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Validating Fatigue Safety Factor Calculation Methods for Cardiovascular Stents

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Abstract

Evaluating risk of fatigue fractures in cardiovascular implants via nonclinical testing is essential to provide an indication of their durability. This is generally accomplished by experimental accelerated durability testing and often complemented with computational simulations to calculate fatigue safety factors (FSFs). While many methods exist to calculate FSFs, none have been validated against experimental data. The current study presents three methods for calculating FSFs and compares them to experimental fracture outcomes under axial fatigue loading, using cobalt-chromium test specimens designed to represent cardiovascular stents. FSFs were generated by calculating mean and alternating stresses using a simple scalar method, a tensor method which determines principal values based on averages and differences of the stress tensors, and a modified tensor method which accounts for stress rotations. The results indicate that the tensor method and the modified tensor method consistently predicted fracture or survival to 10^7 cycles for specimens subjected to experimental axial fatigue. In contrast, for one axial deformation condition, the scalar

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method incorrectly predicted survival even though fractures were observed in experiments. These results demonstrate limitations of the scalar method and potential inaccuracies. A separate computational analysis of torsional fatigue was also completed to illustrate differences between the tensor method and the modified tensor method. Because of its ability to account for changes in principal directions across the fatigue cycle, the modified tensor method offers a general computational method that can be applied for improved predictions for fatigue safety regardless of loading conditions.

1 Introduction

Metallic stents are heavily utilized for minimally invasive treatment of stenotic arteries throughout the circulatory system. Although stenting procedures have proven effective in re-opening arteries and restoring normal blood flow, the mechanical durability of metallic stents remains a critical performance attribute for assessing their safety and effectiveness. In fact, previous studies have reported variable fracture rates in the coronary arteries [1–7] as well as in the peripheral arteries [8–12]. Although the clinical implications of stent fractures are somewhat unclear, researchers have speculated that severe stent fractures play a role in thrombosis and in-stent restenosis [13]. Identifying the root cause of stent fractures is difficult as several factors may contribute to reduced stent integrity. Factors such as stent length, lesion length, artery calcification, tortuous anatomy, overexpansion, arterial deformations, and overlapping stent configuration are thought to play significant roles in stent fracture. Arterial deformations, in particular, have been shown to vary by anatomic site and can be complex and multi-axial [14–20]. In addition to radial deformations from pulsatile blood flow, nonradial deformations due to musculoskeletal motions have been observed in peripheral arteries such as the superficial femoral and popliteal arteries. These nonradial deformations may include bending, torsion, radial compression (pinching), and axial elongation/shortening, and may be associated with higher fracture risk [17,21].

The U.S. Food and Drug Administration published a guidance document for industry (Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems) that provides recommendations for stent fatigue analysis which combine bench testing and computational stress/strain analysis such as finite element analysis (FEA). In particular, an assessment of device durability involves the use of mean and alternating stresses/strains obtained from FEA as critical inputs when calculating safety against stent fracture. While there are several methods to calculate alternating (or fatigue) stresses, none of these methods have been validated against experimental data for stents subjected to cyclic loading. This study examines several methodologies which have been proposed to compute fatigue safety factors (FSFs) for cardiovascular stents and compares their predictions to experimental fatigue results. A combined computational and experimental approach is presented to assess the method most predictive of device fatigue safety.

2 Fatigue Theory

Fatigue laws can either be stress or strain based. Traditional fatigue methods have been stress based and often utilized with principal stress values for brittle materials under high-cycle fatigue situations [22]. Modern engineering fatigue methods have progressed toward strain based techniques [23]. Strain-based methods cover the range from high cycle to moderate cycle fatigue, where local plasticity could occur, and are particularly suited for ductile metals [23]. Although the metals used to construct cardiovascular stents are elastic-plastic ductile materials, such as stainless steel and cobalt-chromium alloys, current practice is to perform stress based computations. This choice is justified because cardiovascular stents have such small dimensions that most of the fatigue life is spent initiating a crack, with very fast propagation once the crack is initiated [24]. These characteristics are consistent with those for a brittle material. Therefore, traditional stress life fatigue rules were applied in this study based on endurance curves ($S-N$, or stress-life curves). Mean stress effects were accounted for via the Goodman diagram. In order to ascertain whether a stent will survive or fracture, a point cloud representing the mean and alternating stresses is generated and compared to the Goodman line. All points are required to fall below the Goodman line in order to predict stent survival. The distance to the line is a measure of the factor of safety and if any point falls above the line, fracture is predicted at its corresponding location on the stent. While the fatigue methodology described utilizes a stress-based approach, it could be adapted to a strain-based approach.

