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Fatigue to Fracture: An Informative, Fast, and Reliable Approach for Assessing Medical Implant Durability

ABSTRACT: This paper compares the differences between the "test to success" and "test to fracture" paradigms for medical implant durability assessment. It recognizes that test to success can be one of the tests within test to fracture, in addition to a series of shorter cycle, higher force/deformation tests. In addition, by "testing to fracture," one can validate the fatigue analysis capability, learn the consequences of in vitro fractures, and provide information that can either be used for product improvement or for clinicians to make life-saving decisions.

KEYWORDS: fatigue, durability, fracture, medical implant, FEA

Introduction

The Fatigue to Fracture (FtF) and Beyond working group, under the ASTM F04.30.06 Endovascular Devices Task Group within the Cardiovascular Standards Subcommittee of Committee F04 on Medical and Surgical Materials and Devices, was formed in May 2006. The scope of the FtF group's effort is to develop improved in vitro methods for assessing and characterizing the long-term fatigue behavior and durability of cardiovascular implant devices, such as stents and stent-grafts. The initial focus of the work addresses devices constructed primarily of metallic materials (initially vascular stents, including both self-expanding and balloon-expandable systems), although in concept this activity could have much broader application. This effort is intended to augment existing medical device industry practices, associated regulatory guidance, and current ASTM device testing methodologies and standards. The purpose of this paper is to present a review of the group's activities and report progress and plans for the near future.

Philosophical Statement

Although the historical paradigm for assessing the fatigue resistance of endovascular devices has been to "test to success" (i.e., conclude testing after application of a pre-specified number of cycles even if device fracture had not yet occurred) under some predefined set of simulated physiologic conditions, the task group adopted the following as working hypotheses:

(1) Any structure will fatigue and eventually fracture. It is a function of time and loading or deformation conditions.

(2) Given the broad differences in human anatomy, physiology, and lifestyle among patients in any target population, it is more informative to determine when fracture may occur, under what conditions, and the consequences of fatigue fractures rather than to assume that fracture will not occur based on a limited amount of "testing to success" under assumed conditions.

(3) Therefore, the actual fatigue characteristics of a device can only be determined by testing to fracture.

(4) The best way to define the fatigue behavior of implant devices is a validated process that combines well-planned tests to fracture with appropriate and sufficient stress-strain analysis (e.g., finite element analysis or FEA).

Background

One of the major design considerations for any cardiovascular implant is its long-term structural integrity. Fracture can conceivably result in loss of performance (e.g., loss of radial support of a stent, failure of an endovascular graft to exclude an aneurysm) or direct threats to safety (e.g., initiate thrombosis, perforate an artery).

The traditional paradigm for ensuring the fatigue resistance of cardiovascular implants has been fatigue testing to a number of cycles equivalent to a service life of 10–15 years with no fractures allowed. For stents subjected to arterial dilation caused by cardiac pulse pressure, this is typically approximately 400 million cycles under quite severe simulated physiological pressures (see ASTM F2477–06 [1]). This approach is very time- and revenue-consuming but has the initial benefit of being relatively easy to set up and interpret. However, recent complicating test parameters, such as the simulation of the deployment of overlapping stents in bent anatomical models to better simulate actual clinical use, are diluting this benefit. Furthermore, when the fatigue safety factor, as calculated based on the material's constant fatigue life diagram in combination with the stress-strain history analysis (e.g., FEA), is greater than one, this 400 million cycle fatigue test actually becomes a "proof test" and provides a qualitative validation of the adequacy of the design. The use of this concept has been relatively successful in coronary stenting indications, where, despite evidence that other cyclic loading modes exist in vivo and are not tested on the bench, the clinical fracture rate is reported to be less than 5 % [2].

