Optimization of Stent Design by Finite-element Modeling

C. KRANZ, S. KAHL
Berlin

Summary

Mechanical design of a stent is a complex three-dimensional problem. Although considerable effort has already been put into stent development, the present state of the art is still not optimal. In order to facilitate the development and evaluation of new stent designs, finite-element modeling can be used as a tool for stress and deformation analysis. After summarizing the state of the art in stenting and the requirements for an "ideal" stent, finite-element modeling of a new microcellular design is introduced (Tenax®, BIOTRONIK). It is shown that calculations are accurate within a 5% error tolerance, and finite-element modeling is a suitable tool for stent development. In addition, the Tenax® design proved to provide good scaffolding properties, a low elastic recoil and a very low fore-shortening during dilatation. Thus, from a mechanical point of view, the Tenax® design is a promising approach to contemporary stenting.

Key Words

Stent, stenosis, finite-element modeling, elastic recoil, stress analysis

Introduction

Coronary stents are made of different (mostly metallic) materials using different manufacturing technologies. To meet the demanding mechanical requirements for stents, the stress and deformation behavior has to be optimized for each design, material and manufacturing technology separately. For example, the design of one stent cannot be transferred to another material without recalculating the stresses and adapting the design to the new material, and vice-versa.

The stenting procedure in practice requires a minimum outer diameter of the balloon-stent system, because the stent has to be transferred via the vessel and vascular system to the target zone, while causing no damage. Thus, in addition to the deployment, the stresses during mounting have to be considered as well. Usually, stents are "crimped" onto the balloons, i.e., they are pushed onto the balloon, and then their outer diameter is reduced until the connection between the balloon and stent is tight. Consequently, the deformation has to be evaluated in both directions: Reducing the diameter to approximately 0.9 mm as well as increasing it to a maximum of 5.0 mm.

The aim of this article is to demonstrate the feasibility

and power of finite-element modeling for optimizing the stent design. After summarizing the mechanical requirements for stents, finite-element modeling is introduced. Finally, the design of a new stent (Tenax®, BIOTRONIK, Germany) is calculated as an example.

Mechanical Requirements for Stents

In general, the "ideal" stent must be deployable simply and safely to various locations in the coronary arteries, be capable of sustaining the artery's wall stress and must not induce any negative side-effects in the patient.

With regard to the mechanical design, it must allow a safe and simple introduction. In other words, the stent has to be low in profile and flexible. The dilatation of the stent must be possible between 2 and 4 bar and consistent from stent to stent. This requires a high plastic ductility and low elastic recoil (defined as the % reduction of the outer diameter of the stent when the inflated balloon is removed). In addition, it is advantageous for a stent to avoid significant longitudinal shortening or strut twist during dilatation in order to reduce the

mechanical stress on the vascular wall. Stress reduction has a positive effect on restenosis. The same reason espouses a microcellular design. Finally, the hemodynamics must not be disturbed, because turbulences as well as shear stresses on cellular blood components have been shown to increase clinically significant thrombosis and restenosis [1,2].

These general requirements require a bulk material for the body of the stent with high tensile strength, yield strength and ductile yield. Recoil has to be reduced by means of a high Young's modulus and an appropriate design. Macroscopic design features should include stress relief at strut junctures to reduce strut torsion and relatively thin strut cross-sections to minimize the hemodynamic interference caused by the stent.

Finally, the stent has to be biocompatible and corrosion resistant. Although a coating with optimized biocompatibility and hemocompatibility can provide this function, the bulk material itself must not be toxic or dangerous in order to avoid any negative effects in case the coating fails.

Thus, for contemporary coronary stenting, the ideal stent has to meet the following requirements with regard to the mechanical design and the bulk material:

- High radial stability for sustaining the contraction forces of the heart and muscular coronary arteries
- Low profile for safe introduction into small and tortuous vessels
- High longitudinal flexibility for introduction into non-linear stenoses

- High plastic ductility for optimal dilatation
- Low elastic recoil after dilatation
- Low foreshortening during dilatation
- Linear dilatation properties, i.e., no wing formation or strut torsion
- Small strut-to-strut gaps for minimizing the vascular wall stress
- Low profile (strut thickness) to reduce shear stress for cellular blood components
- Good long-term hemocompatibility
- Good long-term biocompatibility (e.g., no cell toxicity)
- Good corrosion resistance

Material Selection

Based on these mechanical requirements, the material can be selected. The stent material must allow an irreversible change in geometry by simply inflating a small balloon inside the stent. This requires plastic deformation with minimum recoil. In other words, the material must have a high plasticity together with a small spring effect. At the same time, the stent has to provide good scaffolding properties in the dilated state. Technically, the requirements are a high tensile strength and Young's modulus. Only metals can be considered as substrate materials for stents. Ceramics are brittle and have an extremely low plasticity under normal conditions; polymers suffer from a low Young's modulus.