In this study, three methods were used for computing the mean and alternating stress in cardiovascular stents. These include the scalar method, the tensor method, and the modified tensor method. The scalar method computes maximum principal values at the extremes of cyclic loading, and does a scalar computation of mean and alternating stresses. In contrast, the tensor method averages and subtracts the stress tensors at the extremes of cyclic loading and then computes their maximum principal values to determine the mean and alternating stress values, respectively. The modified tensor method expands upon the tensor method by first computing the maximum principal values and principal directions of the alternating tensor and then projecting the mean tensor onto the (alternating) principal directions to obtain an associated mean value. This method produces very similar results to a more general critical plane method used in other industries [25], which is versatile enough to handle multiple fatigue laws. An example of alternating and mean stress calculations follows below, and step-by-step mathematical instructions for each method are provided in Sec. 3.6.

The scalar method is the most common way to generalize the stress life equation to three-dimensions (3D) in cardiovascular stents, because it makes use of stress life data and the Goodman diagram in a straightforward manner. As general context, early cardiovascular stents available commercially were indicated for coronary arteries, and the predominant cyclic loading mode was then considered as radial pulsatile loading. Due to vessel preload on the stent as well as small cyclic displacements under radial pulsatile loads, computations of FSFs using the scalar method was, in fact, a reasonable first assumption. However, even for simple uniaxial loading, this method has limitations. For example, consider uniaxial loading cycling between zero and a given stress, σ . In such cases, the scalar method would produce meaningful results; namely that the alternating stress and mean stress are the

expected values of $\sigma/2$. In contrast, if the cyclic loading produces deformation which alternates between tensile and compressive stresses of the same magnitude, σ , the scalar method yields incorrect results. On the tensile side, the maximum principal stress is σ , and on the compressive side, the maximum principal stress is zero. Therefore, using the scalar method, the alternating stress becomes $\sigma/2$ (instead of the expected σ), and the mean stress becomes $\sigma/2$ (instead of the expected zero). These two examples, one with a nonzero mean stress and the second with a zero mean stress, suggest that the scalar method may not adequately predict fatigue safety for zero (or small) mean deformations. Furthermore, for situations in which the orientation of the maximum principal stresses/strains changes within a loading cycle, the most damaging values become difficult to define and may not be directly applicable. Therefore, an improved methodology from the scalar method is needed to compute meaningful values for fatigue predictions.

A logical improvement to the scalar method is the tensor method which utilizes the three-dimensional stress state at ends of the fatigue cycle to compute the tensor average and difference. These tensors are then used to compute the mean and alternating stresses based on their principal values. In the simple, uniaxial loading cases described earlier, the tensor method gives the expected mean and alternating stress.

However, for more complex three-dimensional states of stress, there is no guarantee that the principal directions of the tensor difference are the same as the principal directions of the tensor average. This situation may arise for cardiovascular stents due to their flexibility. Even for modest loading magnitudes, large rotations may occur which can easily change the geometrical configuration depending on the stent design. Therefore, a simple application of the tensor method could easily produce misleading results and it becomes critical to filter out rigid body rotations. Accounting for rigid body rotations can be accomplished by using the modified tensor method to measure stresses and strains in a coordinate system that follows and rotates with the material point. Because it is unclear which combination of alternating and mean stresses are the most damaging, all three principal values are plotted on the Goodman diagram. In this method, the mean stress and the alternating stresses are aligned, and therefore, both contribute to whatever mechanical effect causes fatigue fracture.

It can be difficult to determine alternating and mean stresses when significant rotation of stresses occurs during cyclic loading. A simple example can be seen in Fig. 1. Consider a fragment of a device which is subjected to a uniaxial vertical stress σ_{yy} , at one peak of the load cycle and a uniaxial horizontal stress σ_{xx} , at the other peak of the load cycle. Application of the scalar method to this situation is relatively simple because we assume that there are no shear stresses present, and therefore, the vertical direction and the horizontal direction are always principal directions. This results in a (scalar) alternating stress of $|\sigma_{xx} - \sigma_{yy}|/2$ and a (scalar) mean stress of $(\sigma_{xx} + \sigma_{yy})/2$. In contrast, the alternating and mean stresses are different for both the tensor method and modified tensor method. The alternating stress tensor is $([\sigma_1] - [\sigma_2])/2$, where $[\sigma_1]$ and $[\sigma_2]$ are the stress tensors at the two peaks of the load cycle. This alternating stress tensor has principal values with magnitudes of $\sigma_{yy}/2$ in the vertical direction and $\sigma_{xx}/2$ in the horizontal direction. Since these are orthogonal, they are both acting independently to damage the material and both need to be investigated to see which causes more damage. Similar reasoning is applied to the mean stress. While the mean

