Numerical Analysis of the Balloon Dilatation Process Using the Explicit Finite Element Method for the Optimization of a Stent Geometry

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Abstract:

Endovascular stent surgery is a minimally invasive surgical procedure to treat disorders of the circulatory system as blockage of blood vessels caused by the build up of plaque (fatty deposits, calcium deposits, and scar tissue) in the arteries, a condition called atherosclerosis. Nearly all of the medium-sized and large blood vessels in the body's vascular system can be accessed by a catheter system. This fact has contributed to a rapid increase in the performance of endovascular stent surgery.

Before implantation the stent is crimped onto a balloon which results in a diameter reduction. The balloon catheter with the collapsed stent is placed in the narrowed artery. In the blood vessel the stent is dilated through inflation of the balloon. Then, the balloon catheter is deflated, leaving the stent in place to hold the artery open. The catheter and the guide wire are removed. Deflation of the balloon leads to a certain amount of recoil, reinforced by the outer pressure of the blood vessel. The remaining mean stresses at this state are the initial condition for a possible fatigue calculation. Due to heartbeat induced blood pressure oscillation the stent is exposed to high cycle fatigue loading on one side and to low cycle fatigue loading due to daily body movement on the other side.

The introduction of new stent materials and the optimization of the stent design can be supported by Finite Element Simulation. Within this study the load steps crimping, balloon dilatation and recoil will be investigated. The correct modelling of the described load steps with the finite element method demands the use of an isotropic-kinematic hardening model as changes in the loading direction appear. Therefore the Chaboche model for a combined isotropic-kinematic hardening has been used in the virtual development process with the FEM-code. The Chaboche model is an optional hardening model in the general user material MF_GenYld developed by MATFEM. Additionally it has to be taken into account that the maximum fracture strain is a function of the stress state. The algorithm *CrachFEM* can be coupled with *MF_GenYld* for a prediction of fracture initiation during dilatation.

As a prerequisite for the simulation of the balloon dilatation process a folded structure of the balloon has to be generated. For the given balloon geometry – with conical shapes at both ends - analytical folding tools for airbags exhibit problems in mapping the unfolded structure to the folded structure. Therefore the balloon folding process has been simulated directly with FEA.

The explicit FEA code LS-DYNA in MPP version has been used for all analyses in this project. The explicit-dynamic integration method has significant advantages for FEA model with a great number of DOFs (CPU times increases only linearly with number of DOFs) and complex contact conditions (i.e. contact of tools and stent, possible self contact in the final phase of crimping and contact between stent and balloon).

Keywords:

Stent Dilatation, Balloon Dilatation, Isotropic Kinematic Hardening, Fracture Prediction, Finite Element Simulation

1 Balloon Folding and Balloon Compliance

The balloon is modeled with more than 60.000 selective reduced co-rotational shell-elements according to Hughes-Liu (type 7). Due to symmetry a half model has been used. The skin thickness is 0.03 mm and the material model *MAT_PIECEWISE_LINEAR_PLASTICITY is used. All tools are defined as rigid bodies applying the *MAT_RIGID material card.

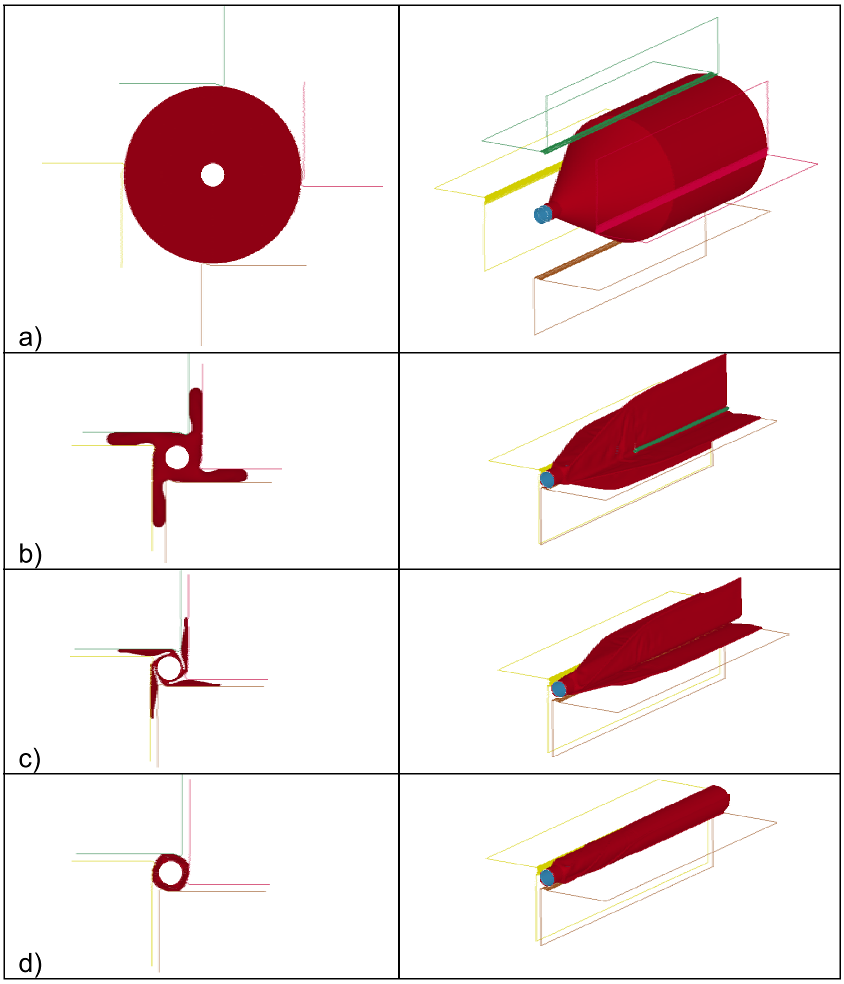
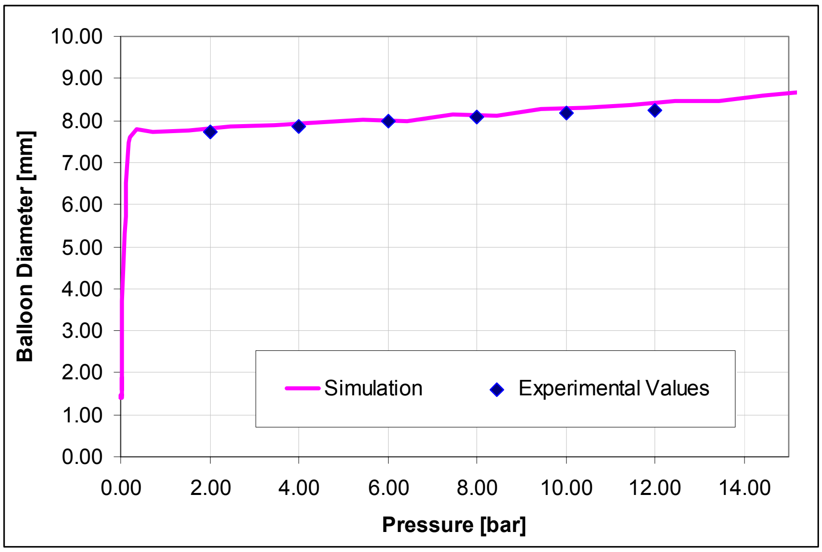


