fraction $z$ versus time diagram, proving elastic shakedown (top right). Stent model showing the locations of the points. Point B is the critical point from the fatigue analysis (top left). Contour plot of the martensite fraction $z$ after stabilization. The arrows indicate the critical point from the fatigue analysis, that is, point B (bottom).

Figure 5. Contour plot of the von Mises equivalent stress (MPa) (top) and of the pressure stress (MPa) (bottom) along the unit cell for the cyclic bending case.
Dang Van–type criterion for SMAs

The criterion has been recently proposed in Auricchio et al. (2016b). It studies the high-cycle fatigue problem through the introduction of the mesoscopic grain scale, in addition to the macroscopic scale of continuum mechanics, according to physical observations showing that fatigue damage is controlled by mechanisms at the grain scale in the polycrystalline material. Without entering into details of the formulation (see Auricchio et al., 2016b), the criterion states that a structure subjected to cyclic loading has an infinite lifetime expressed as an elastic shakedown state at both macroscopic and mesoscopic scales, if, for all points \( x \) of the structure

\[
\max_{t > t_0} \left\{ \tilde{\tau}(x, t) + a(\alpha(x)) \tilde{\sigma}_h(x, t) \right\} \leq b(\alpha(x)) \tag{1}
\]

where \( \tilde{\tau} \) and \( \tilde{\sigma}_h \) are, respectively, the mesoscopic shear and hydrostatic stress and \( a \) and \( b \) are parameters depending on the phase transformation–induced variable \( \alpha \). In the paper by Auricchio et al. (2016b), the variable \( \alpha \) is assumed to be the martensite volume fraction \( z \). If condition (1) is not respected in a point, the structure will have a finite lifetime.

The linear inequality (1) splits the representation of the mesoscopic stress space \((\tilde{\sigma}_h, \tilde{\tau})\), by a straight line, denoted as the Dang Van line, in a safe and an unsafe domain: the lifetime of the structure will be infinite if the stress path lies below the line or finite if the stress path crosses the line. Such a line is defined once calibrated the parameters \( a \) and \( b \) that can be easily identified on two uniaxial fatigue experiments in tension and/or torsion on classical specimens (e.g., dogbone-shaped; Auricchio et al., 2016b). Since \( a \) and \( b \) depends on \( z \), a set of Dang Van lines is obtained for each value of \( z \) and for a fixed number of cycles to failure \( N \). It is suggested to construct a set of lines for \( z \) equals to 0 and 1 and, at least, two cases between 0 and 1.

To highlight the critical points of the structure, the following Dang Van fatigue damage parameter can be computed for each point \( x \)

\[
C_{DV} = \max_{t > t_0} \frac{\tilde{\tau}(x, t) + a(\alpha(x)) \tilde{\sigma}_h(x, t) - b(\alpha(x))}{b(\alpha(x))} \tag{2}
\]

Positive values of the parameter indicate failure, while negative values indicate no failure.

The criterion is computed as post-processing of the mechanical stress quantities obtained by the FE simulation of the structure. The computation of \( \tilde{\tau} \) is performed by solving a min-max problem, which can be done by using optimization approaches (Auricchio et al., 2016b; Scalet, 2018).

Strain-based constant-life diagram for SMAs

The strain-based constant-life approach is an uniaxial diagram reporting the strain amplitude \( e_a \) and the mean
strain \( \varepsilon_m \) at a fixed number of cycles \( N \) for a certain material.

If a complex multiaxial cyclic loading is applied on the structure under investigation, as in case of stents, the computation of equivalent strains, that is, equivalent strain amplitude \( \varepsilon_{eq}^m \) and mean strain \( \varepsilon_{eq} \), is required in order to use the strain-based constant-life diagram. Once the equivalent strain amplitude and mean strain are calculated, the multiaxial strain state is thus reduced to an equivalent uniaxial strain state. Here, we consider two approaches for the definition of the equivalent strain quantities.