stress tensor can be denoted by $([\sigma_1] + [\sigma_2])/2$, it may enhance fatigue damage in each principal direction separately. Therefore, the projection of the mean stress in the vertical direction is $\sigma_{yy}/2$ and the projection in the horizontal direction is $\sigma_{xx}/2$. The end result is the same as having a vertical stress alternating from zero to σ_{yy} and a horizontal stress alternating from zero to σ_{xx} , both acting independently to damage the material. The material is expected to fail when any of the two mean and alternating stress pairs, i.e., $(\sigma_{xx}/2, \sigma_{xx}/2)$ or $(\sigma_{yy}/2, \sigma_{yy}/2)$, reach the Goodman line.

3 Computational and Experimental Approach

This section presents the approach for fatigue studies conducted on the bench as well as the process for computational predictions of fatigue safety factors using the scalar method, the tensor method, and the modified tensor method.

3.1 Test Specimen Geometry.

The fatigue test specimen (Fig. 2) was designed to incorporate characteristics of a finished stent while also including features to facilitate the bench fatigue tests. During axial loading, the connectors (i.e., the thinner geometrical features which run axially and connect adjacent circumferential rings) undergo the largest magnitude of deformation; therefore, this was the primary feature considered during the test specimen design. The circumferential rings were simplified as “solid” without any undulations for purposes of these tests. Further, to minimize artifacts associated with the affixation of the specimen during fatigue experimentation (i.e., “grip artifacts”), the width of the various connectors was varied along the length of the specimen. Specifically, the connector width was the greatest at the specimen ends and gradually decreased toward the connector at the center in order to ensure that the specimen presented fractures away from the gripped regions. These “mock stent” test specimens were manufactured by laser-cutting the geometry from L605 cobalt-chromium alloy tubing with subsequent electropolishing to final dimensions. The specimen geometry was designed for testing without crimping and balloon expansion steps and for direct gripping of the specimen after laser cutting and electropolishing. Although crimping and balloon expansion are essential for cardiovascular balloon-expandable stents, they were purposefully eliminated here to simplify the experimental procedure and reduce computational assumptions.

3.2 Test Specimen Material Model.

The material stress–strain response was generated from uniaxial tensile testing of L605 tubing (used to manufacture the test specimens). Three lots of tubes were tested with 10 tube samples per lot from which the average engineering stress–strain response was determined, and subsequently converted to a true stress–strain response. The elastic-plastic material response used to represent the constitutive relationship is shown in Fig. 3. Based on the tensile test results across the three tubing lots, the stress–strain curve incorporated an average yield-strength (at 0.2% offset) of 85.6 ksi. The material properties utilized in the computational (FEA) model are summarized in Table 1. The plastic portion of the response assumed isotropic von Mises plasticity. Although plasticity was included in the simulation

for completeness, it was found that no significant magnitude of plasticity was observed during cyclic loading in the finite element simulations.

3.3 Material Fatigue Limit of Test Specimen.

The material fatigue limit for the test specimens, i.e., mock stents, was established by cyclic testing of L605 alloy, in wire form, with equivalent mechanical properties relative to the stent tubing. The L605 wire specimens used to determine the 10^7 cycle fatigue limit were fabricated by conventional cold-drawing methods. In-process and final annealing treatments were used to achieve equivalent mechanical properties in the drawn wire lots to the stent tubing (yield strength and ultimate tensile strength - σ_U). The wire diameter (nominally 0.005 in) was chosen to represent a generally similar wall thickness of the mock stents (which had a nominal wall thickness of 0.0039 in). The wire samples were not electropolished implying a larger propensity for manufacturing related defects on the sample surface than electropolished surfaces. This suggests that the use of unpolished wire samples could generate a slightly lower fatigue limit relative to the finished stent material.