If the additional requirements for biocompatibility are

Material	Yield strength [MPa]	Tensile strength [MPa]	Ductile yield [%]	Young's modulus [MPa]	Atomic number
Ti (ASTM F 67)	200....300	250....600	up to 30%	105	22
Ta (ASTM F 560)	200....300	300....600	up to 50%	186	73
316 L (ASTM F 138)	200....300	500....690	up to 50%	200	mostly 26 (Fe)

Table 1. Mechanical parameters of commonly used metallic biomaterials after appropriate annealing. The exact parameters depend on the annealing process.

considered, only metals with a thin, so-called spontaneous, passivation layer are suitable. All other metals would corrode and initiate negative effects due to the ion release. Spontaneously passivating metals are titanium, niobium, tantalum, or zirconium, as well as stainless steels. Chronic experience with biomedical applications exists for titanium (ASTM F67), tantalum (ASTM F560) and the stainless steel 316L (ASTM F138). Some titanium alloys are used in implant manufacturing. Table 1 summarizes the most important parameters of these materials.

The first important information is the relatively low ductile yield of titanium. When mounted on a balloon, stents aim at a low profile (diameters less than 1 mm) in order to provide good crossability. This requirement is combined with the need for high dilatation diameters (up to 5 mm). Because cracks in the stent structure limit the mechanical performance or may cause perforation or other medical complications, the ductile yield is of major importance. In conclusion, although titanium is widely used for implants, it is not the first choice for stent applications.

Tantalum offers a good ductile yield, and the other parameters are acceptable as well. Consequently, a number of stent designs are based on tantalum. However, with regard to quantitative coronary angiography, tantalum has a major disadvantage — its high x-ray opacity. In addition, manufacturing tantalum stents of the slotted tube type is extremely difficult and expensive due to the high melting point of tantalum. Laser cutting, a commonly used method in this field, is not suitable for tantalum.

Stainless steel is the most commonly used stent material, especially 316 L. The material 316 L is an iron-based CrNi alloy containing 16.87% Cr, 12.72% Ni, 2.49% Mo, 1.65% Mn, 0.23% Si, and 0.04% C. It offers the biomechanical properties which are required for stents, and its biocompatibility has been proven over the years. Although this special alloy contains some nickel and chromium, which may induce toxic or allergic reactions, no severe problems have been observed. The reason for that effect is the spontaneous formation of a thin chromium oxide layer on top of the 316L bulk material that serves as a diffusion barrier [3]. Thus, 316 L is the first choice for stent designs. However, it should be noted that there are some concerns regarding the use of 316 L in implants. Pitting corrosion has been reported on the stems of hip implants [4].

In conclusion, 316 L stainless steel and tantalum meet the material requirements. In the following, both materials will be considered in the calculations.

Stent Design

Prior to calculating the dimensions exactly, the basic design has to be defined. A net-type design that meets the above mentioned requirements can be realized in different ways. The first approach would be a rhombic pattern to provide homogenous scaffolding properties. Oval patterns will also change into rhombic elements during dilatation. However, the main disadvantage of this design is the relatively high foreshortening of the stent.

By separating the oval or rhombic elements this foreshortening can be reduced. Figure 1 shows the basic idea of a new stent design with optimized foreshortening properties (Tenax®). The basic keyhole-like elements are coupled in pairs. Neighboring elements have opposite orientation and are shifted along the longitudinal stent axis. Small S-shaped struts that connect the neutral points of each element couple the elements. Alternating the orientation of these struts reduces the foreshortening significantly, since relative movements are compensated.

