Dynamic simulation of stent deployment - effects of design, material and coating

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Abstract. Dynamic finite-element simulations have been carried out to study the effects of cell design, material choice and drug eluting coating on the mechanical behaviour of stents during deployment. Four representative stent designs have been considered, i.e., Palmaz-Schatz, Cypher, Xience and Endeavor. The former two are made of stainless steel while the latter two made of Co-Cr alloy. Geometric model for each design was created using ProEngineer software, and then imported into Abaqus for simulation of the full process of stent deployment within a diseased artery. In all cases, the delivery system was based on the dynamic expansion of a polyurethane balloon under applied internal pressure. Results showed that the expansion is mainly governed by the design, in particular open-cell design (e.g. Endeavor) tends to have greater expansion than closed-cell design (e.g. Cypher). Dogboning effect was strong for slotted tube design (e.g. Palmaz-Schatz) but reduced significantly for sinusoidal design (e.g. Cypher). Under the same pressure, the maximum von Mises stress in the stent was higher for the open-cell designs and located mostly at the inner corners of each cell. For given deformation, stents made of Co-Cr alloys tend to experience higher stress level than those made of stainless steels, mainly due to the difference in material properties. For artery-plaque system, the maximum stress occurred on the stenosis and dogboning led to stress concentration at the ends of the plaque. The drug eluting coating affected the stent expansion by reducing the recoiling phenomenon considerably, but also raised the stress level on the stent due to property mismatch.

1. Introduction

Finite-element method has been widely employed to assess the biomechanical behaviour of stents by modelling their deployment inside diseased arteries. Chua *et al*. [1] simulated the expansion of a Palmaz-Schatz stent inside an artery with stenotic plaque. The results demonstrated the capability of slotted-tube stents in resisting the recoil of blood vessel and preventing restenosis after expansion. Zahedmanesh *et al*. [2] modelled the deployment of an ACS Multi-Link RX DUET stent in a stenotic artery based on the digitalization of 3D angiography images of a human coronary artery. They suggested that direct application of pressure on the inner surface of stent may be used as an optimal modelling strategy for complex arterial geometries. Pericevic *et al*. [3] investigated the influence of stenotic plaque compositions (i.e., hypecellular, hypocellular and calcified) on stent deployment, and showed that a calcified plaque exhibited less stress level but higher resistance to expansion compared to other types of plaque. Lally *et al*. [4] performed a comparative study of two stents (i.e. S7 and NIR

stents) by simulating their deployment inside a stenotic artery. Their results showed that the S7 stent caused lower stress on the blood vessel wall compared to the NIR, which was consistent with clinical observations that the NIR stent has a higher restenosis rate than S7. Tambaca *et al*. [5] studied the mechanical behaviour of different fully expanded stent designs under uniform compression and bending forces. It was shown that the latest stent designs (i.e. Xience) exhibited good radial stiffness and bending flexibility.

In addition, Gu *et al*. [6] studied the influence of an ultra-thin silicone coating during deployment of drug eluting stent in an artery with long fusiform aneurysm. It was shown that the coated stent needed an appreciatively 30% higher pressure to expand the artery than its bare metal version. On the other hand, Hopkins *et al*. [7] investigated the 2D delamination effect of the stent coating during deployment, which occurred mainly in the region of hinge with high plastic strain. The initiation of coating debonding depended on the coating thickness, the coating material and the curvature of the hinge.

Currently, there is a lack of research in the modelling of the full deployment process of the latest stent designs, in particular the effects of stent materials and coatings on the expansion behaviour of stents. It is also not well understood how the deformation and stress of the artery-plaque system are influenced by different stent designs during deployment.

In this paper, finite-element analyses have been carried out to simulate stent deployment for four representative stent designs (Palmaz-Schatz, Cypher, Xience and Endeavor). Comparisons have been made to assess the effects of cell design, material and coating on stent expansion, stress distribution and geometrical change during the deployment process inside a diseased artery.