The alternating stress (or stress amplitude) versus life (S/N) curve for the L605 wire was characterized to determine the fatigue limit under conditions of zero mean stress, i.e., at a load ratio of $R=-1$. The fatigue tests were performed in 0.9% saline solution at 37 °C on three lots of wire specimens using a rotary-beam fatigue testing machine, operating in displacement control. A fatigue limit of 59 ksi corresponding to a 10^7 cycle threshold was determined for the L605 alloy.

3.4 Fatigue Safety Factor Validation Approach.

As mentioned earlier, a combined experimental and computational approach was undertaken in order to determine which FSF calculation method (i.e., scalar method versus tensor method versus modified tensor method) would be more predictive of the experimental fatigue results. Computational models were generated for the nominal test specimen geometry under fully reversed tension-compression axial fatigue using a range of input deformation magnitudes. The range of simulated deformation magnitudes allowed for FSF predictions with different implications for survival or fracture. Specifically, a deformation magnitude of 0.7% was used which predicted survival out to 10^7 cycles with all three fatigue safety methods. A deformation magnitude of 1.3% was used which predicted fracture prior to 10^7 cycles by all three methods. Finally, a deformation magnitude of 1.05% was used which predicted fracture by the tensor and the modified tensor methods but was predicted to survive by the scalar method. Experimental testing was completed at these three deformation magnitudes consistent with the deformation magnitudes simulated computationally ($n=3-6$ samples per magnitude). The experimental fracture results were then compared to computational predictions using each method.

3.5 Computational Fatigue Model.

The fatigue simulation utilized a finite element model (Abaqus/Standard 6.12-3). The solution was assumed quasi-static; therefore, a static solution procedure, which included nonlinear geometric effects, was utilized. The procedure included two steps, where axial

deformation was applied first in tension (lengthening the specimen) and compression (shortening the specimen), thus replicating the experimental fatigue test procedure.

The finite element mesh consisted of 524,970 elements and 422,190 nodes. The elements included 298,800 C3D8I (linear brick elements with incompatible modes of deformation) and 226,170 M3D4 (linear membrane elements). The C3D8I elements provided superior solution accuracy for the bending mode of deformation (at the connector apex), and M3D4 elements were used to “coat” the surface of the solid geometry to better predict stresses at the outer surfaces of the connector.

During the simulation, one end of the test specimen was held fixed in all translational degrees-of-freedom. An axial motion was applied to the opposite end, while lateral motions were fixed as shown in Fig. 4. As noted in Sec. 3.1, the test specimen was specifically designed to present peak stresses in the connectors located at the (axial) center of the specimen. Furthermore, the circumferential rings at which the displacement constraints were applied can be considered rigid in the radial direction. Therefore, any potential Poisson effect resulting from displacement constraints at the specimen ends are expected to be negligible and not impact the stress field at the axial center of the specimen.

3.6 Fatigue Safety Factor Calculations.

The computational procedures for the scalar, tensor, and modified tensor methods are detailed in the following:

3.6.1 Scalar Method

- (1) Compute the scalar maximum principal stress, σ_A , for the first peak of the load cycle at each material point.
- (2) Compute the scalar maximum principal stress, σ_B , for the second peak of the load cycle at each material point.
- (3) Compute the mean stress from the principal values: $\sigma_{\text{mean}} = (\sigma_A + \sigma_B)/2$
- (4) Compute the alternating stress from the principal values: $\sigma_{\text{alt}} = |\sigma_A - \sigma_B|/2$
- (5) Generate data pairs consisting of the alternating stress and their associated mean stresses for each material point (σ_{mean} , σ_{alt})
- (6) Plot the data pairs as points on a scatter plot where the abscissa represents the mean stress and the ordinate represents the alternating stress. This scatter plot is used in conjunction with the material Goodman line to calculate the FSF.

3.6.2 Tensor Method

- (1) Compute the mean stress tensor by adding the stress tensors from the first and second peak cyclic load conditions (i.e., A and B) and dividing by 2:

$$[\sigma_{\text{mean}}] = ([\sigma_A] + [\sigma_B])/2$$
- (2) Compute the alternating stress tensor by subtracting the second peak tensor from the first peak tensor and dividing by 2: $[\sigma_{\text{alt}}] = ([\sigma_A] - [\sigma_B])/2$

- (3) Compute the absolute maximum scalar principal stress of the alternating stress tensor. That is, the alternating stress σ_{alt} for performing fatigue evaluations.
- (4) Compute the scalar maximum principal stress of the mean stress tensor. That is, the mean stress σ_{mean} for performing fatigue evaluations.
- (5) Generate data pairs consisting of the alternating stress and their associated mean stresses for each material point (σ_{mean} , σ_{alt})
- (6) Plot the data pairs as points on a scatter plot where the abscissa represents the mean stress and the ordinate represents the alternating stress. This scatter plot is used in conjunction with the material Goodman line to calculate the FSF.