The successful implementation of coronary stenting revolutionized the treatment of vascular disease. Most recently, the success of drug-eluting stents in the coronary arteries also stimulated the expansion of stenting to other indications, such as the superficial femoral artery (SFA). However, the complex combined deformations in the SFA that often includes bending, axial tension or compression, and torsion, in addition to radial dilation, along with a lack of validated methodologies for bench testing under these modalities, has led to an increased prevalence of clinical stent fractures [3]. Stent fractures of various designs used in the SFA were widely observed in independent clinical trials or outside the United States commercial use. There have been adverse clinical consequences resulting from these stent fractures [4,5]. SFA stent fractures compelled the industry, clinical community, and regulatory agencies to devote significant attention to better methods for the non-clinical assessment of stent fatigue.

In May 2006, the Endovascular Devices Test Methods Task Group formed two working groups to address two technical issues that could eventually improve the current durability assessment of devices. The first working group focuses on developing the understanding of physiology, including anatomic variation, arterial properties, and body motions in specific locations, and transfers this knowledge into boundary conditions appropriate for use in stress-strain analysis and fatigue testing and evaluation. The second group, the FtF group, was charged with developing alternative methods for ensuring device fatigue resistance/durability to complement or eventually replace the test to success paradigm.

Review of Test to Success Methodology

The current methodology of test to success was reviewed through two informative and educational papers presented to the Endovascular Device Task Group [6,7]. As described in these two papers and other common industry practices, the approach in the coronary stent industry as of 2006 was as follows:

- Estimate the radial distension of the stent in a typical indicated artery under "worst-case" or conservative arterial compliance and blood pressure conditions.
- Fatigue test 8–12 samples under constant radial distension ($\Delta D/D$) to simulate assumed severe clinical conditions, for approximately 400 million cycles. The acceptance criterion was no stent strut or bridge fractures.
- Establish and justify the ultimate tensile strength (UTS, σ_u, in Fig. 1) and fatigue strength or strain at 400 million cycles (σ_{400M} in Fig. 1) either from the literature, material supplier's data, or experiment. Construct a 400 million cycle constant life diagram for the applicable material. Either the median values (50 % survival) or reliability-based values (e.g., 90 % survival with 95 % confidence) are used for fatigue safety factor calculations. This is represented by the solid line for 400 million cycle constant life boundary in Fig. 1. This is commonly referred to as a stress-based Goodman diagram.
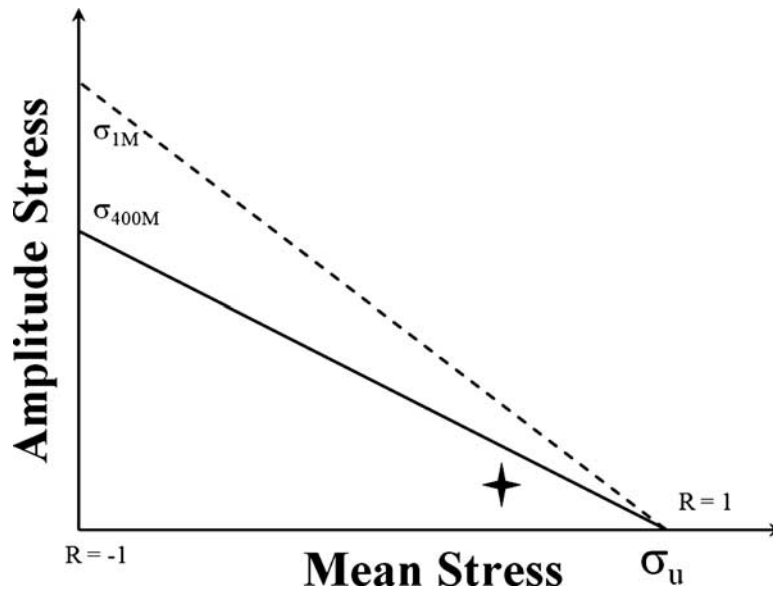- Demonstrate from fatigue calculations (normally based on FEA) that the mean and amplitude

FIG. 1—*Demonstration of 400 million cycle fatigue safety, i.e., worst-case fatigue stresses from FEA (shown in star in the chart) are below the 400 MM constant life diagram.*

maximum principal stresses-strains are safe relative to the constant life diagram (star marker in Fig. 1). Quantitatively, a safety factor can be calculated based on the Goodman equation.

