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The influence of strut-connectors in coronary stents: A comparison of numerical simulations and µPIV measurements

Abstract: This paper discusses the influence of different designs of strut-connectors of stents by numerical flow simulations and flow examinations using micro particle image velocimetry (µPIV). Many studies have shown that there is a correlation between the hemodynamics after stent implantation and the cause of biological responses like thrombosis and the in-stent restenosis. Recirculation areas may occur through a stent, which are considered to be the cause of these clinical complications. In this study, three different coronary stent designs are investigated and the hemodynamic effects from the different designs is presented. The study focuses on the design of the strut-connectors that connect two struts. Numerical simulations were performed to evaluate various flow features like recirculation zones, velocity profiles and wall shear stress (WSS) patterns. To verify the numerical results µPIV-measurements were performed. It could be shown that the alignment in the main stream of the connectors influences the size and number of recirculation zones.

Keywords: Stents, Strut-Connectors, Thrombosis, In-Stent-Restenosis, Computational fluid dynamics, Micro-PIV, Coronary heart disease

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1 Introduction

The causes of the coronary heart disease are arteriosclerotic changes in the coronary blood vessels. A typical treatment method is the stent, a tubular mesh structure which is usually inserted to the stenotic region. [1] However, stents often induce adverse biological responses such as thrombosis or in-stent restenosis. The in-stent restenosis is a reduction in lumen size as a result of formation of the neointima. This process represents a major clinical limitation of bare metal stents (BMS) but has been successfully attenuated by the use of drug eluting stents (DES). The in-stent thrombosis is a formation of a blood clot inside the stented vessel. [2]

Many previous studies show that there is a correlation between the hemodynamics after stent implantation and the cause of these biological responses. It could be shown that a reduction in strut–strut intersections would help to reduce the risk of restenosis. [3-5] This reduction in strut thickness resulted in significant reduction in clinical restenosis. The hemodynamics are affected by the stent design, particularly strut spacing, and the overall flow environment.

A stent changes the geometric conditions in the vessel so that the stent strut acts as a flow barrier. Recirculation areas can occur around the stent struts. These recirculation areas are characterized by low velocities and low wall shear stresses ($\tau_w < 0.5$ Pa). In these areas, thrombocytes may remain and attach themselves to the vessel wall thereby promoting the process of in-stent restenosis. For that reason it is important to evaluate the stent design to minimize the disturbing influence of the stent structure for future stent designs. [3-5]

Computational fluid dynamics (CFD) is an excellent tool for studying the hemodynamics of stents and has been widely used for flow analysis through stented vessels. Although many studies have tried to understand the effect of stent geometry on altered hemodynamics, most have focused on parameters of the design of the struts such as strut spacing and strut thickness.

Connectors (mostly flex) are an essential component of a stent design. The connectors hold the stent struts together and stabilize the stent design. The number of connectors determines the flexibility of the stent structure. A decrease in the number of connectors gives the stent more flexibility and better adaptation to the vessel, but at the same time reduces the strength in the longitudinal direction. The aim of this study is therefore to investigate the influence of different connector

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types on the hemodynamic flow conditions. For this purpose, different connector designs are compared to anticipate the strength of the recirculation areas in order to optimize them in the future.

In the first step, numerical flow simulations were performed. In order to validate the numerical results, experimental investigations are carried out using µPIV. In this measurement method, particles are added to the flow and their movement is evaluated by image processing to reconstruct the velocity field and thus make the flow within a stent and around the stent struts visible.

2 Methods and Experiments

The stent designs were idealized and constructed by means of the CAD software Solid Edge ST 10 (see figure 1). In order to make a comparison between the stents, representative geometries with the same diameter (3 mm), same stent length (11 mm), same strut thickness (0.15 mm) and same strut height (0.15 mm) but different connector types: a straight connector, a round connector and a flex connector are constructed for each stent.

Figure 1: CAD-geometries for the investigated stents with the different strut-connectors.

The numerical flow simulations were performed with ANSYS fluent 18.2. In the simulations, blood was assumed to be a single-phase flow. In this study, the blood flow in a stented artery was assumed to be steady, incompressible and laminar. A fully developed parabolic Hagen–Poiseuille velocity profile with a mean velocity of $u_\infty = 0.19$ m/s and zero pressure were specified as inlet boundary conditions. The Reynolds number at the inlet of 175 corresponds to the laminar flow. Blood was modelled as an incompressible fluid with a density of ρ=1060 kgm^{-3}. In order to consider the shear thinning behavior of the blood, the non-Newtonian Carreau model (see eq. 1) was implemented:

$$\eta = \eta_\infty + (\eta_0 - \eta_\infty)[1 + (\lambda\dot{\gamma})^2]^{\frac{n-1}{2}} \qquad (1)$$

In the formula η is the kinematic viscosity, η_0 and η_∞ are the low and high shear viscosities with values of 0.25 and 0.00345 Pas, respectively, while λ is the time constant and n is the power law index with assigned values of 0.25 s and 0.25, respectively. [6] This model fits also well to real values for blood. [7] Approximately, 5.000.000 unstructured mesh grids were generated for one quarter of the structures for each stented artery.