3.6.3 Modified Tensor Method

- (1) Compute the mean stress tensor by adding the stress tensors from the first and second peak cyclic load conditions (i.e., A and B) and divide by 2:

$$[\sigma_{mean}] = ([\sigma_A] + [\sigma_B]) / 2$$
- (2) Compute the alternating stress tensor by subtracting the second peak tensor from the first peak tensor and divide by 2: $[\sigma_{alt}] = ([\sigma_A] - [\sigma_B]) / 2$
- (3) Compute the eigenvalues (principal stresses) σ_{alt-1} , σ_{alt-2} , σ_{alt-3} and eigenvectors (principal directions) $\mathbf{n}_1$, $\mathbf{n}_2$, $\mathbf{n}_3$ of the alternating stress tensor. The magnitudes of the alternating principal stresses represent alternating stress for performing fatigue evaluations.
- (4) Use the principal directions (eigenvectors) obtained from the alternating stress tensor to transform the mean stress tensor into a coordinate system which is aligned with the alternating tensor principal stress directions. The 1-1 component of the transformed mean stress tensor $\sigma_{mean-11}^{tr}$ is aligned with the alternating tensor σ_{alt-1} principal stress; like-wise, the transformed mean stress tensor 2-2 and 3-3 components are aligned with the alternating tensor σ_{alt-2} and σ_{alt-3} principal stresses. They are readily computed as:

$$\sigma_{mean-ii}^{tr} = \mathbf{n}_i^T \cdot [\sigma_{mean}] \cdot \mathbf{n}_i$$

- (5) Generate data pairs consisting of the alternating tensor principal stress magnitudes and their associated transformed mean stress components.
 - (i) $(\sigma_{mean-11}^{tr}, | \sigma_{alt-1} |)$
 - (ii) $(\sigma_{mean-22}^{tr}, | \sigma_{alt-2} |)$
 - (iii) $(\sigma_{mean-33}^{tr}, | \sigma_{alt-3} |)$
- (6) Plot the data pairs as points on a scatter plot where the abscissa represents the mean stress and the ordinate represents the alternating stress. The scatter plot is used in conjunction with the material Goodman line to calculate the FSF. This

procedure must utilize peak cyclic load stress tensors whose components are output with respect to a set of local material axes that travel with the stent structure while undergoing large displacements and rigid body rotations.

For a given state of stress, there are different ways of computing an FSF. Here, for each point in the scatter plot, we draw a line connecting the origin to each point in the scatter plot and extend it until it crosses the Goodman line. The FSF is then the ratio of the distance of the intersection point on the Goodman line to the origin and the distance of the point in the scatter plot to the origin. That ratio can easily be computed as

$$FSF = \sigma_E \sigma_U / (\sigma_{alt} \sigma_U + \sigma_{mean} \sigma_E)$$

where σ_E is the appropriate fatigue limit and σ_U is the ultimate strength of the material. An FSF equal to one implies that the corresponding point in the scatter plot is on the Goodman line. FSF values progressively decreasing from the unity value indicates that the point is further outwards from the Goodman line with corresponding increasing likelihood of fracture. Conversely, FSF values increasing beyond one imply that the corresponding point in the scatter plot is further inward from the Goodman line with a corresponding increasing probability of survival. The FSF for the entire structure is then the worst (or lowest) of the FSF among all the points in the scatter plot. Although the 3D methodology described here is based on stresses, this method can also be applied to strain based fatigue methods.

3.7 Monotonic Testing for Computational Model Comparison.

In order to validate the computational model, experimental tests were performed on the test specimens under monotonic axial loading and the resultant force–displacement response compared to corresponding computational results. For the purpose of characterizing the experimental response, a total of three specimens were tested at a rate of 0.5 mm/min. The computational simulation of the experimental test utilized the same geometry, mesh, material properties, and constraints as those used to simulate the earlier mentioned axial fatigue loading. The experimental/computational force–displacement curves, and in particular the stiffness values, were compared to determine the extent to which the model could represent experimental behavior and predict the force response of the test specimen (Fig. 5). The comparison was focused in the linear elastic range since this was the applicable deformation range in the axial fatigue simulations. The results in Fig. 5 indicate an approximately 20% stiffer response for the computational model in the linear elastic range. Inclusion of stent edge-rounds (rounded edges as a result of lasercutting and electro-polishing during manufacture) in the numerical model led to a more consistent experimental/computational comparison in the linear elastic range. However, the stent stress predictions were not sensitive to presence of edge-rounds, demonstrating a stress difference of less than 3% under identical displacement magnitudes. These findings suggested that the computational model without edge-rounds was adequate for stress predictions and therefore implemented for fatigue predictions in this study.