The disadvantages of this test to success philosophy have been recognized as follows:

(1) The definition of "worst-case physiological" is inconsistent and inexact. The Food and Drug Administration (FDA) advises that it is the manufacturer's choice to determine and justify the loading environment for the device and application. However, manufacturers, especially small start-up companies, often need to make critical decisions based not on clinical data but on very limited pre-clinical studies, such as comparisons of their product to existing devices via bench tests or from animal studies. Although all the devices ultimately have the same service environment (the patient), the device may change that environment and that leads to different mechanical and in vivo performance among competing designs.

(2) There is no quantitative experimental validation to verify the analytical fatigue safety factor calculation from FEA or other operational stress analysis. Fatigue test to success only qualitatively "validates" the fatigue analysis; the analysis and experiment agree only on "no fractures" at 400 million cycles. When failure would eventually occur is unknown due to the lack of the testing to fracture.

(3) Material behaviors, especially cyclic fatigue characteristics, are known to be different for small structures. Use of literature fatigue data without validation that accounts for differences between the literature and the stent structure and material does not necessarily lead to reliable fatigue safety.

(4) No experimental failure mode information is gleaned for use in Failure Mode, Effects, and Criticality Analysis (FMECA). Without knowing the true fracture mode and possible progression, this leads to the conservative assumption that all fractures constitute clinical failure and cannot be tolerated, which may not necessarily be true.

(5) The experiment itself is time-consuming (typically 6 months for 400 million cycles) and expensive.

(6) If extremely conservative worst-case loads are superimposed on worst-case material properties and worst-case dimensions/geometries, devices are unnecessarily over-designed, or other critical attributes, such as deliverability, may be diminished for the sake of structural conservativism.

(7) Systolic-diastolic pulsatile pressure is not the only clinical force/deformation mode that must be addressed in bench testing or analysis. Other cyclic deformation modes, such as arterial bending, crushing, axial tension or compression, and torsion can occur, at various frequencies and phases, due to the different physiological forcing functions (e.g., cardiac, respiratory, locomotion). As a

result, duty cycles for all possible deformation modes at body specific locations should be carefully studied and implemented into stent designs and validation testing.

(8) Devices are and will continue to be used clinically outside their labeled indications and in different patient populations. The current paradigm reports only that the device should not fracture under one specific set of conditions, presumably consistent with the labeled indications. Should a clinician need to use the device in different circumstances for which it was not designed, he has absolutely no guidance as to how far he can "push the envelope." This concern was reported well for multiple clinical considerations, not just fracture, by Rogers and Edelman [8].

Uniqueness of Stent Durability

A vascular stent is a small tubular structure commonly made of one of a few biocompatible and corrosion-resistant metals, such as 316L stainless steel, nitinol, or cobalt-based alloys. Stents have unique attributes that influence the assessment of their durability. First, the overall size of the stent can be quite small—some coronary stents are less than 2.5 mm in diameter and 10 mm in length. Typical cross-sectional dimensions of a single strut, the fundamental structural unit that forms the stent, are on the order of 0.1 $\times 1$ mm². Fatigue of such a small structure is unique and often not predicted by test and analysis of larger specimens or from mechanical properties typically determined on larger specimens. Furthermore, the properties of the stent in vivo can be influenced significantly by handling and processing, including catheter loading, delivery, and deployment into the body. This leads to difficulties in generating representative fundamental material fatigue data that are necessary for a total life approach. Similarly, the most advanced technology in assessing metal fatigue, that is, damage tolerant fatigue life approach, or fracture mechanics, does not apply directly to small structures owing to the lack of small scale yielding conditions as well as the size effects in the crack growth diagram. This leads to the conclusion that well-established bulk material fatigue data may not be applied directly to the analysis of a vascular stent.