Figure 1-1: Simulation of balloon folding process

Between the folding tools and the balloon, forming contacts of type *CONTACT_FORMING_NODES_TO_SURFACE_ID are defined. For the balloon self contact the *CONTACT_AIRBAG_SINGLE_SURFACE without friction is used. Figure 1-1 displays several states of the folding process.

For the balloon linear-elastic material properties are assumed. To check the correct modelling of the balloon material a compliance test is simulated. The inflation of the balloon is performed by using an airbag model (*AIRBAG_SIMPLE_AIRBAG_MODEL in LS-DYNA). Based on the known correlation between balloon diameter and pressure from experiment the material parameters have been iteratively adjusted (wall thickness of balloon is known). Here the dilatation process is carried out without stent. As shown in Figure 1-2 a good correlation between experiment and simulation could be achieved.



Linear elastic properties of balloon material (isotropic):

Young's modulus: 1500 MPa
Poisson's ratio: 0.35

Figure 1-2: Compliance test of balloon- comparison between experiment and simulation

2 Material model for Stent Alloy

2.1 MF_GenYld+CrachFEM

The user material model MF_GenYld+CrachFEM has been developed by MATFEM with a modular architecture. MF_GenYld can combine different yield loci with different hardening models. MF_GenYld includes a model for combined isotropic-kinematic hardening based on the Chaboche model. CrachFEM allows a comprehensive failure prediction (localized necking for shells, ductile and shear fracture for shells and solids). The link of MF_GenYld+CrachFEM to an explicit FEA code is shown in Figure 2-1.

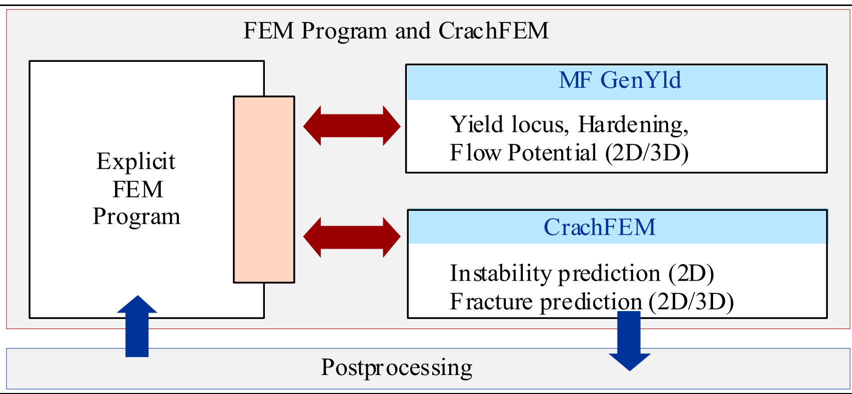


Figure 2-1: Material Model MF_GenYld and CrachFEM.

The models in CrachFEM for the prediction of material failure due to shear fracture and ductile fracture in metallic materials (these criteria are used for solid elements) are discussed and compared with other types of fracture models in [2] and not reported here.

2.2 Implementation of Isotropic-Kinematic Hardening Model in MF_GenYld

The total hardening for monotonous loading is described via the Swift model:

$$\sigma = a\left(\varepsilon_0 + \varepsilon_{eq}\right)^n \tag{3.1}$$

The yield locus of the initially isotropic material with isotropic-kinematic hardening behaviour is described by the equation

$$\left(s_{ij} - X_{ij}\right)\left(s_{ij} - X_{ij}\right) = \frac{2}{3}\sigma_i^2(\varepsilon_{eq}) \tag{3.2}$$

where s_{ij} represent the deviatoric stress tensor components, X_{ij} the back stresses, σ_i the equivalent stress of the isotropic hardening and ε_{eq} the equivalent plastic strain.