2. Finite element simulation

2.1. Geometrical models
Models of Palmaz-Schatz, Cypher, Xience and Endeavor stents were produced using ProEngineer software according to their real geometrical features. The length of all stents was chosen to be 10mm and the diameter at the crimpled state was fixed at 3mm. The strut thickness is 100μm, 140μm, 81μm and 91μm for Palmaz-Schatz, Cypher, Xience and Endeavor, respectively. To study the coating effect, a two-ring model was created for Xience stent, with a length of 4mm and a diameter of 3mm, coated with a thin layer of polymer (7.8μm). The balloon was modelled as a simple cylinder with an outer diameter that matched the inner diameter of the stent. The balloon was always 2mm longer than the stent (i.e., one millimetre longer at each end). The blood vessel was modelled as a cylinder with axisymmetric stenotic plaque inside. The artery has a length of 20mm and a wall thickness of 0.4mm, while the plaque has a length of 5mm and a maximum thickness of 0.58mm. The outer diameter was 5.4 mm and 5.0 mm for the artery and the plaque, respectively.

2.2. Materials
The materials used to manufacture the stents are 316L stainless steel for Palmaz-Schatz and Cypher and Co-Cr alloy for Xience (type L605) and Endeavor (type F562). These materials were modelled with a bilinear elastic-plastic stress-strain relationship with parameters given in Chua *et al*. [1] and Pochrząst *et al*. [10]. The stent coating was made of Phosphorylcholine (PC) polymer with bilinear model parameters obtained from Hopkins *et al*. [7]. The balloon was modelled using a Mooney-Rivlin hyperelastic strain energy potential [1] and the blood vessel was described by 5-parameter hyperelastic strain energy potential and considered uncompressible [4]. Material properties are summarized in Tables 1, 2 and 3.

2.4. Load and constraint
A uniform and linearly increasing pressure was applied to the inner surface of the balloon to simulate the inflation process, followed by deflation (pressure decreased to zero). The step time was chosen to be 25ms for inflation and 5ms for deflation. Implicit dynamic analyses have been used to simulate the

whole process using Abaqus. In all simulations, the ends of the balloon were fully constrained to avoid rigid body motion.
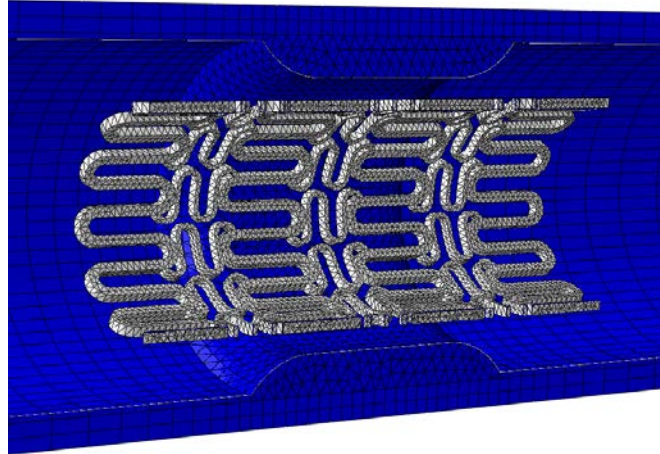

Figure 1. Finite element mesh for Cypher stent and stenotic artery.

Table 1. Parameters for stent and coating materials.

Material	ρ (kg/mm^3)	E (MPa)	ν	S_y (MPa)	E_t (MPa)
SS316L	$7.8 \cdot 10^{-6}$	193000	0.27	207	692
Co-Cr L605	$9.7 \cdot 10^{-6}$	243000	0.3	476	680
Co-Cr F562	$8.8 \cdot 10^{-6}$	233000	0.35	414	744
PC-Polymer	$1.2 \cdot 10^{-6}$	240	0.5	16	7

Table 2. Mooney-Rivlin coefficients for polyurethane balloon.

Material	ρ (kg/mm^3)	C_{10}	C_{01}	D_1
Polyurethane	$1.07 \cdot 10^{-6}$	1.03176	3.69266	0

Table 3. Coefficients of the hyperelastic model for the blood vessel.