Second, the loading/deformation environment and duty cycles of stents are not generally known. This is due to the lack of knowledge of mechanical properties of cardiovascular tissues and how they deform together with surrounding hard/soft diseased tissue. This void in the knowledge base required for stent durability is being addressed by the Arterial Deformations Working Group within F04.30.06. This is the first attempt within the industry to standardize the most important input for implant durability assessment. Traditionally, it has been left to each individual device manufacturer to define what in vivo conditions should be used as part of the design requirements for each product.

The third challenge specific to stent durability analysis is the material and geometric nonlinearity and anisotropy of the metal, artery, and stent-tissue interactions. Balloon-expandable stents are deformed far beyond the material's yield strength during crimping and deployment. The elastic "shakedown" of L605 Co–Cr alloy after first loading beyond yield was recently observed (Appendix) but this phenomenon was not included in any of the current stent fatigue analyses. In general, fatigue analysis of both balloon-expandable and self-expanding stents requires an understanding of the material characteristics far beyond current knowledge. Yet cyclic properties of these materials are often difficult to generate because material forms, such as thin-walled tubing, sheets, or fine wires, are not suitable for the traditional fully reversed strain or stress-cyclic testing. The nonlinear mechanical properties of diseased arteries, and the influence of post-stent healing, often in the presence of pharmacological agents, are not considered. The anisotropy of the artery is well-known but is rarely considered in fatigue analysis. When all these factors are combined, it is not hard to understand why durability assessment of stents is difficult and further refinement and standardization is necessary.

Proposed Approach or Elements of Durability Assessment

The proposed FtF approach was summarized by Chwirut in May 2006 [7]. The procedures are as follows:

(A) Analytical—Use FEA or other stress analysis tools to determine the operational stresses-strains (peak static plus in vivo cyclic) under reasonably conservative (so-called worst-case) physiological forces or displacements, plus other elevated hyper-physiological forces/deformations sufficient to cause device fracture.

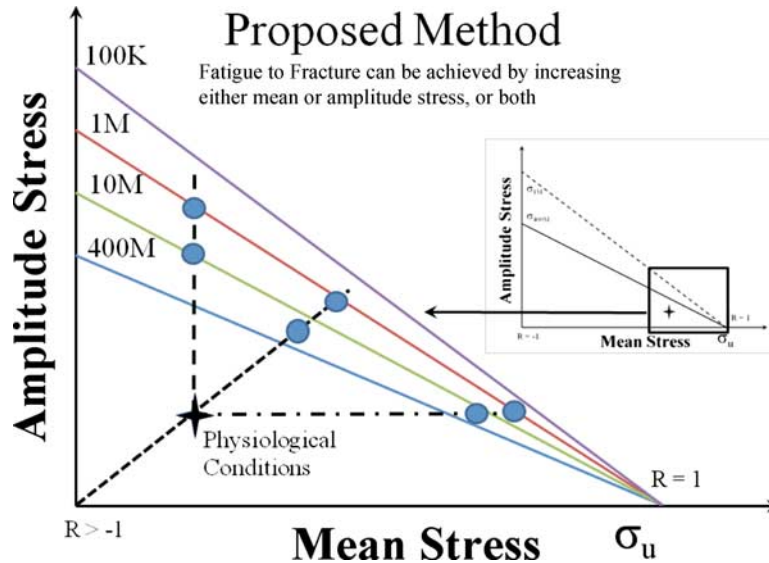(B) Material properties—Develop statistical monotonic (modulus of elasticity, yield strength , UTS,

FIG. 2—*Proposed possible testing conditions shown on a refined constant life diagram.*

etc.) and fatigue (*S-N* or *ε-N*) characterization of the material, out to the necessary product life (e.g., 400 million cycles for stents).

(C) Fatigue analysis I—Operational stress analysis results are compared to mechanical properties for the material. Static and constant life-type fatigue safety factors are calculated for physiological loads.