According to the associated flow rule, equation 3.2 results in

$$d\varepsilon_{ij} = \frac{3d\varepsilon_{eq}}{2\sigma_i}\left(s_{ij} - X_{ij}\right) \tag{3.3}$$

The various models for kinematic hardening use different definitions of the back stresses.

According to Chaboche [1] these back-stresses can be described by the following equation

$$dX_{ij} = dX_{ij}^{(1)} + dX_{ij}^{(2)}$$
$$dX_{ij}^{(k)} = \frac{2}{3}C_k d\varepsilon_{ij}^p - \gamma_k X_{ij}^{(k)} d\varepsilon_v \tag{3.4}$$

C_k and γ_k (k = 1, … , n) are material parameters, which can be identified in tension-compression reversal tests or in compression-tension reversal tests. n = 2 provides already a very accurate approximation in most cases and is used in this project.

Equation (3.2) with n=2 is used to describe the kinematic hardening. The evolution of the back stress for the special case of uniaxial tension is given in equation (3.5):

$$X_x^{(k)} = \frac{2}{3}\frac{C_k}{\gamma_k}\left(1 - \exp\left(-\gamma_k \varepsilon_{eq}\right)\right) \tag{3.5}$$

Equation (3.6) follows as a result for the isotropic hardening in uniaxial tension:

$$\sigma_i\left(\varepsilon_{eq}\right) = a\left(\varepsilon_0 + \varepsilon_{eq}\right)^n - \frac{C_1}{\gamma_1}\left(1 - \exp\left(-\gamma_1\varepsilon_{eq}\right)\right) - \frac{C_2}{\gamma_2}\left(1 - \exp\left(-\gamma_2\varepsilon_{eq}\right)\right) \tag{3.6}$$

The combined isotropic-kinematic hardening is described by the 7 material parameters $a, \varepsilon_0, n, C_1, \gamma_1, C_2$ and γ_2. The parameters of this material model are determined in monotonic tensile tests and tests with tension-compression reversal.

The 3 parameters a, ε_0, n are received by approximation of the strain hardening curve of the monotonic tensile test. The 4 parameters C_1, γ_1, C_2 and γ_2 can be derived from the measured function $\beta(\varepsilon_{eq})$. β is the ratio of the new compressive yield strength and the last tensile flow stress in a tension-compression reversal test. The function $\beta(\varepsilon_{eq})$ can be build up by tension-compression tests with different pre-strain in tension. The software „MFA_Chaboche“ (developed by MATFEM) can be used to derive parameters C_1, γ_1, C_2 and γ_2 from $\beta(\varepsilon_{eq})$.

The back stress is calculated for different values of the equivalent plastic strain according to equation (3.7).

$$X_x = \frac{1-\beta}{3} a\left(\varepsilon_0 + \varepsilon_{eq}\right)^n \tag{3.7}$$

A gradient method is used to minimize the sum according to equation (3.8).

$$S = \sum_i \left(\frac{2}{3}\frac{C_1}{\gamma_1}\left(1-\exp\left(-\gamma_1 \varepsilon_{eq,i}\right)\right) + \frac{2}{3}\frac{C_2}{\gamma_2}\left(1-\exp\left(-\gamma_2 \varepsilon_{eq,i}\right)\right) - X_{xi} \right)^2 \Rightarrow \min \tag{3.8}$$

The parameters C_1, γ_1, C_2 and γ_2 are the result of the optimization.

2.3 Material Data Evaluation for Isotropic-Kinematic Hardening Model

Strain hardening curves of the stent material are necessary for the simulation of the stent deformation (crimping, expansion, spring-back). Due to the small dimensions of the available raw material of the stent (tubes with diameter 2.0 – 3.2 mm, wall thickness approx. 0.2mm) standard tensile tests are not possible. Special tensile test with tubes have been developed.

For the characterization of the kinematic hardening behaviour of the stent material tensile specimens from a tube have been pre-strained to 2%, 4% and 8% engineering strain, as shown in Figure 2-2. Afterwards compression specimens have been cut from each tensile specimen after pre-straining. The new yield strength in compression is measured with the secondary specimens. The function $\beta(\varepsilon_{eq})$ is achieved by the approximation of the measured data with equation (3.9)

$$\beta(\varepsilon_{eq}) = \beta_m + (1-\beta_m)\exp(-c\varepsilon_{eq}) \tag{3.9}$$

β_m and c are material dependent parameters.