3.8 Experimental Fatigue Testing.

Axial fatigue testing was conducted on an Electroforce 3300 mechanical testing system (TA Instruments) equipped with a 22 N fatigue rated load cell. An additional displacement calibration was undertaken prior to experiments in order to ensure adequate resolution in the cyclic displacement range ($\pm 3 \mu\text{m}$). The specimen was mounted onto mandrel grips which fit freely into the specimen's inner diameter and secured with compliant silicone tubing and zip ties (Fig. 6). Care was taken to ensure mandrel and specimen axial alignment.

Fully reversed cyclic axial displacement was applied corresponding to three deformation magnitudes of 0.7%, 1.05%, and 1.3%. The applied cyclic displacement was calculated from the desired deformation magnitude (in percentage) and the gauge length of the test specimen. The gauge length was determined for each test specimen using gimp (GNU Image Manipulation Program) by converting the number of pixels between the upper end of the first connector ring and the lower end of the 12th (last) connector ring to millimeters based on the number of pixels in the known 1.75 mm diameter mandrel (Fig. 6). Fatigue testing was completed at 50 Hz in room temperature air with fan cooling per ASTM F2942 [26]. Fatigue loading proceeded until fracture or survival, which was considered to be completion of 10^7 cycles. Fractures were detected by monitoring the peak force, which decreased to near zero at full separation of a connector ring.

4 Results

4.1 Experimental Results.

The experimental fatigue results are shown in Fig. 7. As expected, the number of cycles to fracture decreased with increasing axial deformation magnitudes. All test specimens loaded at 1.3% deformation magnitude exhibited fracture before reaching 300,000 cycles. Four out of the six specimens tested at a deformation magnitude of 1.05% exhibited fracture at cycle counts between 200,000 and 10^6 cycles, while the other two test specimens ran out to 10^7 cycles. All specimens tested at the lowest deformation magnitude of 0.7% ran out to 10^7 cycles without fracture. All fractures occurred near connector apices at the thinnest connector (CONN-4 as shown in Fig. 2) and were spaced anywhere within the CONN-4 region; there were no stent fractures near the grips. A representative image of a fractured stent is shown in Fig. 8.

4.2 Computational Results.

For a deformation magnitude of 1.3%, the scalar, the tensor, and the modified tensor methods predicted specimen fracture (Fig. 9(a) and Table 2). At a slightly lower deformation magnitude of 1.05%, the scalar method predicts specimen survival to 10^7 cycles, while the tensor and the modified tensor methods predict specimen fracture (Figs. 9(b) and 9(c)). At a further decreased deformation magnitude of 0.7%, all three methods predict specimen survival (Fig. 9(d)). For these loading conditions, it is evident that both tensor-based methods clearly impact the predicted mean and alternating stresses, in that the alternating stresses are higher and mean stresses are lower as compared to the scalar method. In fact, for these particular loading conditions, the tensor and the modified tensor methods produce almost identical results, which can be appreciated by interrogating stress values near the

alternating stress axis (Fig. 9(c)). For this case study, the FSFs using the tensor and modified tensor approaches (Table 2) were consistently found to be around 35% lower than the FSF calculated using the scalar approach, regardless of whether fracture was predicted or not.

An example pseudocolor plot from the computational models at 1.05% axial deformation is shown in Fig. 10. The computational model predicted the high-stress regions to be at the apices of the thinnest connectors (i.e., CONN-4) and as such determined the critical locations for potential fatigue fracture. This computational result for the high-stress region was identical to the observed fracture location in experiments. The stresses at this critical location indicate a predominantly uniaxial stress state with S_{22} and S_{12} exhibiting values that are less than 5% of the S_{11} magnitude. Furthermore, since the two extremes of cyclic loading are virtually symmetric from a stress magnitude perspective, this material point is sustaining an alternating stress that is nearly uniaxial with near zero mean stress. Since the principal stress directions at both extremes in loading are aligned, the alternating stress tensor and the mean stress tensor are also aligned. As a result, both the tensor method and the modified tensor method produce almost the same results, as shown in Table 2. This result is in contrast to the positive mean stresses calculated by the scalar method which ranged from 25–50 ksi.