Material	ρ (kg/mm^3)	a_{10}	a_{01}	a_{20}	a_{11}	a_{30}
Artery Wall	$1.066 \cdot 10^{-6}$	18.90	2.75	590.42	857.18	0
Calcified Plaque	$1.45 \cdot 10^{-6}$	495.90	506.61	1193.53	3637.80	4737.25

2.3. Mesh

Stents were meshed with tetrahedral elements (C3D10), and the number of elements was 58428, 44222, 46221 and 63076 for Palmaz-Schatz, Cypher, Xience and Endeavor, respectively. The balloons were meshed using hexahedral elements with reduced integration and hybrid formulation (type C3D8RH), and the number of elements was about 10000 for all simulations. The artery wall was also meshed using hexahedral elements with reduced integration and hybrid formulation (C3D8RH), while the plaque was meshed with tetrahedral elements with hybrid formulation (C3D10H). The artery and plaque system has 40247 elements in total. Figure 1 shows the generated mesh for the whole system (Cypher stent). Interaction between the interfaces (balloon-stent-artery/plaque) was modelled as

surface-to-surface hard contact. Mesh sensitivity study has confirmed the convergence of results for the current mesh.
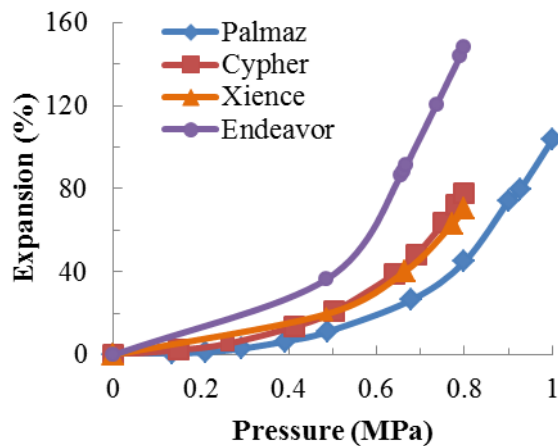

Figure 2. Radial expansion (in percentage) against inflation pressure for the four stents under free expansion.
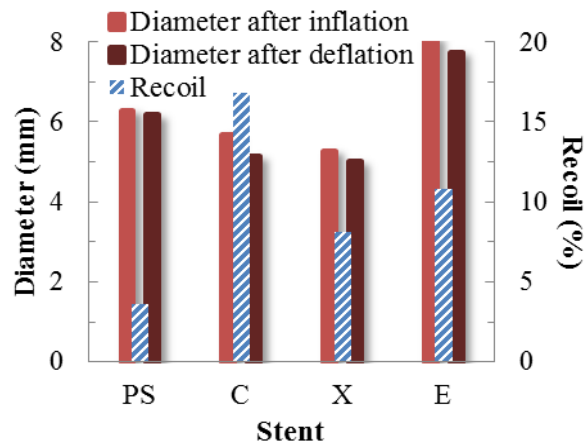
Figure 3. Diameter change and recoil effect for Palmaz-Schatz (PS), Cypher (C), Xience (X) and Endeavor (E) under free expansion.

2.5. Model validation
The model was first validated by reproducing the Palmaz-Schatz expansion and obtained results are in close agreement with those in Ju *et al.* [8] and Chua *et al.* [9]. This was purely for model validation purposes, to ensure that the mesh, boundary/loading conditions and solvers were correctly adopted and the materials and contacts were also properly simulated.

3. Results and discussion

3.1. Free expansion
Figure 2 shows the change of diameter against the pressure, applied inside the balloon, for all four stent designs during free expansion. The diameter change is mainly controlled by the radial stiffness of stent. Among the four designs, Endeavor is the most flexible stent, which expanded 143% of its original diameter at 0.8 MPa pressure, due to its open-cell design and peak-to-peak strut connection. Xience, with a spiral-cell design and peak-to-valley strut connection, and Cypher, with a closed-cell design and peak-to-peak strut connections, exhibited similar flexibility and expanded about 71% and 78% of their original diameter, respectively, under the same pressure. Palmaz-Schatz, with a slotted tube design, showed the highest stiffness with an expansion of only 45% at 0.8MPa. In fact, Palmaz-Schatz stent required a pressure of 1MPa in order to reach an expansion of 103%.