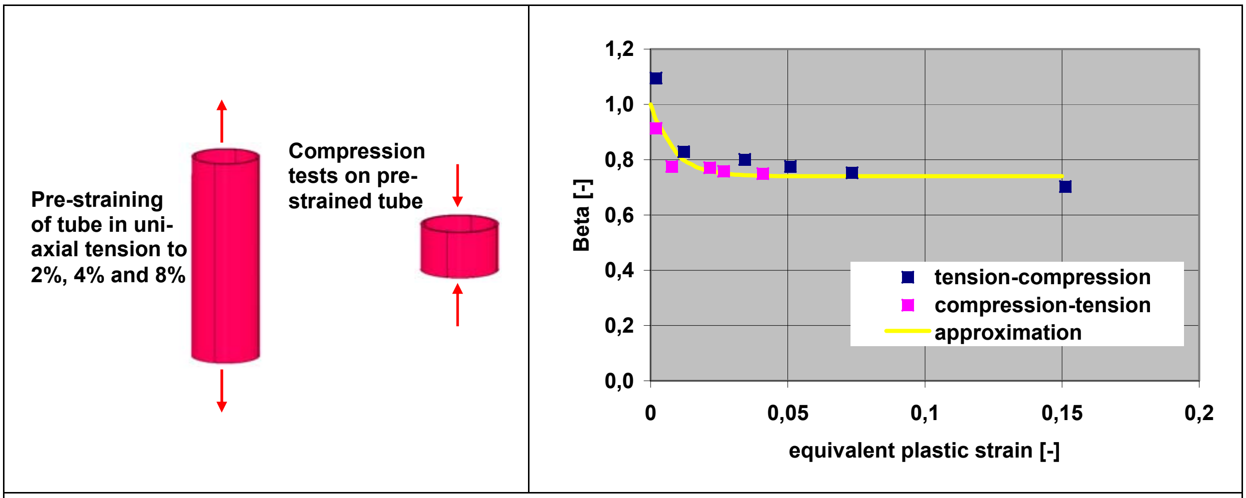


Figure 2-2: Testing procedure for the evaluation of isotropic-kinematic hardening of the stent alloy

In order to test the isotropic-kinematic hardening model of material model MF-GenYld one hexagonal solid element is used in to simulate tension-compression reversal tests with different levels of pre-strain in tension. Figure 2-3 gives the resulting stress-strain curves which clearly indicate the Bauschinger effect. Additionally the evolution of the parameter β as a function of prestraining is shown

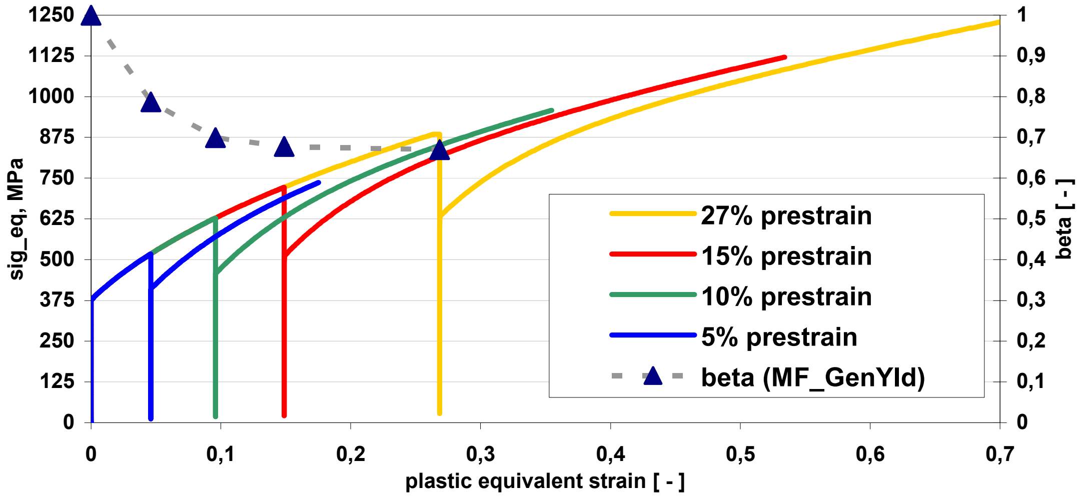


Figure 2-3: Stress versus plastic strain from simulation of tension-compression reversals with different pre-straining in tension with LS-DYNA user-material model MF_GenYld.

3 Simulation of Crimping and Balloon Dilatation

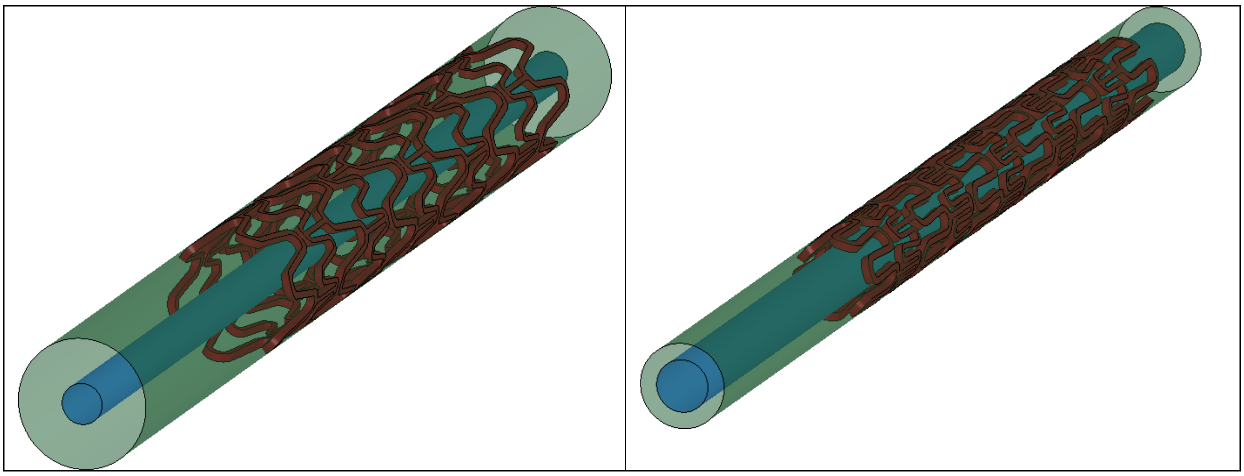
3.1 Stent Model

The stent consists of about 240.000 solid elements of type constant stress element with one integration point. In the radial dilatation model, see Figure 3-1, both cylinders are modeled with shell elements. As boundary condition a prescribed displacement acting normal to the cylinder surfaces is defined. In the balloon dilatation model, see Figure 3-2, the balloon is modeled with more than 120.000 selective reduced co-rotational shell-elements according to Hughes-Liu (type 7). As boundary condition a prescribed volume flux is applied.