5 Discussion

The current study presents a comprehensive computational fatigue approach for calculating FSFs of cardiovascular stents under general conditions of cyclic loading and uses new experimental data to estimate the predictability of the approach. The case example presented here highlights differences in estimating the predictability of fatigue safety for mock cardiovascular stents undergoing fully reversed axial fatigue based on three FSF computations. For the low axial deformation magnitude, all three approaches predicted a “no-fracture” outcome, i.e., $FSF > 1$, which was consistent with the bench-test result. At the intermediate axial deformation magnitude chosen, the computational prediction using the tensor and the modified tensor approaches was able to predict stent fractures as well as the fracture location observed during bench-testing, while the scalar approach still indicated a “no-fracture” outcome. At the further increased axial deformation magnitude, all three methods were predictive of fracture ($FSF < 1$) consistent with the bench-test outcome.

These differences in the FSF and the resulting degree of agreement between the computational prediction and the bench result were primarily driven by different values of mean and alternating stress calculated by the three methods. The tensor and modified tensor approaches resulted in larger alternating stresses relative to the scalar approach along with near zero mean stresses; this trend was significant when predicting fatigue fracture in comparison to experimental samples. The close to zero mean stresses using the tensor and modified tensor approaches is intuitive considering the applied loading condition is a fully reversed axial tension-compression fatigue cycle. However, the scalar approach does not predict this state of stress and instead showed significant positive mean stresses due to the intrinsic assumption of utilizing maximum principal stresses at both extremes of the fatigue cycle. As a result, FSFs computed by the scalar method did not consistently agree with

experimental data, while both tensor-based methods consistently predicted the experimental fracture outcome as shown in Table 2.

As illustrated with a simple conceptual example in Sec. 2 as well as in the presented case study, the scalar method can incorrectly predict mean and alternating components when the stresses change sign across the cycle. This can occur, for example, when the stent is subject to small preloads leading to small or zero local mean stresses (R -ratio is close to minus one). With a larger stent preload and a resulting increase in local mean stresses, the scalar method is expected to converge to the tensor and modified tensor methods assuming that the principal directions do not change during the fatigue cycle.

Additionally, the mean and alternating stress results derived using both scalar and tensor methods can be erroneous if the principal directions increasingly shift orientation during the fatigue cycle. The shift in principal directions can occur due to a complex (multi-axial) state of stress, large cyclic deformations, rigid-body rotations, or a combination of these three conditions. This point is illustrated using another case, where a computational analysis was performed under cyclic torsion loading, with a static axial load superimposed. Specifically, a 1.05% tensile preload was modeled followed by cyclic torsion using a magnitude of ± 10 deg. Figure 11 shows the resulting stress contours and highlights the critical stress location at which the stresses are captured at the two ends of the torsion fatigue cycle. While the critical stress location is still located at the apices of the thinnest (centrally located) connectors, the stresses are clearly not equivalent in magnitude across the ends of the fatigue cycle. For this example, all three methods produce safe, but more importantly different FSFs as shown in the last row of Table 2. The difference in results between the tensor method and the modified tensor method can be understood in light of rotations of the principal directions presented in Table 3. The principal directions at the ends of the fatigue cycle are near identical for the cyclic axial loading case, which explains why the FSFs calculated with the tensor method and modified tensor method were so similar. However, for the cyclic torsional case, the principal directions change drastically across the fatigue cycle (bottom row of Table 3), clearly resulting in different FSFs between the tensor and modified tensor method. For this case, the mean stress tensor and the alternating stress tensor are not aligned, thus projecting the mean tensor onto the alternating tensor is important in order to calculate appropriate FSFs. It should be noted that only two components of the principal directions are shown in Table 3, as these results are derived from membrane elements on the specimen surface (with third principal direction normal to the surface).

Collectively, the results from this study suggest that both of the following conditions need to be met for the scalar method to present a reasonable approximation for mean and alternating stresses under cyclic conditions:

- (i) The principal directions do not substantially change direction during the cycle.
- (ii) Presence of large local mean stresses such that stresses do not change sign during the fatigue cycle.