Another design issue is recoil. Optimal scaffolding properties require low elastic recoil of the stent after dilatation. In terms of design this means that plastic deformation must be much higher than elastic deformation. Therefore, the design of the Tenax® is characterized by long and slim struts that undergo a bending during dilatation. The stress at the bending points exceeds the yield strength at a very early point
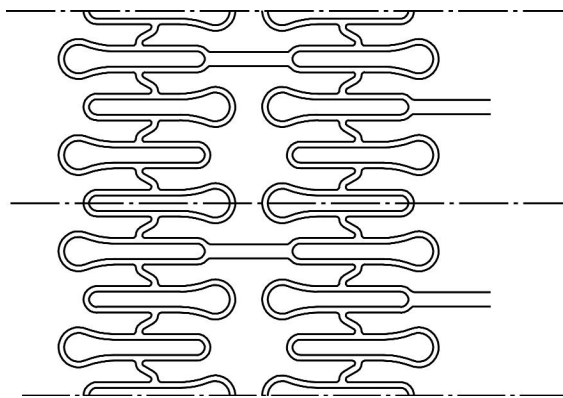

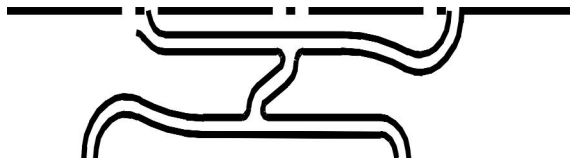*Figure 1. Basic design concept for the new stent (Tenax®, BIOTRONIK, Germany).*

Figure 2. Finite-element model of the stent segment.

leading to a mostly plastic deformation. Thus, this design provides very low elastic recoil.

Finite-element Modeling

Finite-element modeling allows calculating stresses as well as the deformation behavior of complex parts under external loads quantitatively. A detailed overview of finite-element modeling is given in [5]. Today's computer technology provides capacity for three-dimensional calculations with high accuracy. In addition, it allows the calculation of high deformations considering nonlinear properties of the material. For this purpose, the deformation is subdivided into small steps. Each deformation step leads to a new state with new material parameters (e.g., due to strengthening) that acts as a starting point for the next deformation step. This iterative procedure follows the method of Newton and Raphson.

The following calculations have been performed with the software package ANSYS (version 5.4), a complete system for analyzing complex structures. It offers all the tools necessary for analyzing parts with high deformations, nonlinear properties or anisotropic materials. The transfer of design parameters from a CAD system is technically feasible via the IGES interface. The software is available for Windows NT and UNIX systems. For simple calculations, it runs on a PC, but for more complex problems on large machines. Due to the rotational symmetry of this special stent design, only one quarter of a stent segment was modeled. This approach does not consider inhomogeneities with regard to pressure, balloon shape or vascular structure. However, it allows an understanding of the basic mechanical performance. The model was reduced to a two-dimensional element plane with 42 two-dimensional structural solids with a quadrangle structure (see Figure 2). The model contained 328 elements and 472 knots.

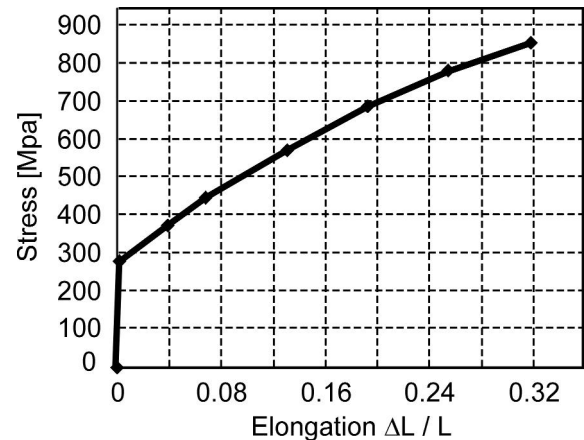As input, the above mentioned material parameters were used. In addition, a wall thickness of 0.08 mm

Figure 3. Stress-elongation relationship of 316 L stainless steel that has been used for finite-element modeling.

was assumed. Young's modulus was set to 210 GPa, and the bottling factor to 0.35. To consider the bottling of the material, the stress-elongation relationship has been corrected according to [6]. Figure 3 shows an example of the relationship for 316L stainless steel as it has been used for the calculations.

The calculated results (see Figure 4 and following) are fairly comparable to experimental results. Thus, it can be concluded that the underlying material parameters as well as the numerical methods and the criteria of convergence are realistic. The error tolerances are estimated to be below 5%.