The contact between stent and the crimping and dilatation tools – balloon and cylinder (idealized balloon), respectively – are defined as *CONTACT_ NODES_TO_SURFACE_MPP. For the stent-self contact a *CONTACT_ AUTOMATIC_SINGLE_SURFACE_MPP is used.

3.2 Radial Dilatation for 1st Step of Stent Design Optimization

In Figure 3-1 the radial crimping and dilatation process is shown schematically.



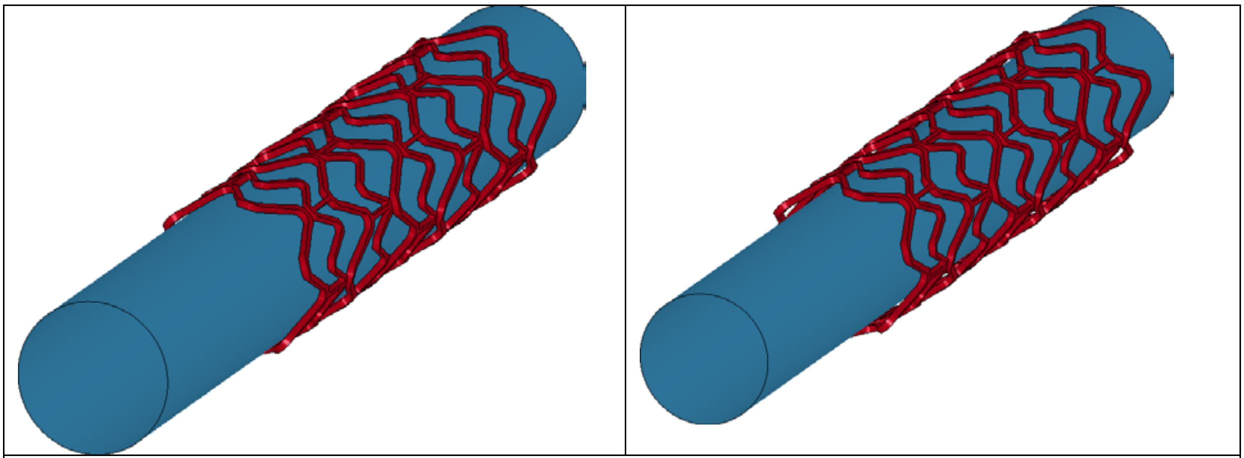


Figure 3-1: Stent crimping and dilatation with cylinder (idealized balloon).

3.3 Balloon Dilatation for an Enhanced Evaluation of an Pre-Optimized Stent Design

In contrast to the radial dilatation, the stent is crimped directly on the folded balloon, in order to take into account the influence of the balloon stiffness onto the stent recoil after crimping. Figure 3-2 a – d) shows several states of the crimping and balloon dilatation simulation. Plot a) depicts the initial stent geometry with the folded balloon, plot b) shows the stent after crimping on the balloon. In plot c) the stent can be seen during dilatation and in plot d) the fully expanded stent is shown.

