Design and Testing of a New Vascular Stent with Enhanced Fatigue Life

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Abstract. Vascular stents could suffer from repetitive motions due to pulsatile blood pressure and daily activities. Stent fatigue resistance has thus become a critical issue for stent design. In this paper, an intriguing stent design concept aimed at enhancing the fatigue life was investigated. The concept was to re-distribute stresses more uniformly by tapering the stent strut width. Finite element models were developed to evaluate the mechanical integrity and fatigue safety factor of the stent under various loading conditions. Simulation results show that the fatigue safety factor of this novel stent design increased by 4 times that of a conventional stent. Conceptual stent prototypes were cut by a pulsed-fiber laser, followed by a series of expansions and heat treatments to gradually shape the stent to its target size. A rotating bending fatigue tester was built for this study and stent fatigue tests were conducted for proof of concept. Experimental results show that this stent design concept successfully enhanced the fatigue life as designed. Its fatigue cycle number jumped to 6~7 times that of a conventional stent, which agreed well with the trend predicted by FEA simulations. The findings of this paper provide an excellent guide to greatly improve stent fatigue life.

1. Introduction

Stenting procedure has received great attention from the medical society since its introduction. However, these vascular stents could suffer from various repetitive motions due to pulsatile blood pressure and daily body activities after implantation, especially in the indications of peripheral arteries. Such motions oscillate the stents repeatedly, leading to the potential risk of stent fatigue failure. Such failure has drawn much attention in recent years and, therefore, stent fatigue resistance has become a critical issue for stent design.

Nitinol is an excellent candidate for medical devices due to its unique properties. The peripheral stents are perhaps the most celebrated applications of the nitinol material [1-4]. They are super-elastic, i.e., crush recoverable, exert a gentle chronic outward force (COF) to the artery wall, and are more physiologically compatible than balloon-expandable stents in many indications such as carotid, superficial femoral, popliteal, iliac, and renal arteries. Implantation of self-expanding nitinol stents has demonstrated good clinical results for the treatment of peripheral arterial diseases; however, a fracture rate of up to 50% has been reported in some cases [5]. These fractures are likely due to in vivo cyclic deformations of vascular motion. Stent failure may cause loss of radial support to the arteries, focal restenosis, thrombus formation, vessel perforation or dissection by the protruded stent struts [6-9].

In this paper, a simple yet intriguing stent design concept that significantly enhances the fatigue life, first proposed by Duerig et al. in their U.S. patent and further explored by Hsiao et al., was...
investigated [10-12]. Finite element analysis (FEA) models, widely used in the medical society today [13-16], were developed to evaluate the mechanical integrity and fatigue safety factor of this novel stent under various loading conditions. A rotating bending fatigue tester was built and stent fatigue tests were conducted to validate this design concept. The findings of this paper provide an excellent guide to the optimization of future stent design for the enhancement of stent fatigue performance.

2. Methods

2.1. Tapered-strut stent design concept

A stent is a combination of a series of nested rings interconnected with bridging connectors. Figure 1(a) defines a vascular stent and its three important elements (crown, strut, and connector). Among them, the most critical element is the crown which controls key clinical attributes of a stent such as acute fracture, crimp profile, and long-term fatigue life. The strut thickness is believed to play a critical role in restenosis, whereas the strut width and length dictate the stent radial strength and scaffolding, respectively [17, 18]. During the stent crimping and deployment procedures, the maximum stresses usually occur at the most highly curved crown. In contrast, there are little to no stresses on the straight portion of the strut, which connects two opposing crowns. Therefore, modifications on the stress-free strut has great potential to achieve our goal, with minimal negative impact on other stent clinical attributes.

This design concept is to shift the highly-concentrated stresses away from the crown and re-distribute them along the stress-free strut by tapering the strut width. This design tweak of narrowing the strut width at the midpoint of the struts (Figure 1(b)) could reduce the burden on the crown and enhance the stent fatigue life.

![Figure 1](a) Definitions of three important stent elements, (b) Tapered-strut design concept of narrowing the strut width at its midpoint (2-D sketch).

2.2. Finite element model

Finite element analysis has emerged as an important tool for the optimization of stent designs. It is able to give insights into various aspects of the stent behavior, which may consequently improve the clinical outcome [19-22]. The making of a self-expanding nitinol stent requires an alternating series of expansion and heat treatment procedures as it is formed into its final shape and dimension. The repeated heat treatment in each incremental expansion relieves stresses within a stent, thus allowing it to be expanded to the next size without fractures. After implantation, the stent is then subjected to various modes of loading and may eventually fracture during its functional life.