(D) Fatigue analysis II—Using multiple material *S-N* or *ε-N* family of curves, draw constant life curves for fracture at each decade (10^8, 10^7, 10^6 cycles, etc.) on mean and amplitude stress (or strain) plane. From the stress analysis results for "hyper-physiological" deformations, predict the cycles to fracture for these loads.

(E) Experimental—Conduct fatigue testing to fracture under hyper-physiological loads/deformations on finished devices, with device fractures occurring in the range of 1–100 million cycles.

(F) Compare the results of the FtF experiments (step E) with the fatigue analysis II (step D), per Fig. 2. Establish reliability values for predictive fatigue analysis (e.g., median, 90 % survival).
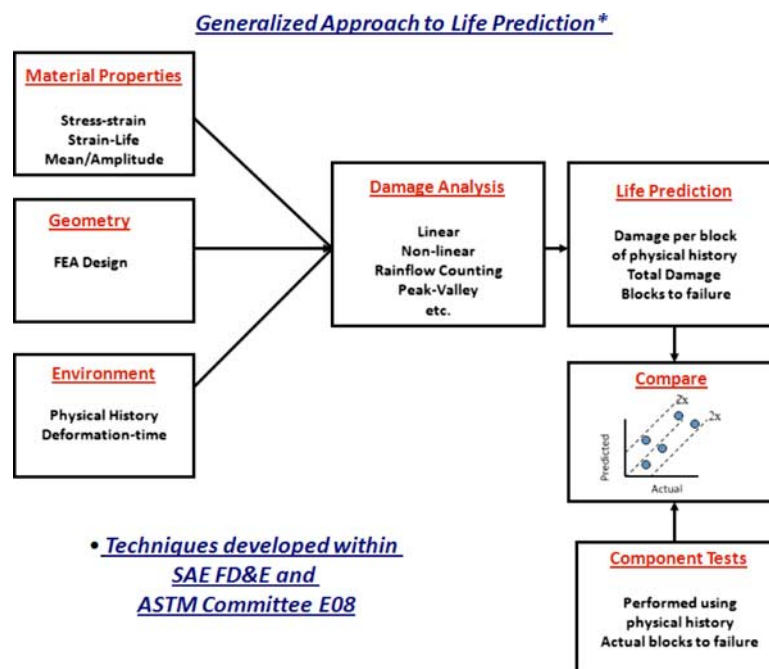

FIG. 3—*Schematic representing inputs for fatigue lifetime predictions.*

In a presentation to the FDA in February 2008, as shown in Fig. 3, Mitchell presented a methodology that has been successfully used in the ground and aerospace vehicle industries for nearly 5 decades [9]. This approach requires the consideration of variable amplitude loading or the duty cycle of the device through detailed strain-life prediction with a damage accumulation model. It was Mitchell's belief that the strain-life predictive method was well accepted since its inception in the early 1950s primarily due to the fact that strain or deformations (as opposed to stress) can be measured directly. Cyclic and fatigue data is available on many commonly used materials. Although these data may not be directly applied to the stent applications, they offer good references to plan the test. Strain-life or the local stress-strain approach is a robust, technology in life prediction that has not extensively been utilized to evaluate stent durability. Such a successful methodology deserves consideration for small length scale structures such as stents.

There are two key issues that are consistent in both Chwirut's [7] and Mitchell's [9] approaches to FtF:

(1) Generate the cyclic and fatigue material properties.

(2) Test to fracture to validate the predictive method.

The top left box in Fig. 3 explains item 1 in the proposed approach. Both authors reminded engineers that cyclic stress-strain properties were likely to be different from the monotonic properties. The reason is that metals are unstable under cyclic force or displacement conditions and the metal's deformation response changes due to the repetition of such forces or displacements. Depending on the initial state of the metal (annealed, quenched and tempered, cold worked, etc.), it may cyclically harden, cyclically soften, remain cyclically stable or exhibit mixed softening and then hardening responses depending on amplitude strain levels. Because material properties, in general, vary due to cycling, one must be aware that the monotonic behavior is not adequate in analyzing a design required to resist cyclic force or displacements. For this reason, cyclic and fatigue properties of metallic materials must be characterized through proper experiments. The reader is referred to two published standards: ASTM E606 "Recommended Practice for Strain-Controlled Fatigue Testing" and ISO12106 "Metallic Materials—Fatigue Testing—Axial-Strain-Controlled Method" for the test methodology involved in performing such evaluations.