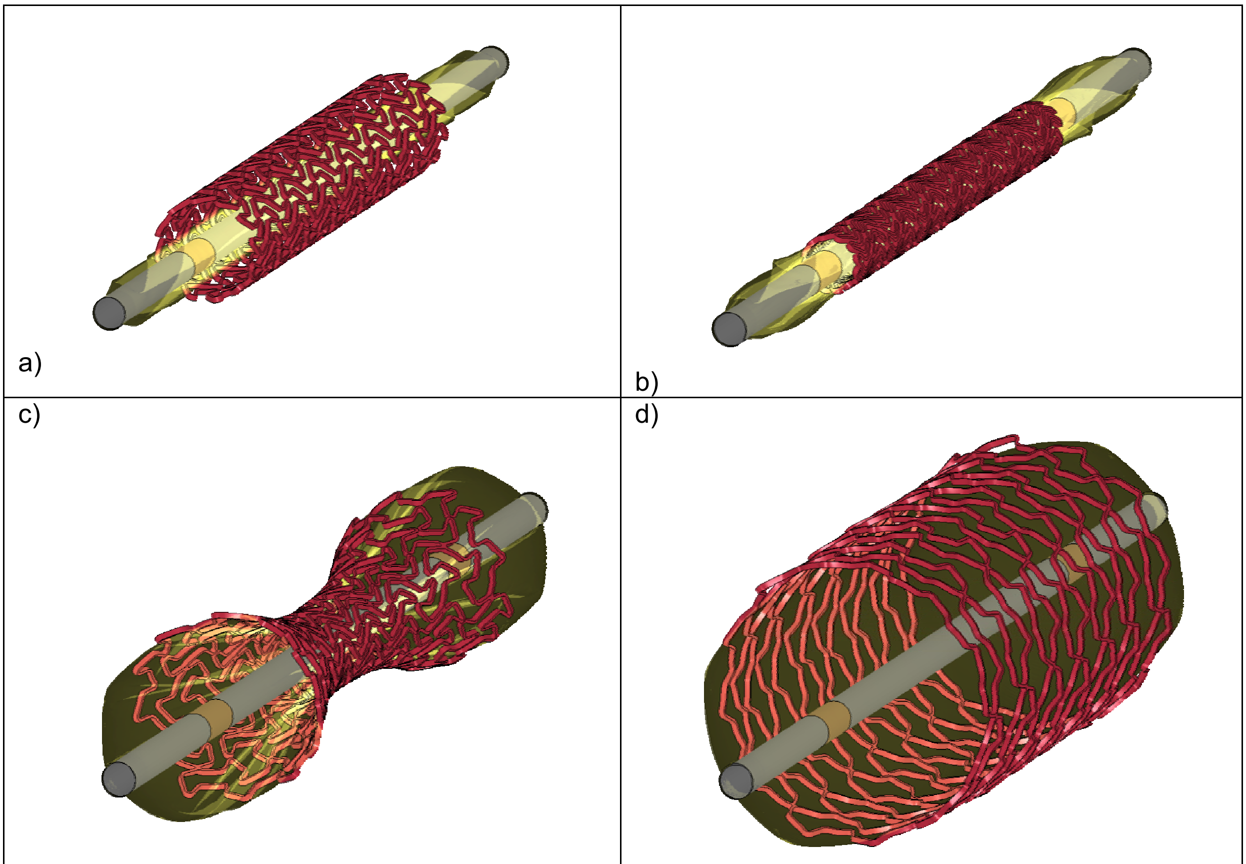


Figure 3-2: Stent Crimping and Balloon dilatation.

4 Results

Figure 4-1 shows the cross section force against the outer stent diameter during crimping and dilatation for different stint geometries and different materials.

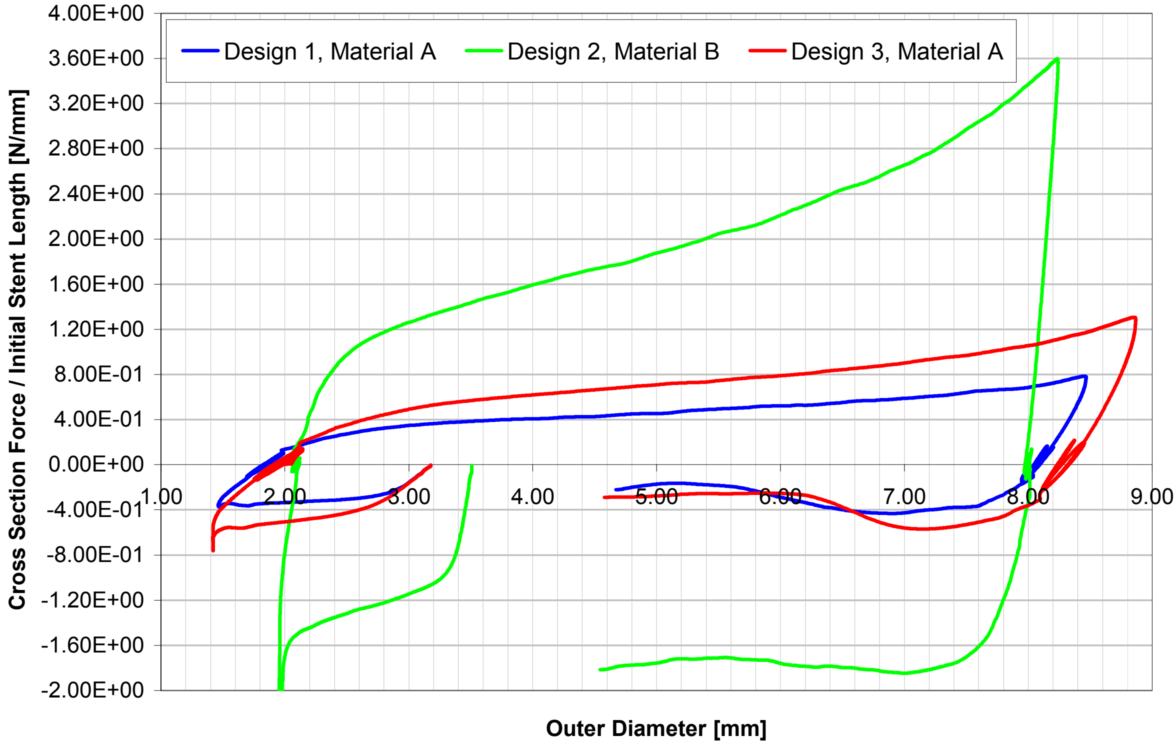


Figure 4-1: Cross Section Force against outer Diameter.

In Figure 4-2 the maximum failure risk against the outer stent diameter is during crimping, dilatation and recoil is depicted.