The first approach consists in evaluating the equivalent mean strain and strain amplitude in terms of maximum principal strains. In particular, we calculate mean and alternating first principal strains, respectively, \( \varepsilon_m^i \) and \( \varepsilon_a^i \), that occur in each point of the structure in response to the application of a cyclic loading. The following definitions are used

\[
\begin{align*}
\varepsilon_{eq}^m &= \varepsilon_m^i = \varepsilon_m^i + \varepsilon_m^{i+1} \\
\varepsilon_{eq}^a &= \varepsilon_a^i = \left( \frac{\varepsilon_a^i - \varepsilon_m^{i+1}}{2} \right)
\end{align*}
\]  

where subscripts \( i + 1 \) and \( i \) denotes, respectively, the last sub-step of a generic load step and the last sub-step of the following unload step.

The second approach consists in calculating the equivalent mean strain and strain amplitude in terms of the effective von Mises strain. In particular, we first calculate the mean and amplitude strain tensors, that is, \( \varepsilon_m \) and \( \varepsilon_a \), at each point of the structure, as follows

\[
\begin{align*}
\varepsilon_m &= \varepsilon_m^i + \varepsilon_m^{i+1} \\
\varepsilon_a &= \frac{\varepsilon_m^i - \varepsilon_m^{i+1}}{2}
\end{align*}
\]  

where \( \varepsilon_m^i \) and \( \varepsilon_m^{i+1} \) are the strain tensors at, respectively, the last sub-step of a generic load step and the last sub-step of the following unload step. The effective von Mises strain amplitude and mean strain can be then obtained from the deviatoric components of the mean and amplitude strains, indicated, respectively, as \( \varepsilon_m \) and \( \varepsilon_a \)

\[
\begin{align*}
\varepsilon_m^{eq} &= \varepsilon_m^{eff} = \sqrt{\frac{2}{3} \varepsilon_m \cdot \varepsilon_m} \\
\varepsilon_a^{eq} &= \varepsilon_a^{eff} = \sqrt{\frac{2}{3} \varepsilon_a \cdot \varepsilon_a}
\end{align*}
\]  

The limit curve in the diagram, which denotes the safe and unsafe domain, is generally obtained from uniaxial experimental tests performed on classical specimens. In fact, the diagram plots the maximum mean strain and strain amplitude for each test, assuming that the results represent strain values at a single point. This assumption may be true for tests where the strain can be assumed to be uniform throughout the gauge length, for example, tension–tension tests (Bonsignore, 2017). In case of surrogate specimens, for example, stents or subcomponents, and/or specific loading conditions, for example, high mean strains, the location of the maximum mean strain differs from that of the maximum strain amplitude. This creates uncertainties about the most critical points to consider for the analysis (Bonsignore, 2017). Moreover, given the complex behavior of Nitinol, several tests are needed to construct the limit curve.

The computation of the quantities reported in equations (3) and (5) as post-processing of the mechanical field, obtained by the FE simulation of the structure under investigation, is simple and direct. However, its success in correlating multiaxial fatigue data is generally limited to few loading conditions (i.e. proportional).

**Fatigue results**

This section presents the results of the fatigue analysis. Fatigue quantities, reported in equations (1), (3), and (5), are computed at each integration point of the stent.

Figure 7(a) and (b) represents the diagram in terms of the mesoscopic shear stress \( \tau \) and the hydrostatic stress \( \sigma_h \) obtained by applying the Dang Van–type criterion, respectively, to the diastolic–systolic pressure and cyclic bending cases. The Dang Van limit line, referred to \( N = 10^7 \) cycles and \( z = 1 \), is represented as green line. The parameters \( a \) and \( b \), defining this line, have been calibrated in Auricchio et al. (2016b) on the same material experimental data (Pelton, 2011) and result in the following

\[
\begin{align*}
a &= 0.808 \\
b &= 138 \text{ MPa}
\end{align*}
\]  

It is noticed that the use of an endurance limit at \( 10^7 \) cycles is a reasonable practice for stents (Pelton, 2011).