No matter what predictive method is used, it is often found in practice that the consistency between the material's fatigue characteristics and the operational stress analysis plays a more critical role than anything else. One should note that there are multiple ways to perform detailed durability analysis. Regardless of the fatigue and durability analysis methods, inputs of material properties, geometry, and the environment (left three boxes in Fig. 3), are always necessary. One will also find that there are many details required to perform life prediction under conditions that involve different loading modes and magnitudes. To emphasize these important details, they are summarized below.

In the strain-based approach, a series of smooth companion specimens is subjected to completely reversed, $R=-1$, axial strain-controlled fatigue tests. A series of hysteresis loops is collected from each companion specimen and the stable response is noted, i.e., where the stress required to enforce the strain remains reasonably constant. The stabilized stress response is then plotted against the controlled strain amplitude of each companion specimen tested to obtain the cyclic stress-strain curve—that describes the metal's cyclic behavior.

Along with the development of the cyclic stress-strain curve from each companion specimen test result, the stabilized hysteresis loops can also be employed to determine the elastic and plastic strain components of the total strain (i.e., the controlled variable in the fatigue tests). With some manipulation, one can then construct the strain-life curve. In conventional metals, the total strain can be decomposed to elastic and plastic strain components that are plotted on the strain-life curve. It will be noted that in many cases the elastic strain-life and the plastic strain-life curves are linear on a log-log plot. Typically, the abscissa is "Reversals to Failure, $2N_f$" or twice the number cycles to failure. The reason for this is that in typical deformation (strain)-time component histories in actual applications, it is quite simple to define a "reversal" rather than a "cycle." A reversal can be thought of as a change in the slope on a deformation (strain)-time history.

Mean stress can be simply included in this approach by a modification of the elastic strain-life intercept by an amount equal to that of the mean stress. That is, the familiar strain-life equation can be modified to

$$\frac{\Delta \varepsilon}{2} = \frac{\sigma_{f'} - \sigma_o}{E}(2N_f)^b + \varepsilon_{f'}(2N_f)^c,$$

where:

σ_o=mean stress with appropriate sign,

$\Delta \varepsilon / 2$=strain amplitude,

$\sigma_{f'}$=fatigue strength coefficient,

E=modulus of elasticity,

$2N_f$=reversals to failure,

b=Basquin's exponent,

$\varepsilon_{f''}$=fatigue ductility coefficient, and

c=Coffin's exponent.

Compressive mean stresses are negative and therefore additive so that there would be an increased influence on long life fatigue and very little influence on short life fatigue. It is also necessary to understand that the sequence of events in a component's history is important in the fatigue lifetimes because of the mean stresses that can result in a transfer sequence from compression to tension and vice versa. Since there are four quadrants in stress-strain space, one might have a tensile mean stress with a compressive strain and vice versa.

The strain-based approach lends itself readily to fatigue lifetime predictions and damage analysis in a pseudo-random loading spectrum (i.e., a repeated block-type, random history duty cycles). This is contingent upon a means of "counting" closed hysteresis loops in a pseudo-random, repeated block-type, strain-time history. This is typically accomplished by what is called the "rain flow" counting algorithm as described in ASTM E1049. Finally, a Palmgren–Miner linear damage summation is commonly employed to sum damage for each closed-loop event in a history.

So, as one might expect, these types of analyses lend themselves readily to computerized techniques, as can be found in more detail in several references. The software for these types of analyses has been described in a September 2008 ASTM E08/F04 jointly sponsored workshop, "What's Available in Fatigue Lifetime Predictive Software" and is available online at http://www.me.wustl.edu/FSW08/ where the user name is ASTM and the password is Fatigue.