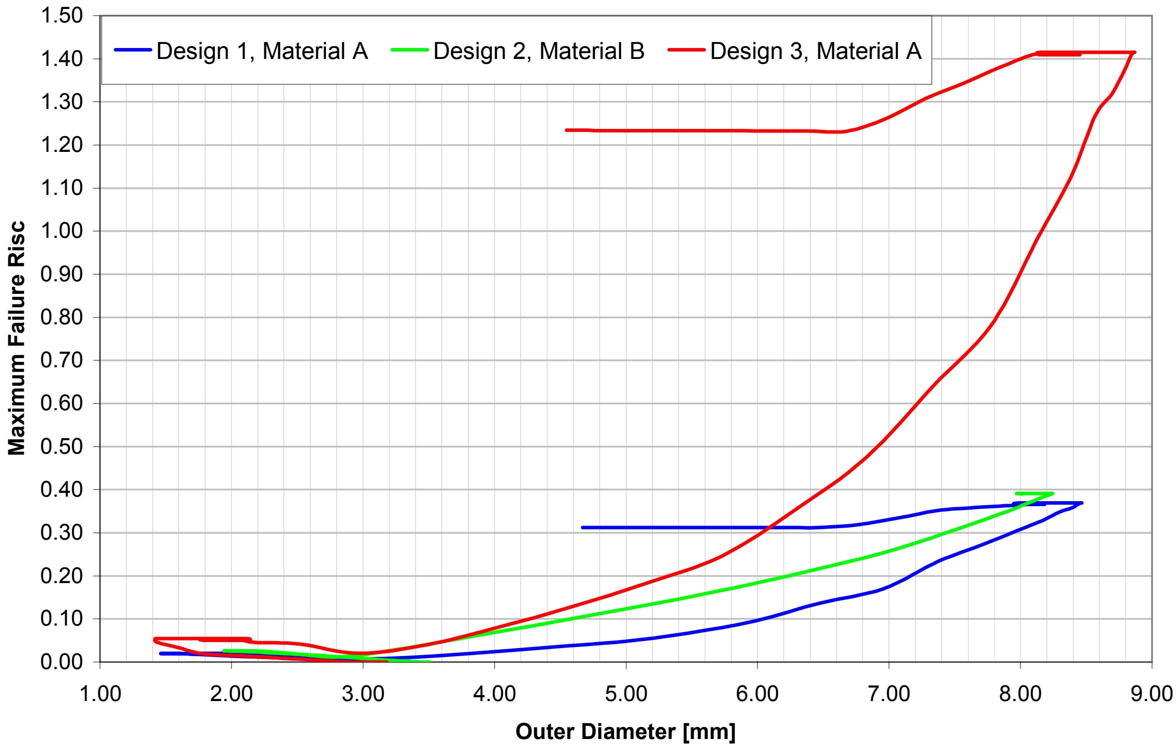


Figure 4-2: Maximum Failure Risk against outer Diameter.

Figure 4-3 shows a detailed fringe plot of the maximum failure risk after crimping, dilatation and recoil.

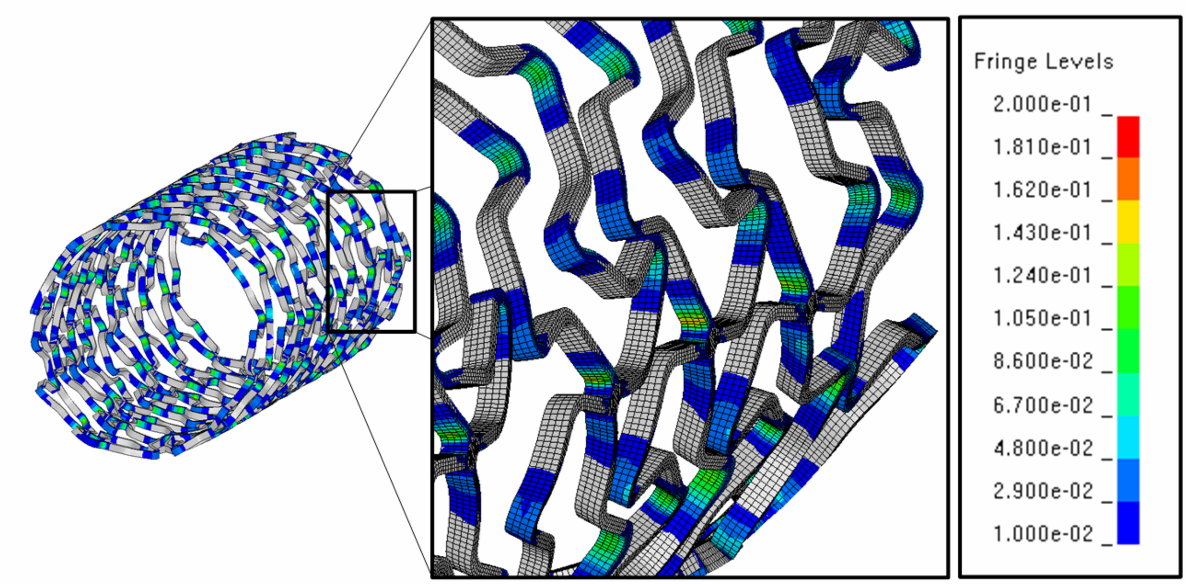


Figure 4-3: Fringe Plot of Failure Risk after Crimping, Dilatation and Recoil.

The shortening behavior during crimping and radial dilatation process is depicted in Figure 4-4. Additionally the corresponding behaviour of the balloon dilatation and the experimental results is compared.