In this paper, finite element models were developed to evaluate the mechanical integrity and fatigue resistance of a stent subjected to various loading conditions consistent with the current clinical practice. These loading conditions include multiple stent expansions and their corresponding heat treatments during manufacturing, crimping of the stent inside a catheter and its final release into an artery, and simulation of fatigue resistance under systolic/diastolic blood pressure cycles. Finite element analysis was performed using the ABAQUS/Standard finite element solver (Dassault Systems Simulia Corp., Providence, RI, USA) with the user-defined super-elastic material subroutine UMAT [23]. The nitinol
material behavior for the ABAQUS UMAT subroutine inputs were obtained from Pham et al. [24]. The material ultimate strain and fatigue endurance limits used in the fatigue life analysis were 10% and 1%, respectively [25]. These procedures were simulated by finite element analysis with the following steps:

- **Step 1**: Expand the stent to 4.0 mm ID and heat-treat.
- **Step 2**: Expand the stent to 6.0 mm ID and heat-treat.
- **Step 3**: Crimp the stent inside the 2.0 mm ID catheter delivery system.
- **Step 4**: Release the stent into the 5.0 mm ID artery.
- **Step 5**: Simulate stent pulsatile fatigue resistance under systolic/diastolic pressure cycles by applying ±3% stent diameter oscillation (4.85 ~ 5.15 mm).

### 2.3. Goodman fatigue life analysis

Goodman life analysis has been widely used for assessing the device fatigue resistance and provides an indication of device long-term fatigue resistance. It is also recommended by the U.S. Food and Drug Administration (FDA) that Goodman life analysis be conducted to determine the stent fatigue safety factor subjected to physiologic loading up to $4 \times 10^8$ fatigue cycles [5].

In Goodman fatigue life analysis, the mean stress/strain and the stress/strain amplitude are typically used to assess the fatigue safety factor of a material or device. Modified strain-based Goodman life analysis has been widely used for the nitinol stent due to the unique material characteristics [5, 25, 26]. It states that fatigue failure will occur if the strain state in the device satisfies the following relation.

$$\frac{\varepsilon_a}{\varepsilon_e} + \frac{\varepsilon_m}{\varepsilon_u} \geq 1$$

where $\varepsilon_a$ is the strain amplitude applied to the device, $\varepsilon_e$ is the modified material endurance limit for non-zero mean strain, $\varepsilon_m$ is the mean strain applied to the device, and $\varepsilon_u$ is the material ultimate strain. The Goodman diagram is a plot of the normalized strain amplitude $\varepsilon_a/\varepsilon_e$ (on the y-axis) vs. the normalized mean strain $\varepsilon_m/\varepsilon_u$ (on the x-axis). The equation $\varepsilon_a/\varepsilon_e + \varepsilon_m/\varepsilon_u = 1$ represents the failure line on the Goodman diagram. The fatigue safety factor (FSF) is defined as the ratio of the strain amplitude against the modified endurance limit. An FSF of less than 1.0 indicates the stent fatigue failure:

$$\text{FSF} = \frac{\varepsilon_e}{\varepsilon_a}$$

### 2.4. Stent laser cutting and heat treatment.

Manufacturing of a self-expanding nitinol stent requires laser-cutting of the designed pattern onto a nitinol hypotube, followed by an alternating series of expansions and heat treatments as it is gradually shaped into our desired dimension. A laser module consisting of a Rofin 100 W pulsed fiber laser, an Aerotech linear X-Y motor stage, and a Z-direction server motor were integrated, with Argon as the assisted gas. A 2-D stent drawing was first sketched on the X-Y plane and then coded into the 3-D cylindrical coordinate system. The design pattern was cut onto a seamless 2 mm ID nitinol hypotube (Minitubes, Grenoble, France) based on the coded geometry by the laser module.

After laser cutting, multiple heat treatments were applied to shape the stent to the final dimension and relieve its residual stresses. Steel rods with diameters of 4.0 mm and 6.0 mm were used to gradually expand the stent at each heat-treatment stage. The high temperatures associated with laser cutting and heat treatments may create spatter, oxide layers, and other debris that must be removed with further surface finishing. Surface finishing was accomplished in two major steps, sand-blasting and electro-polishing, to form a titanium-rich oxide layer (mainly TiO2) on the surface of the stent, which not only increases its corrosion resistance but also improves its surface conditions.
2.5. Rotating bending fatigue testing
The combination of numerical simulations and bench testing usually leads to a better and faster evaluation process for new medical devices. In order to prove our design concept, a rotating bending fatigue tester, similar to the setup for small diameter solid round wires, was built for stent-deployed hollow round tubes instead. This machine design is based on the rotating beam principle by looping a specimen of pre-determined length through an arc. The bending stresses are determined from the geometry of the loop thusly formed. The specimen functions as a simple beam symmetrically loaded at two opposing points. When rotated a half revolution, the stresses in the specimen originally below the neutral axis are reversed from tension to compression and vice versa. Upon completing one revolution, the stresses are again reversed so that the specimen passes through a complete cycle of flexural stresses (tension and compression). This relatively harsh environment makes it possible to test a large number of specimens quickly to provide a statistically significant distribution of fatigue life at a given stress level. A constant temperature can be maintained by immersing the specimen in a constant temperature fluid bath.

Figure 2. Rotating bending fatigue tester for small diameter hollow round tubes with stent deployed inside (front view).