In order to compare the numerical results with experimental data, a µPIV setup with fluorescence microscopy was used. To analyse the influence of the strut-connectors, existing stent designs were transferred into moulds in order to transfer them reproducibly into channel systems made from transparent PDMS. Therefore, the method described in [8] was used. As the test fluid, a 40% mixture of glycerine in water was used. By adding xanthan gum, the rheological behaviour of the liquid was adapted to that of blood.

3 Results

To illustrate the hemodynamic changes of the flow in the stented coronary vessels the differences in wall shear stress patterns and recirculation zones are shown, thereby confirming the effect of the stent connectors on the hemodynamics of the flow.

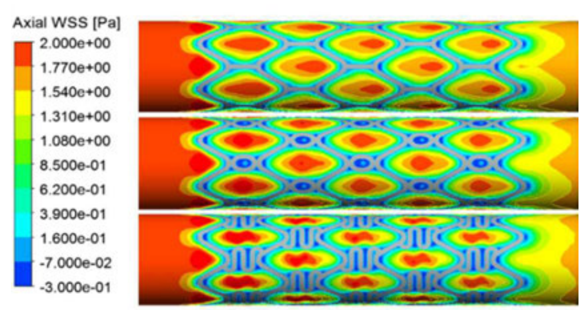

Figure 2: Axial wall shear stress of the different stent designs. The dark and mid blue regions show the artery wall area with negative axial WSS implying formation of recirculation zones.

Figure 2 shows the axial WSS patterns for all of the examined stents. For all stents, axial WSS has a high value proximal to the stent and a relatively lower value in the area occupied by the stent. The WSS at the artery wall distal to the stent experiences a higher value again as the flow returns to the normal level. The artery wall around the first strut reach a relatively high WSS as compared to the area around other struts. The areas of low WSS are localized around the stent struts.

For all of the stents the numerical flow simulations showed the representation of the secondary flow (see figure 3) and thus the recirculation areas around the stent struts except for the regions between the connectors. The recirculation zones are formed at the proximal and distal end of each strut/strut-connector intersection. This causes the WSS to change sign before and after each strut/strut-connector intersection. The dark blue regions of figure 2 show the artery wall area with negative axial WSS implying formation of recirculation zones.

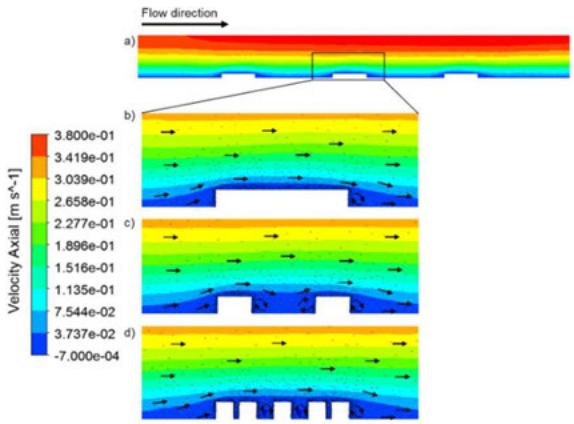

Figure 3: Results of the axial velocity of the different stent designs by the numerical flow simulation. a) entire flow area in the middle plane of the stent with the straight-connector; b, c, d) detailed representation of the resulting speed profile around the different strut-connectors (from top to bottom: straight connector; round connector and flex connector). The black arrows illustrate the formation of the recirculation areas. The colour scale corresponds to the respective speeds.

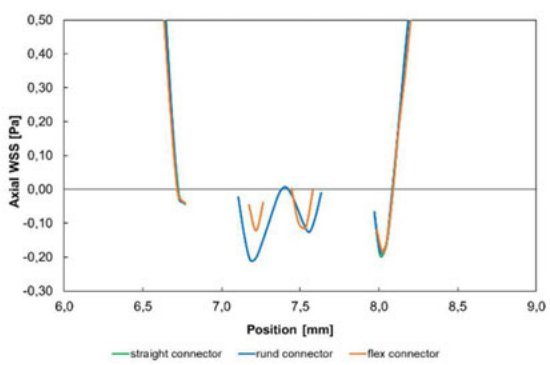

Figure 4: Axial WSS by the numerical simulation of the different stent designs along the central line.

Figure 4 shows the axial-WSS variation, on a central line on the arterial wall for the investigated strut-connectors. For all stents the WSS values proximal and distal to the ends are the same. Depending on the design of the strut connectors WSS oscillates spatially in the connector region between zero, negative, and positive values. The round connectors allow the WSS to recover to a positive value in between the struts. This is due to the fact that the connectors have more open space between the stent struts.