Obviously, the local stress-strain response of a particular design depends on geometry and external driving forces or displacements. Stent geometry is complex resulting in a complex stress-strain state. Thus, stress-strain analyses through appropriate stress analysis (FEA) software is necessary for fatigue predictions of stents. Subtle changes in geometry may alter the stress-strain state requiring a repeat of the stress analysis.

Chwirut [7] and Mitchell [9] both suggested testing to fracture to validate analytical predictions. More details, including the application of test to fracture during product development, were given by Mitchell [9], as follows:

(1) Compare the predicted fatigue lifetimes to actual component lifetimes using the same histories in both analysis and testing.

(2) Modify Design A and predict the expected lifetime with the same history to determine if Design B is better or worse than Design A, then test the device with the same history to see how accurate the prediction was.

(3) Modify the material properties, predict the fatigue lifetime under the typical history, and determine if the change in material properties improves or reduces the fatigue lifetime.

(4) Accelerate fatigue testing once confidence with the lifetime predictions is gained.

In summary, the advantages of test to fracture include the following:

(1) Establishes experimental safety boundary (forces/deformations at which fractures begin to occur at the desired cycle counts).

(2) Once predictions are validated with confidence, shorter device testing time is expected (<10 years).

(3) Quantitative validation of fatigue analysis that can be reliably used to predict longer device fatigue life.

(4) Fracture mode information for use in FMECA.

Summary of Working Group Activities

The primary activity during the first year of FtF working group activity was to look for a robust test and analysis method that would lead itself to validation through round-robin testing and analysis. Different loading modes, including rotary bend, four-point bend, radial pulsatile, and axial fatigue were proposed. Different materials were considered. For logistical reasons, the working group decided to start with an axial fatigue test and analysis using balloon-expandable stents made of 316L stainless steel.

Generic (non-commercial) stents were designed and fabricated by one of the working group participants. Prior to initiating actual testing, the design was analyzed by FEA by one of the participants (EchoBio) to confirm that the small displacements expected to result in stent fracture could be controlled with the available fatigue test equipment. A robustness experiment was then performed and a protocol drafted by another participant (MED Institute). This test protocol was circulated for group review and finalized and is now available online on the group website. Testing articles (stents) and deployment balloons were supplied by a stent manufacturer (Cordis Corp.), and additional deployment balloons were supplied by another producer (MED Institute). Currently, four participants (Boston Scientific, FDA, MED Institute, and Medical Implant Mechanics) are conducting tests as round-robin participants. In parallel, a Phase I FEA was initiated in May 2008 and quickly finalized. The FEA analysis team is currently reviewing the results.

Technical Challenges and Potential Solutions

(1) Material data: Monotonic, cyclic, and fatigue properties for certain materials (e.g., live tissue, nitinol) are difficult to obtain.
Potential solution: Development of a subcomponent or component fatigue test to create displacement-life data. Generalize them using FEA for predictive use. The example of this solution is the work done by Pelton et al. [10].

(2) Fatigue analysis: It was simple and straightforward to analyze a fatigue-safe scenario under the radial pulsatile fatigue condition because the small stress-strain amplitudes and radial distensions limit the stress-strain to the proportional loading condition. When other testing conditions, such as axial, bending and/or torsion of a stent are analyzed, especially at elevated conditions intentionally to test to fracture, the stresses-strains at critical locations on the stent are likely non-proportional, and therefore the calculation of the stress-strain history must be performed with special care. In addition, for new materials such as nitinol, the predictive method is normally not available so the analyst has to create their own.
Potential solution: Apply fatigue theory or use commercial fatigue analysis software to perform multiaxial fatigue analysis that matches the fatigue tests. In cases of a new material in use, develop the proper fatigue analysis method from well-planned tests.

