A Sensitivity Analysis of Stent Design Parameters using CFD

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Abstract: It is commonly known that the stent design has a significant influence on the flow topology and therefore on the wall shear stress (WSS) distribution as well. Post-operative complications like in-stent restenosis correlate with alterations in the WSS distribution. In the present computational fluid mechanic study the key design parameters of a generic model stent were investigated and the hemodynamical efficiency was evaluated by calculating the sensitivity. It can be concluded that the strut thickness is the most significant design parameter regarding the occurrence of low wall shear stress.

Keywords: non-Newtonian, stent flow, CFD

Introduction

Stents are medical micro devices which are used to restore the blood flow in the vascular system. They consist of sequential rings, called struts, which are arranged in a meandering pattern. The struts are linked with connectors on various locations. After the implantation the struts extend into the vessel lumen and cause an alteration of the natural blood flow which leads to the occurrence of regions of low wall shear stress (WSS) [1]. Clinical studies correlate low WSS with post-operative complications like the in-stent restenosis [3]. Therefore fluid dynamical investigations are necessary to reveal the influence of different design parameters on the blood flow and the WSS distribution. CFD is the optimal tool for this purpose. Based on a generic, experimentally validated stent model [5] the key design parameters strut thickness, strut width and crown number were varied over a wide range and the vessel surface area with WSS below the critical value of 0.5 Pa was calculated.

Methods

The numerical simulations were performed using the open source software package OpenFOAM. To consider the non-Newtonian flow behaviour the rheological properties were modelled by the Carreau-Yasuda model (Eq. 1):

$$\nu = \nu_{\infty} + (\nu_0 - \nu_{\infty}) \left(1 + (\lambda \dot{\gamma})^a \right)^{(n-1)/a} \quad (1)$$

where ν_0 and ν_{∞} are the limiting boundary values for finite and infinite shear rates $\dot{\gamma}$, respectively. The time constant λ and the two parameters a and n describe the non-linearity. The parameters were obtained by fitting the Carreau-Yasuda model on the dataset from Chien [2]. The following parameters were used:

$\nu_0 = 1.6 \cdot 10^{-5} \text{ m}^2/\text{s}$, $\nu_{\infty} = 1.8 \cdot 10^{-6} \text{ m}^2/\text{s}$, $\lambda = 0.606 \text{ s}$, $a = 0.874$ and $n = 0.486$ [4]. As inlet boundary condition a fully developed steady state velocity profile was defined. The given vessel diameter of 3.5 mm and the fluid density of 1050 kg/m³ combined with the Carreau-Yasuda model results in a Reynolds number of 160. It is assumed that the inner vessel diameter is conforming to the outer stent diameter. Each model stent consists of six strut rings which constitute a mirror pattern. The connectors between the struts are neglected. The edge length of the basic model stent is about 100 μm and six crowns are situated circumferentially.

Figure 1: Strut pattern in detail with defining design parameters

The length of the stented vessel for all simulations was about 10 mm. Only one of the independent design parameters were changed in each simulation. Additionally the thickness and the width were changed simultaneously for further simulations. The fluid mechanical quality is determined from the size of the area with a wall shear stress below the critical value of 0.5 Pa. The risk area is normalized by the total area of the stented vessel wall. The design parameters were normalized with the basic model stent.

Table 1: Range of the investigated design parameters

design parameter	edge length [μm]					
	100x60	100x100	100x140	100x180	140x100	180x100
thickness	60x100	100x100	140x100	180x100		
width	60x60	100x100*	140x140	180x180		
thickness + width						
number of crowns	3	4	5	6*	7	8

*basic model stent

Sensitivity

The hemodynamical influence of each parameter can be clarified by defining the sensitivity as an auxiliary quantity. The sensitivity describes the change of the risk area relative to the variation of the design parameter. So the

sensitivity corresponds to the gradient of the functions illustrated in Figure 2. For example, a sensitivity of 0 shows that the normalized design parameter has no influence on the size of the risk area and a value of 1 describes a direct proportionality, so that by doubling the quantity of the design parameter also the risk area doubles.

Results

The following figure illustrates the results from the numerical study. The normalized risk area is plotted over the normalized design parameter of the model stent.

Figure 2: Normalized low WSS areas as a function of the normalized design parameters

It can clearly be seen in Fig. 2, blue function, that for all investigated strut widths almost the same size of the risk area was observed. The calculated sensitivity is around -0.06 on average. Therefore the strut width has almost no effect on the flow. A reason could be that the blockage of the fluid domain remains constant and, due to the low Reynolds number, the flow can follow the contour of the struts. In contrast the strut thickness is one of the most significant design parameters. The data depicted in the red function in Fig. 2 shows an average gradient of 1.22 over the whole range. An increase in thickness leads to growing areas of decelerating flow and recirculation zones with low or negative values of wall shear stress, respectively. A combined variation of both parameters, the strut width and thickness, obtains a sensitivity of 1.20 on average. The change of the crown number shows a parabolic behaviour and is therefore completely different compared to that of the strut width and thickness. The local minimum of the parable is at a crown number of 5 which indicates an optimal configuration. The usage of less crowns leads to a sensitivity of -0.98 due to a crown number of 3. By raising the number of crowns the sensitivity increases to 0.41.

Discussion

It can clearly be seen that the design parameters which do not change the pattern of the stent have a linear dependency

referred to the risk area. Only the number of crowns shows a parabolic behaviour. With an alteration of the crown number the strut pattern is strained in circumferential direction and therefore the flow topology changes. The flow is guided along the struts, towards the crowns where the fluid crosses the strut with recirculation zones appearing up- and downstream. In a stent pattern with less crowns the struts are arranged more in a cross stream direction which leads to spacious recirculation zones. By increasing the number of crowns above the optimal value the struts are arranged with a smaller angle to the main flow but the flow across the crowns reaches higher velocity values which results in larger recirculation zones. By changing the width and thickness of the strut the pattern as well as the flow topology remains unchanged. Here the sensitivity is only a constant proportionality factor between the variation of the design parameter and the change of the risk area.

As a result of this study it can be stated that the strut thickness is the most important design factor. To assume the necessary radial strength of the stent the width of the strut should be adjusted whereas a huge thickness should be avoided. Furthermore a crown number of about 5 or 6 emerged as an optimum for this strut pattern. Prospective studies will focus on the combination of different parameters and the dependencies from each other. The simple superposition of the sensitivities does not result in valid predictions.

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SPITZENFORSCHUNG & INNOVATION
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