Recoiling effect after deflation is compared in Figure 3 for the four stents. Palmaz-Schatz stent showed the lowest recoiling effect (4%) due to its high radial stiffness, followed by Xience (8%) and Endeavor (11%). In terms of dogboning, Xience exhibited the strongest negative dogboning effect (-24%), followed by Endeavor (-34%), Palmaz-Schatz (-19%) and Cypher (-18%). Negative dogboning effect is usually appreciated, as it helps with the dilation of the stenotic plaque which is in direct contact with the middle section of the stent. In addition, Palmaz-Schatz had the highest foreshortening effect (6.4%), followed by Cypher (2.0%), Xience (1.0%) and Endeavor (0.4%). It is important to make foreshortening effect as low as possible to ensure a full coverage of the diseased part of the artery.
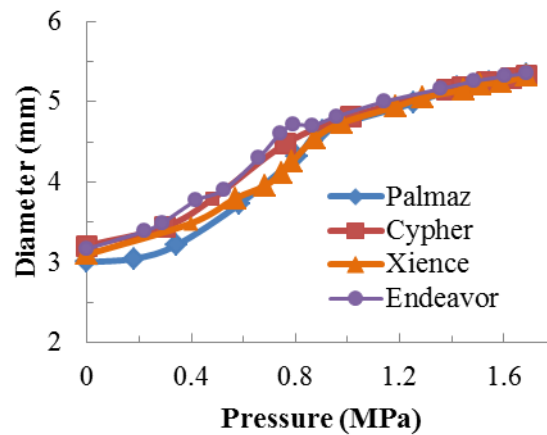
Figure 4. Change of diameter against inflation pressure for the four stents during expansion inside a stenotic artery.
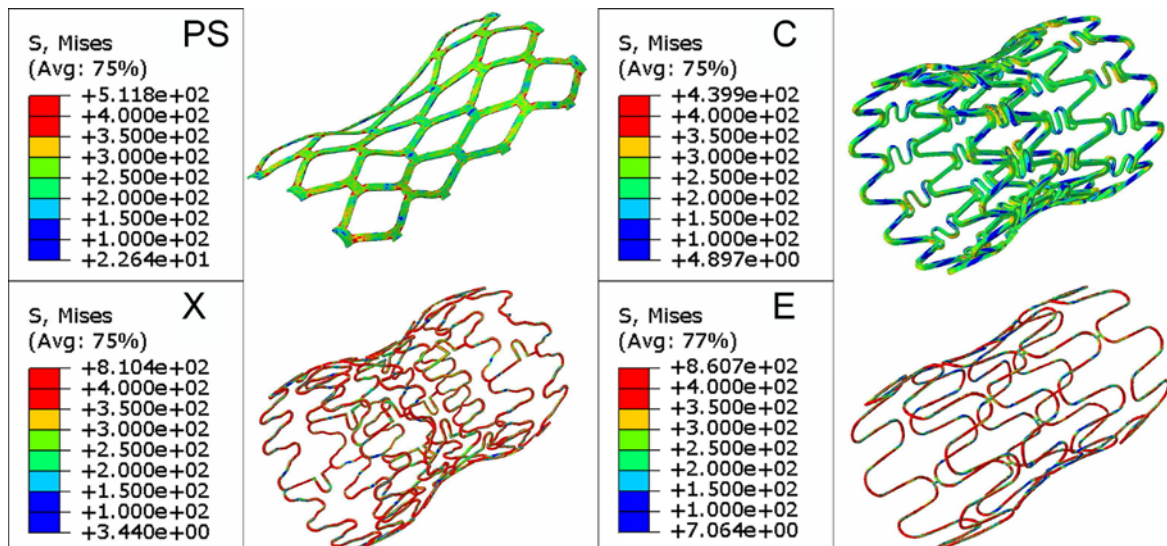

Figure 5. The von Mises stress distribution for Palmaz-Schatz (PS), Cypher (C) and Xience (X) and Endeavor (E) in a diseased artery at an inflation pressure of 1.6MPa.