In Figure 7(a) and (b), the stress paths of each integration point are colored depending on the value of the martensite fraction \( z \) in the same point. The stress paths of the integration points having \( z = 1 \) cross the Dang Van line in the cyclic bending case, therefore indicating the failure of the stent and an endurance limit lower than \( 10^7 \) cycles. For the diastolic–systolic pressure case, the stress paths of the integration points having \( z = 1 \) lie below the limit line. Some stress paths, however, cross the line: these are referred to integration points having \( z = 0 \), for which the Dang Van line is not available due to the lack of experimental data. It has been however, observed in Auricchio et al. (2016b) that the case \( z = 1 \) may be more conservative.

Figure 8 shows the contour plot of the Dang Van parameter \( C_{DV} \) for the diastolic–systolic pressure case. Specifically, the most critical element in the fully martensite state (\( z = 1 \)) has \( C_{DV}^{max} = -0.1705 \), thus resulting safe, and it is indicated in Figure 4. The loading paths in the Dang Van diagram associated to this point are
almost overlapping and only small variations of the mesoscopic shear stress can be noticed. The highest parameter for the cyclic bending case results \( C_{DV}^{max} = 2.1978 \), and it is related to the integration point in the fully martensite state \( \varepsilon_m = 1 \), as indicated in Figure 6.

Figure 7(c) to (f) shows the strain-based constant-life diagrams in terms of both first principal and effective von Mises strains. The experimental limit curve, represented as a green line, is taken from Pelton (2011), and it is referred to \( N = 10^7 \) cycles. Again, each point in the diagrams is colored depending on the corresponding value of the martensite fraction \( z \). Differently from the results of the Dang Van criterion, these results depend on the definition of the equivalent uniaxial strain state. Effective von Mises strain values are higher than the
first principal ones and therefore are more conservative from the fatigue viewpoint. In both diastolic–systolic pressure and cyclic bending cases, the most critical elements are those in the fully martensite state, since having higher strain levels. Moreover, the stent has a lifetime of at least $10^7$ cycles in the diastolic–systolic pressure case, while it fails in the bending case for both diagrams. For the diastolic–systolic pressure case, the point having $C_{DV} = -0.1705$ and $z = 1$ possesses a maximum value of $\sigma$ and $\tau$ of 139 and 1.95 MPa, respectively, while $e_a = 0.0312\%$, $e_m = 6.73\%$, $e_{eff} = 0.029\%$, and $e_{eff} = 6.40\%$.

The outcomes of the computational-based fatigue analyses, obtained by implementing two different approaches, allow us to point out two important characteristics of the Dang Van criterion. First, the more widely adopted constant-life diagram approach has been successfully used to validate the results of the Dang Van criterion even in the absence of complete experimental characterization of the SMA material (i.e. as a function of the martensite volume fraction). Second, both fatigue approaches have provided fatigue-related results which are in accordance. However, the constant-life diagram approach may be too simplistic, and hence not enough accurate, when handling clinical cases where stents are subjected to complex loading conditions or when a specific stent design is required. Indeed, it has been shown that equivalent effective strains are more conservative, while the use of principal strains to compute equivalent strains is suitable for stents having classical designs, where the struts mainly work in bending and compression/tension or proportional to loading conditions. Moreover, the capability of Dang Van fatigue approach in accounting for SMA material phases in the computational design approach appear very promising. Indeed, the FE simulations of preclinical design against in-service conditions entails the opportunity to tailor SMA mechanical properties and material phases to maximize fatigue resistance.

Although the developed methodology is promising, it is worth highlighting that it has not yet been validated on fatigue results obtained from properly designed experimental tests. Thus, further investigations are needed to ensure that the proposed methodology is a relevant fatigue design tool for Nitinol stents. To this purpose, it could be interesting to carry out exhaustive tests to estimate experimentally the lifetime of a stent geometry or complex shaped components under different loading conditions and to compare the results to those predicted with the proposed methodology. Nevertheless, in the absence of this specific testing campaign, we collected the best combination of available experiments suitable for the preliminary validation of our approach.