The rotating bending fatigue tester consists of three parts: (1) a linear bearing module was used to control the displacement and thus the arc formation with high movement precision and load tolerance, (2) three-phase stepper motors were used to provide the tube rotation which generates cyclic stresses at the working speed of 1,000 rpm, with a motor accuracy of 10-4 degrees, (3) RS232 (UTN405) was used for the development of the control module, with Microsoft Visual Studio 2015 as the platform (Figure 2). Since the stent is a hollow cylindrical structure that cannot be mounted directly on the tester as the wire does, we chose a 3 mm ID transparent silicone tube as the medium with a stent deployed inside for rotations. The span of the two rotating couplings was 3 cm which formed the arc radius of 1.5 cm. Upon completing one revolution, tested stents experienced through a complete cycle of combined tension and compression.

3. Results and discussion
A tapered-strut design concept to enhance the stent fatigue life was investigated. In order to quantize such enhancement, the strut width at the midpoint was varied from 100% to 60% of its original dimension in 10% increments. FEA simulation was first performed on a standard nitinol stent with a constant strut width to establish the baseline information for key attributes: maximum strain at expansion and crimping, maximum strain when released inside an artery, and fatigue safety factor subjected to systolic/diastolic blood pressures. During expansion, the maximum strain occurred at the inner surface of the crowns, while there were little to no strains on the struts. Among all five
simulation steps, the crimping step appeared to be the most critical stage of all, as the highest strains were recorded.

For the tapered-strut counterpart stent, its fatigue safety factor jumped to 4.2 times that of the standard stent (from 1.11 to 4.66), as shown in Figure 3. This is amazing considering that such a small design tweak could result in multiple times of increase in stent fatigue resistance. This interesting phenomenon could be attributed to the stress/strain re-distribution after the modification of strut width at the midpoint of the strut, which effectively shifts the stresses/strains away from the crown and towards the strut. In addition, since the stent strut was loaded predominantly in bending, the narrowed strut became easier to bend, thereby taking more energy than usual during deformation. In Figure 4, the none-blue color of the contour plot extended deeper into the mid strut region along the edges for the tapered-strut stent. Its stress distribution was spread out more uniformly than that of the standard case, with lower intensity level near the crown region. From the energy standpoint, this is a more efficient way to manage energy by subjecting a higher volume of the stent structure to the same loading.

Figure 3. Goodman fatigue life analysis of standard nitinol stent and 40% tapered-strut counterpart stent.

Figure 4. Contour plot comparison of strain distribution at 5.0 mm expansion between standard stent (left) and tapered-strut stent with 40% strut width reduction at the midpoint (right).

Figure 5 shows the simulation results of the fatigue safety factor as a function of the narrowed strut width at the midpoint in 10% increments. The fatigue safety factor increased sharply as the strut tapered degree increased, especially between 30% and 40%. A 40% taper in the strut width significantly boosted the fatigue safety factor by 4.2 times.
Figure 5. Fatigue safety factor as a function of the tapered-strut degree at the midpoint in 10% increments.

Table 1. Experimental data of rotating bending fatigue tests.

| Tapered Degree | Cycles       |
|---------------|-------------|
| 0%            | 6464        |
| 40%           | 21022       |
| Sample #1     | 8243        |
| Sample #2     | 66938       |
| Sample #3     | 5374        |
| Sample #3     | 40657       |
| Mean          | 6693        |
| Standard Deviation | 1182 | 18810 |

A rotating bending fatigue tester was built and stent fatigue tests were conducted to prove our design concept. Fatigue tests were manually stopped at approximately every 1,000 cycles for visual inspection. The final cycle number was recorded when the first stent fracture was observed. Three stents were tested in each group (standard stent vs. 40% tapered-strut stent), as shown in Table 1. The average cycle number at break of the standard stent was 6693 cycles, while that of the 40% tapered-strut stent jumped to 42872 circles. This is an impressive 6~7 times increase when compared to the standard stent (Figure 6). This significant increase in the fatigue cycle number at break confirmed the rising trend predicted by earlier FEA simulations.

Figure 6. Fatigue cycle comparison between standard nitinol stent and 40% tapered-strut counterpart stent.
4. Conclusion
A simple yet intriguing design concept for the enhancement of stent fatigue life was investigated. The concept of this tapered-strut stent design was to shift the highly concentrated stresses/strains away from the crown, thus allowing the stress-free strut to carry more loads by narrowing its strut width at the midpoint. Simulation results show that when the strut width was reduced to 60% of its original dimension (or 40% taper) at the midpoint of the strut, the fatigue safety factor could be increased by up to 4.2 times that of its standard counterpart. A rotating bending fatigue tester was built and stent fatigue tests were conducted for proof of concept. Experimental results show that this stent design concept successfully enhanced the fatigue life as designed by 6~7 times that of a standard stent, which agreed well with the rising trend predicted by FEA simulations. This design has great potential for further fatigue enhancement once fully optimized and could help future stent design to achieve vast fatigue enhancement.

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