Results

The aim of the finite-element study was to calculate the type and amount of deformation for different strut dimensions and materials. Two different types of external load were considered: crimping and expansion. Crimping involves mounting the stent on the balloon by radially compressing it to the nominal diameter. This requires a reduction in outer diameter from 1.6 mm to 0.9 mm. Elastic recoil after crimping has also been considered in a second step. Dilatation or expansion starts from the crimped and relieved state to an increased outer diameter of up to 4.5 mm.

Deformation shapes and the maximum v. Mises stress were calculated (see Figures 4 - 7 and Table 2). Especially Figure 6 shows a nearly homogenous distribution of stress across the long and thin struts. Stress concentration appears at the strut junctures, an effect that reduces elastic recoil. Recoil is calculated to be approximately 3.4%.
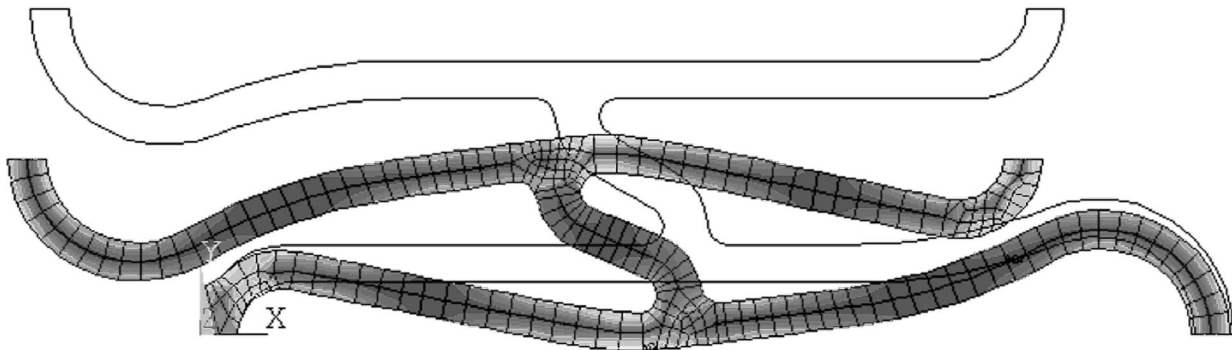
Figure 4. Deformation of a 316 L stent body after crimping (outer diameter reduced from 1.6 mm to 0.9 mm). Isochrones show v. Mises stress.

After implantation, the stent is loaded with an oscillating force analogous to cardiac contractions. Due to the different mechanical behavior and geometry of different stenoses, no valid model exists that allows fatigue simulations. Thus, fatigue lab tests are mandatory in different deformation states before any clinical application is started.

Nevertheless, a first approximation can be given using data from literature. Cahoon et al. as well as Morita et al. evaluated the fatigue of 316 L stainless steel in corrosive environments. Cahoon's experiments resulted in a fatigue strength of 415 MPa in physiologic saline [7], whereas Morita arrived at 620 MPa [8]. One explanation for this difference may be the imprecise annealing of the samples.

However, comparing the maximum stresses (4.5 mm dilatation) with the even lower value of 415 MPa results in a safety margin of 44 MPa. In conclusion, within the accuracy of the material parameters and the finite-element modeling, the stent can be regarded as a safe device.

Summary and Conclusion

The demanding and partly contradictory requirements for an ideal stent design require a detailed analysis of the plastic deformation behavior and the stresses as a function of material and design. This includes all states, i.e., after crimping, after relieving the crimp stress, after dilatating and again after relieving the dilatation stress.

Finite-element analysis showed good agreement with the experimental results. Thus, finite-element modeling has been proven to be a reliable tool for prototyping and evaluating new stent designs.