Finally, we recall that fractures of closed-cell carotid stent designs after the implant have been reported by several authors (Chang et al., 2011; Garcia-Toca et al., 2012; Sfyroeras et al., 2010; Valibhoy et al., 2007). In these works, the combination of repetitive mechanical forces present in the arteries, that is, pulsatile blood flow, and stent compression resulting from severe calcification has been shown to increase the incidence of stent fracture. However, in vitro experiments showed that strains imposed by pulsatile blood flow are not sufficiently high to cause the fatigue failure of the stent, and it has been deduced that significant rotational stresses on carotid stents are the result of movements around the atlantoaxial pivot joint as well as of flexion/
extension stresses caused by movements of the cervical vertebral joints. As demonstrated by our numerical results, in fact, the only diastolic–systolic pressure case does not result in failure, while a more complex loading condition and implant configuration, such as cyclic bending, may cause fracture due to a different strain/stress distribution in the stent. The results reveal that complex in-service conditions of stents should be handled using suitable computational approaches which couple multiaxial fatigue criteria and, at the same time, take into account the two-phase nature of SMAs. This could be highly useful for the lifetime assessment and design of SMA stents as well as for the preclinical validation of stents.

**Conclusion**

This article has presented a computational approach to fatigue analysis of Nitinol self-expanding stents.

The selection of an accurate fatigue formulation is essential for the overall accuracy of a prediction methodology. Given the multiaxiality of the problem, fatigue criteria have to be used with attention, and a comparison between different methodologies is useful to approach SMA stent lifetime assessment. The wrong choice can produce, in fact, conservative or optimistic results, which are directly reflected in the corresponding life assessment.

Based on the reported results, we can provide some recommendations concerning the applicability, advantages, and disadvantages of these fatigue approaches. First, given the variability of Nitinol behavior, a coherent calibration of model parameters should be done. Second, the adopted fatigue approach should be a good compromise between reliability, number of experiments for its calibration, and simplicity of implementation. The simplicity offered by strain-based constant-life diagrams may compromise accuracy when applied to Nitinol stents and under complex cyclic loading conditions and entails the problem of constructing the experimental limit curve. The Dang Van–type criterion is able to take into account SMA shakedown behavior, the effect of microstructural phase evolution on fatigue damage, as well as the multiaxiality of the problem. The limit line, for a fixed martensite fraction, can be constructed based on two uniaxial fatigue tests determining uniform strain, stress, and martensite distributions.

Third, the loading conditions imposed on the stent may lead to high stress gradients, especially close to the curvature zones of the stent strut, strongly affecting fatigue damage phenomena. Under these conditions, a fatigue design methodology reflecting the effect of a stress gradient on the fatigue strength can be considered, since the direct application of a criterion on the critical point at the notch root may lead to underestimations of the fatigue limit. As an example, volumetric approaches applied to the discussed Dang Van criterion (Auricchio et al., 2014) may offer promising solutions.

Four, given the complexity of SMA behavior, attention should be paid in choosing the suitable modeling approach. For instance, in small components, such as stent struts, the behavior and mutual interaction of individual grains become essential (Paul et al., 2017), especially at length scales where the specimen size or any machined feature approaches the intrinsic microstructural length; in those cases, micromechanics-based approaches (Weafer and Bruzzi, 2017) should be adopted. In addition, recent studies (see, for example, Zheng et al., 2017 and references therein) showed that martensitic phase transformation can take place in a macroscopic homogeneous mode or a heterogeneous mode (forming macro-domains like Lüders bands), influencing the fatigue behavior of NiTi SMAs. Such an aspect clearly highlights that local strains taking place at the transformation front are not easily known and/or predicted by computational models. In such case, probabilistic analyses (Bonsignore, 2017) associated with a computational methodology may offer a solution to take into account such a high degree of scatter.

To conclude, the proposed methodology represents a promising engineering tool for the evaluation on Nitinol fatigue life; ongoing work by the authors is focused on its validation on appropriate experimental fatigue data and on its application to other designs, implant configurations, and loading or boundary conditions.

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