In other simulation studies, the WSS magnitude of less than 0.5 Pa is used as a benchmark to compare the design of stents because this value correlate to areas that show most intimal thickening. Figure 5 shows a histogram of the percentage of vessel wall area exposed to WSS less than 0.5 Pa and the percentage of negative axial WSS. The stent with the flex-connector and the round-connector have a significantly higher percentage of low WSS area as compared to the stent with the straight-connector. The better hemodynamic parameters can be attributed to the better alignment in the flow direction.

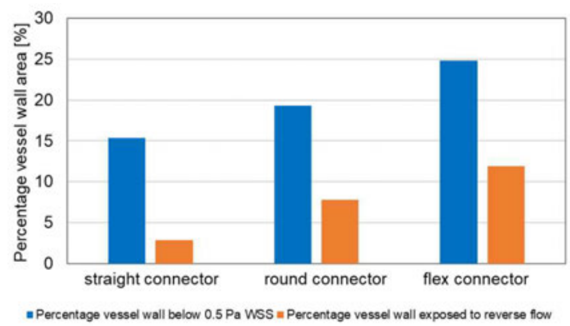

Figure 5: Percentage of the vessel area characterized by low WSS and reversed flow.

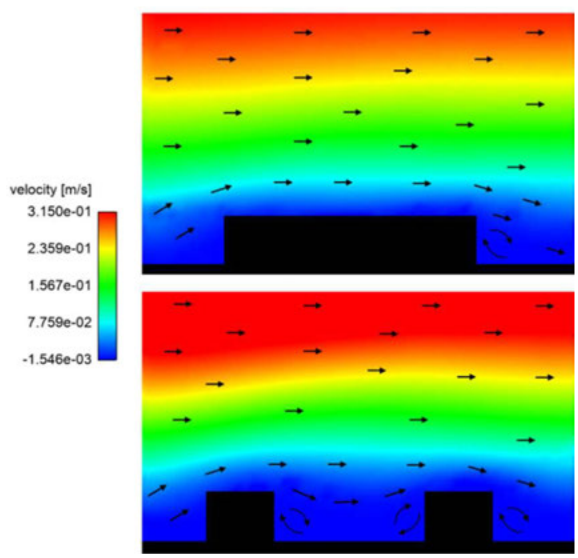

Figure 6: µPIV results of the different stent designs. Detailed representation of the resulting speed profile around the top: straight connector bottom: round connector. The black arrows illustrate the formation of the recirculation areas. The colour scale shows the respective speeds.

The μPIV measurements confirm the results already acheved in the simulations (see Figure 6). The recirculation zonesare also formed at the proximal and distal end of each strut/strut-connector intersection. Recirculation zones in the cross-flow direction are observed for these designs close to th artery wall. This is due to the fact that the connectors in these designs protrude into the space between the struts due to their undulating nature and thus cause a larger change in the flow.

To compare the axial-WSS from the simulation with the μPIV-results, the axial-WSS were calculated. Therefore, the velocity gradient was determined from the 2d velocity field. Taking into account the viscosity by the Carreau model, the axial-WSS could be calculated.

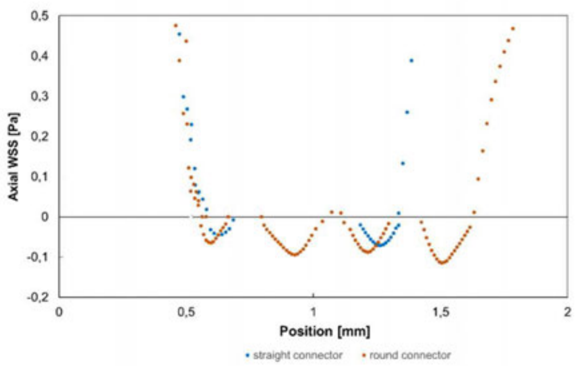

Figure 7: Axial wall shear stress calculated from the μPIV-measurements of the different stent designs along the central line.

Figure 7 shows the axial-WSS variation on a central line on the arterial wall for the examined strut-connectors investigated with the μPIV-technique. For all the stents the figure also shows the same trend as the results from the simulation.

The orientation in the main stream of the connectors influences the size and number of recirculation zones. Due to the different stent designs, reductions of the critical areas are possible and representable by the use of a suitable connector design.

4 Conclusion

The aim of this study was to investigate the influence of different designs of the strut-connectors. Therefore, mathematical flow simulations were compared with experimental investigations using micro-particle image velocimetry. Different strut-connectors were investigated**.** It could be shown that a reduction of the critical areas is possible by suitable choice of the connector design. Therefore, from a fluid mechanic point of view, the straight connector showed the fewest recirculation areas. The μPIV-measurements clearly confirmed the numerical results.

5 Outlook

In this paper, the μPIV-measurements and the numerical simulations were performed only with a stationary inflow with a velocity of $u_\infty = 0.19$ m/s. In reality, the blood flow is subject to a natural pulsatile velocity. Therefore, experimental investigations with a pulsatile inflow should be carried out. In the study we focused only on the hemodynamic effect of the different stent designs. However, mechanical flexibility must also be considered in the development of future stents.

Author Statement

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