All four stents showed severe stress concentrations at the corners of struts. At the same deformation level, stents made of Co-Cr alloys tend to have higher stress level compared to those made of stainless steel, in line with material properties. After deflation, residual von Mises stresses were obtained for all simulated stents. For Cypher, residual stress was 58.1% (211MPa) of the stress at the peak pressure, while for Palmaz-Schatz it was 52.9% (230MPa). Xience and Endeavor have a residual stress level similar to that at the maximum inflation pressure, i.e., 84.7% (466MPa) and 90.6% (690MPa) of the peak stress, respectively. The high stresses in some regions also indicate a potential fracture during the deployment process, which has been also frequently reported by clinical studies.

3.2. Expansion inside a stenotic artery
For stent expansion inside a diseased artery, the diameter change during the inflation and deflation for each stent is shown in Figure 4. All four stents had similar expansion behaviour with a maximum diameter of 5.35mm achieved at 1.7MPa pressure. Endeavor was the stent that expanded the artery slightly more than others while Cypher was the stent that expanded less.
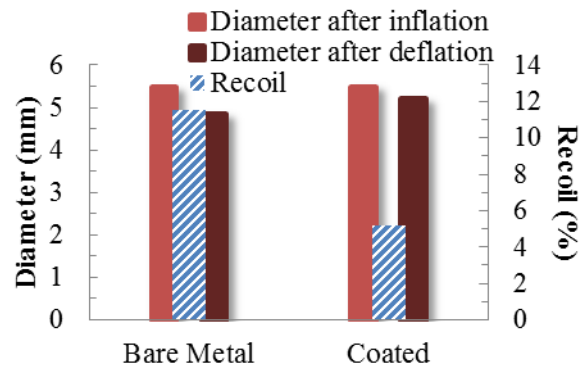
Figure 6. Diameter change and recoil effect for coated and bare metal Xience stent.
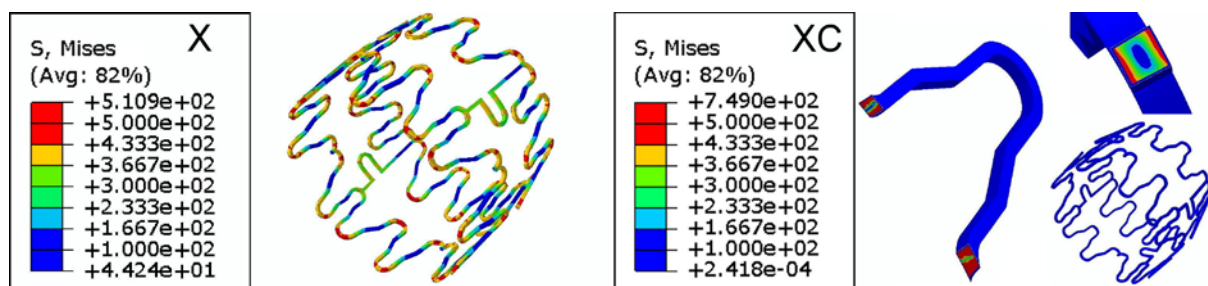

Figure 7. The von Mises stress distribution on bare metal Xience stent (X) and coated Xience stent (XC) at the end of inflation (i.e., peak pressure).

The von Mises stress distribution within the stents is shown in Figure 5 at the same pressure 1.6MPa. The location of the maximum stress is consistent with the case of free expansion. Endeavor and Xience showed higher magnitudes (861 MPa and 810MPa respectively) compared to the Cypher and the Palmaz-Schatz (440MPa and 512MPa, respectively), which is also consistent with free expansion simulations.

For dogboning effect, Xience exhibited the lowest level (1.8%), Endeavor showed also a very low level (3.7%), while Cypher and Palmaz-Schatz had higher levels (12% and 13%, respectively). This indicates the advantage of the latest stent designs which can expand the artery more uniformly and prevent damage to the healthy section of blood vessel. Furthermore, at the same diameter, Xience had the lowest foreshortening effect (1.2%), followed by Cypher and Endeavor (2.0% and 2.1%), whilst the highest value was ehibited by Palmaz-Schatz (6.2%). All these results are again consistent with free expansion simulations, showing that Xience tends to preserve its length better during deployment.