It should be noted that for the tensor method, the second condition is already met since it intrinsically accounts for low mean stresses/low preload. However, the tensor method may present erroneous results when the first condition is not met. In the presented cyclic axial

compression test case, negligible rotation of stress principal directions was observed across the fatigue cycle. Therefore, the first condition was already satisfied due to the nature of the test problem geometry and loading conditions. This explains the reason that the tensor method led to similar results as the modified tensor method. However, the case of torsional cyclic loading demonstrated the importance of meeting the first condition because when it was not met, the tensor method and modified tensor method diverged from each other.

The two conditions listed earlier are expected to be largely applicable for the specific scenario of stents undergoing radial pulsatile loading. While the vessel distension under blood pressure loading is predicated by the regional anatomy, the local stent radial excursion is small along with minimal rotations of principal directions during the fatigue cycle. Additionally, the vessel radial preload onto the stent is expected to lead to positive R -ratios, such that the fatigue prone regions are subject to tensile–tensile cyclic loads. Therefore, it is intuitive that for these simpler loading conditions, the scalar (and tensor) method would predict similar mean, alternating stresses, and FSFs as the modified tensor method.

On a final note, the authors acknowledge that the Goodman line (signifying the pass/fail threshold of fatigue safety) was assumed as deterministic, while practically there exists a probability distribution around it. The material fatigue limit (as well as the ultimate tensile strength) utilized in this case study were established conservatively from the derived test data, and the Goodman line could potentially lie further outward in the positive mean and alternating stress quadrant. This may shift the reported FSFs and should be considered when estimating specimen survival.

In summary, the scalar method and both tensor-based methods can result in reasonable predictions for FSFs under specific loading and local stress conditions. The modified tensor method presents a more comprehensive and general approach for calculation of mean/alternating stresses as well as the resulting FSFs. In conclusion, the authors believe that the modified tensor method will be applicable regardless of loading and stress conditions.

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Fig. 1.
Simple example of rotating stresses during loading

Fig. 2. Schematic of stent test specimen (top) and diagram illustrating the varying connector widths along the stent length (bottom)

Fig. 3.
Material true stress versus true plastic strain response

Fig. 4.
Finite element model boundary conditions

Fig. 5.
Comparison of the experimental and simulation load–deflection behavior due to monotonic axial loading

Fig. 6.
Depiction of the method to calculate gauge length (distance between arrows) for the test specimen

Fig. 7.
Experimental fatigue data showing fractures and survival to 10^7 cycles

Fig. 8.
Typical fractured test specimen with fractures near the apices of the thinnest connector
CONN-4

Fig. 9.

Goodman scatter-plots for axial deformation magnitudes of 1.30% (a), 1.05% (b), zoomed in 1.05% (c), and 0.70% (d). For plots (a), (b), and (d), it should be noted that the scatter plot for the tensor method is not visible due to similar results with the modified tensor method.

Fig. 10. Surface stresses at the point with lowest FSF (based on both tensor and modified tensor methods) at 1.05% deformation

Fig. 11. Surface stresses for cyclic torsion (± 10 degrees) superimposed on a 1.05% tensile pre-load

Table 1

Material properties used in computational model

Modulus of elasticity	35.3×10^6 psi
Poisson's ratio	0.3
Yield stress (0.2% offset)	85.6 ksi
Ultimate tensile strength (true stress)	220.8 ksi

Table 2

FSFs from computational modeling. A value above 1.0 predicts survival to 10⁷ cycles while a value below 1.0 predicts stent fracture.

Cyclic deformation mode	Cyclic deformation magnitude	Scalar method FSF	Tensor method FSF	Modified tensor method FSF
Axial	0.70%	1.6529	1.0705	1.0711
	1.05%	1.1029 ^a	0.7135	0.7141
	1.30%	0.9057	0.5890	0.5891
^b Torsion	10 deg cyclic torsion superimposed on a 1.05% tensile preload	1.6288	1.2646	1.4138

^aThe computational prediction did not match the experimental result.

^bExperiments with these conditions were not performed.

Table 3
Principal stress directions at the two ends of the fatigue cycle (unit vectors are shown in local coordinate system)

	Unit vector at first peak of fatigue cycle	Unit vector at second peak of fatigue cycle
1.05% cyclic axial deformation	Principal-1 direction	(0.9995, 0.0309)
	Principal-2 direction	(-0.0309, 0.9995)
10 degree cyclic torsion (superimposed on a 1.05% tensile preload)	Principal-1 direction	(0.9524, 0.3048)
	Principal-2 direction	(-0.3048, 0.9524)