(3) Customized fatigue tests: Deformation modes other than radial pulsatile, axial fatigue, and/or mixed mode fatigue tests often require customized testing equipment and resources due to the lack of standard testing methods for these deformation modes.
Potential solution: Develop customized in-house testing methods and equipment, or out-source to external testing services. Participate and contribute to the non-pulsatile fatigue testing method standard development.

Conclusions

The F04.30.06 FtF working group believes fatigue testing to fracture provides advantages over testing to success in addressing the durability of metallic stents and/or stent-grafts in the two following major areas:

(1) It provides quantitative experimental validation of the analytical fatigue life prediction method.
(2) It provides failure mode information to allow evidence-based consideration of potential hazardous clinical hazardous outcomes secondary to *in vivo* fractures.
(3) Once validated, it is faster and more accurate in predicting the device life.

The in vitro generated FtF scenarios can be used for FMECA to understand the criticality of the possible in vivo fractures. The in vitro test conditions under which fracture might be anticipated could (and should) be reported in the Instructions for Use as a reference for clinicians when the device must be used

in extraordinary circumstances so that the potential hazards are properly anticipated and follow-up treatment be planned.

The full FtF methodology requires material level, component, or subcomponent level fatigue characterization (i.e., *S-N* or *ε-N*) that adequately represents the device scale, material, and surface conditions. The resources and time required to obtain such data are considerably higher and more expansive than a single test to success. However, once these data are obtained and a series of FtF tests on devices are conducted to confirm fatigue predictions based upon these data, one can reliably predict longer term fatigue life from relatively short term fatigue testing, cutting the test time substantially. When the material level fatigue characterization is impossible or too burdensome, a partial implementation of the FtF methodology, where unit cells or complete devices are tested at multiple levels (including a test to success level to the expected lifetime of the device), provides the critical information to assess the durability of a device.

Finally, this article identified several challenging issues that need to be completed for a full realization of the FtF methodology, including development of standardized non-radial fatigue testing methods, determination of the in vivo conditions expected in various arteries, research of multiaxial fatigue theories, and methods to characterize fatigue material properties of materials used for devices of small length scales.

Acknowledgment

Appendix

Elastic shake down of the Cr–Co medical grade tubing at 20 % total strain is shown in Fig. 4 below. The tubing sample was pulled to 20 % and then cycled within 19.9 % and 20.1 %. Stress drops during the cycles indicated the elastic shakedown of the material. This test is provided to the FtF working group courtesy of Dr. Fei Zhou at Edwards Lifesciences, LLC of Irvine, CA. Material is a courtesy of Accellent Inc. of Wilmington, MA.
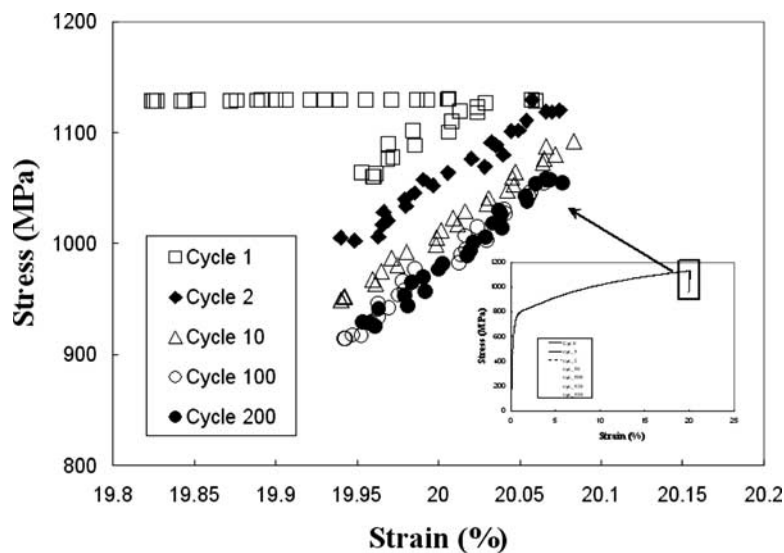

FIG. 4—*Cyclic behavior of Cr–Co medical grade tubing at high mean strain.*

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