3.3. Effect of stent coating

To study the influence of stent coating, expansion of 2-ring Xience stent (coated and uncoated) was simulated under an inflation pressure of 1MPa. We used Xience as an example study and we assumed the effects of coating were similar for other types of stent.

Figure 6 shows the diameter change during expansion process. The maximum diameter reached 5.5mm in both simulations, but the coated stent recoiled only 7.3% while the bare metal one had a recoil effect of 12.7%. Results suggest that drug eluting coatings do not affect stent expansion (i.e. radial stiffness) but reduce recoil effect significantly. For both cases, the maximum von Mises stress was located at the peaks and the valleys of the sinusoidal struts, as shown in Figure 7, at the maximum pressure. The coated stent had a higher stress level (749MPa) compared to the bare metal stent (510MPa). After recoil, the residual stresses were found to be 691MPa and 448MPa for the coated and uncoated stents, respectively. The increase of stress level on the coated stent is due to property mismatch between the stent and the coating.
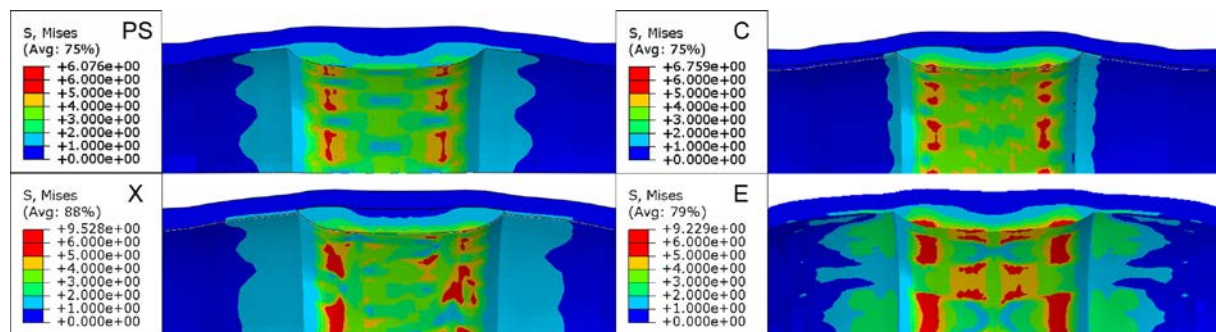
Figure 8. The von Mises stress distribution on stenotic blood vessel, expanded with Palmaz-Schatz (PS), Cypher (C), Xience (X) and Endeavor (E) stents, respectively, under a pressure of 1MPa.

3.4. Stresses on plaque/artery

The von Mises stress distribution on the plaque/artery had a similar pattern for all stents (Figure 8), with the maximum stress located towards the ends of the plaque where the stent and the plaque were directly in contact. At a pressure of 1MPa, Xience and Endeavor caused higher stress magnitude on the plaque (18.7MPa and 16.1MPa, respectively) than Cypher (6.8MPa) and Palmaz-Schatz (6.1MPa).

4. Conclusions

Effects of cell design, material choice and drug eluting coating on the expansion behaviour of stents have been studied using finite element simulations. Results showed that stent expansion is mainly controlled by its design. Stents with open-cell design (e.g. Endeavor) tend to have greater expansion than those with closed-cell design (e.g. Cypher). Among the four designs, Xience, with a spiral-cell design and peak-to-valley strut connection, seems to have the lowest dogboning and foreshortening effects. For given deformation, stents made of Co-Cr alloys tend to have higher stress level than those made of stainless steels due to the difference in material properties. The drug eluting coating affected the stent expansion by reducing the recoiling phenomenon considerably, but also raised the stress level on the stent due to material property mismatch. The von Mises stress distribution on the plaque/artery had similar pattern for all four stents, with stress concentrations located towards the ends of plaque where it experienced a strong contact with the stent due to the dogboning effect.

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