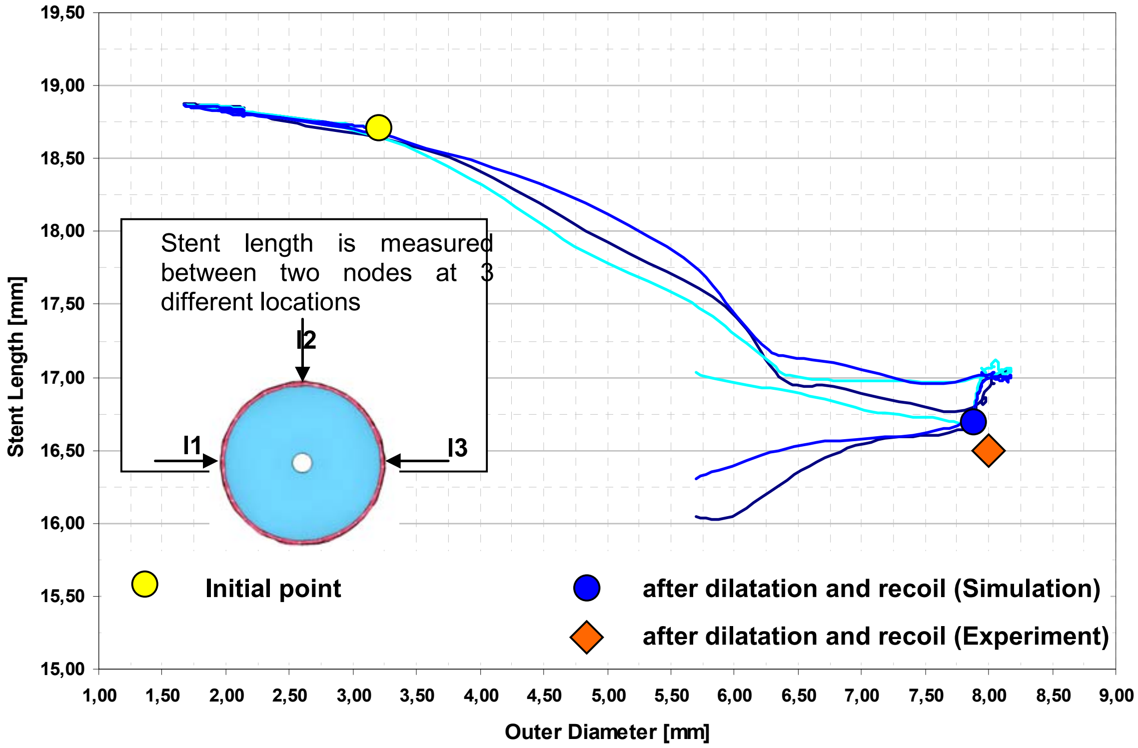


Figure 4-4: Stent length vs. outer diameter (Balloon dilatation).

5 Discussion

The explicit finite element method used in LS-DYNA provides a very stable simulation technique which is able to handle such complex and highly non-linear problems as show in this stent-balloon model. Due to its possibility of massive parallel processing (MPP) this stent-balloon model with more than 1 million DOF's can be simulated in an adequate simulation time.

The stent-balloon model shows a much more realistic dilatation behavior than a radial dilatation model. In Figure 5-1 a qualitative comparison of "dog bone" effect of in vitro and simulation is shown.

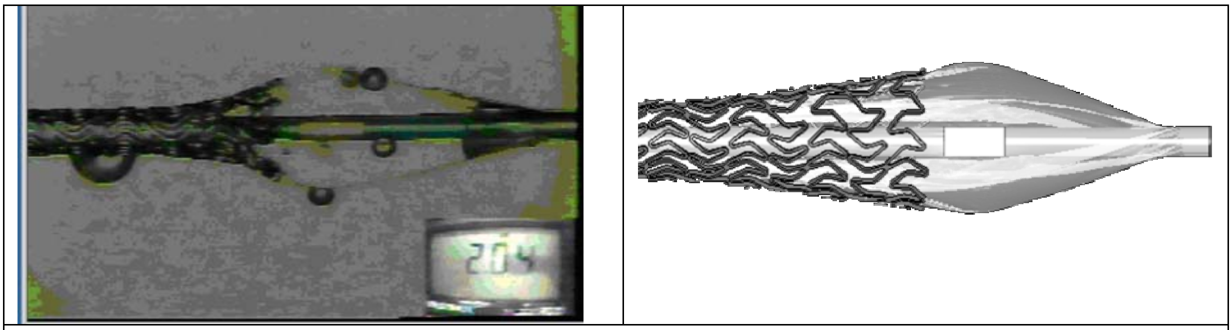


Figure 5-1: Qualitativ comparison of „dog bone" effect of in vitro (with courtesy of BSCI TZ GmbH) and simulation. Here different stent designs are depicted.

At the end of dilatation and recoil the stent length shows a good correlation between simulation with balloon and experiment. For the quantification of changes in the stent length during the dilatation process the simulation with balloon is essential. In this case a simplified radial dilatation model is not able to provide correct results in general.

The correct description of the combined isotropic kinematic hardening behavior is essential as load reversals appear during the deformation process. To take into account the influence of kinematic hardening is also important for a correct prediction of the residual stresses at the end of the dilatation process. The consideration of these stresses is important for a subsequent fatigue analysis.

Using the *MF_GenYld* material model with isotropic-kinematic hardening (Chaboche) coupled with the *CrachFEM* algorithm the evolution of the predicted failure risk can be followed during the whole crimping, dilatation and recoil process and thus provides a very helpful tool in the above mentioned stages of stent design.

6 References

[1] Chaboche, J. L. Equations for Cyclic Plasticity and Cyclic Viscoplasticity, International Journal of Plasticity, Vol. 7, pp. 247-302 (1989)

[2] Wierzbicki, T., Bao, Y., Lee, Y.-W. and Bai, Y.: Calibration and evaluation of seven fracture models, International Journal of Mechanical Sciences, Vol. 47, Issues 4-5, April-May 2005, pp. 719-743