The calculation of critical loads as well as maximum fatigue loads requires a more precise knowledge of the material properties. In principle, better calculations are
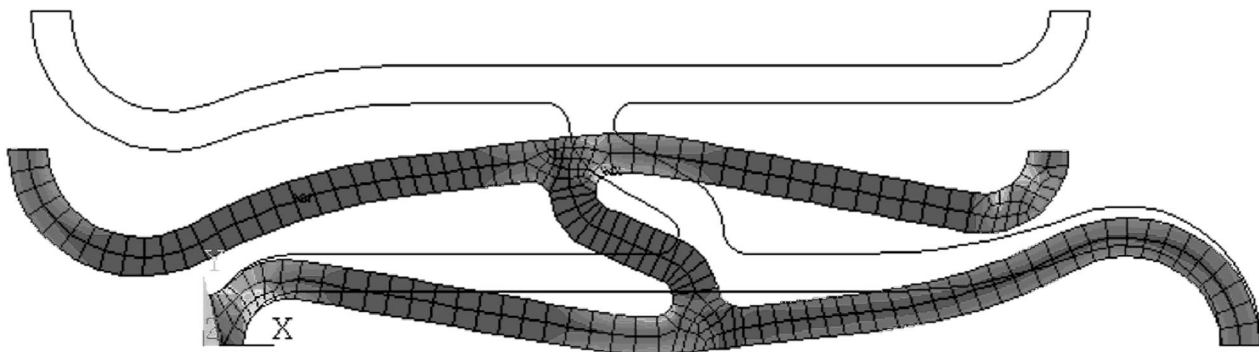

Figure 5. Same as Figure 4 but including elastic recoil

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U. Wilke
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Figure 6. Dilatation of a crimped stent to 4.5 mm outer diameter starting from the state shown in Figure 5. Again v. Mises stress is shown as isochrones
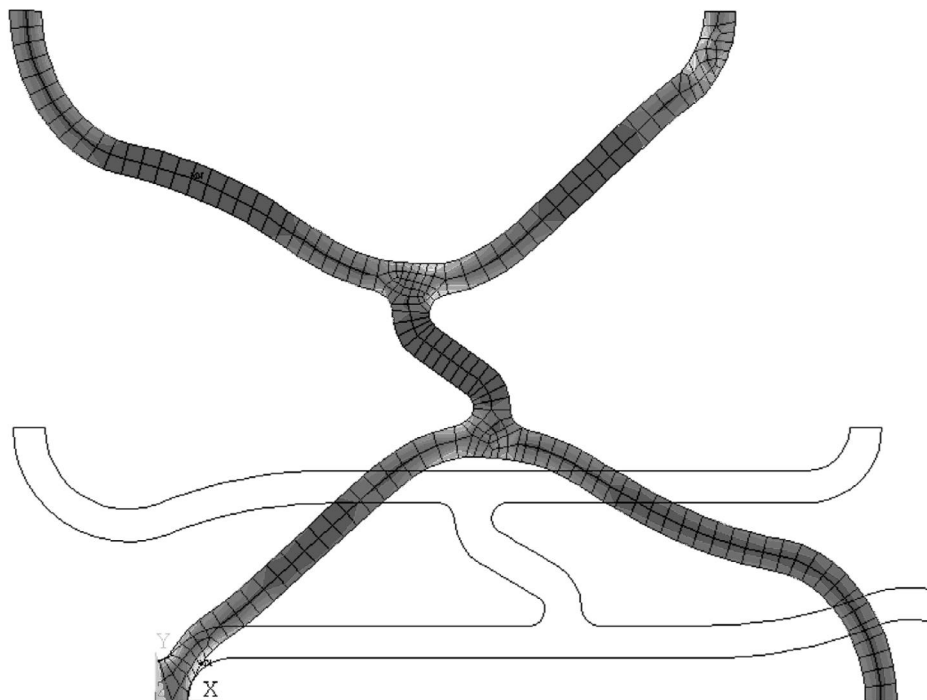

Figure 7. Same as Figure 6 but after elastic recoil.

Step of deformation	Stainless steel 316L Outer diameter 4.5mm	Tantalum Outer diameter 3.0mm
Crimped	477 MPa	444 MPa
Relieved	235 MPa	260 MPa
Dilatated	897 MPa	525 MPa
Relieved	371 MPa	217 MPa

Table 2. Maximum v. Mises stress for different diameters, deformations and materials.

technically feasible. Very often the combination of finite-element modeling for the first evaluation and an experimental testing afterwards is preferable.

The new design (Tenax®) meets the mechanical requirements that characterize an ideal stent from a contemporary point of view. It offers a high radial stability and good dilatation combined with excellent scaffolding properties. At the same time it has a low stent-to-vessel-surface-ratio. Finite-element stress analysis also proved the basic design considerations with regard to recoil and foreshortening. In conclusion, the Tenax® design can be considered a high-end stent from a mechanical point of view.

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