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Partial CFD Models of Cardiovascular Stents

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SYNOPSIS

This paper outlines the use of a partial CFD stent model in order to improve discretisation of important small features. The effects of mesh size on the performance measure are investigated. The results are compared with those from full models and also comparisons with clinical trials are made. It is shown that partial models provide a better approximation to reality than full models when using modest PC workstation resources. The general conclusion is that computer-based design of medical devices must take into account the variations in geometry between patients by means of, for example, a flat performance curve against noise.

1 INTRODUCTION

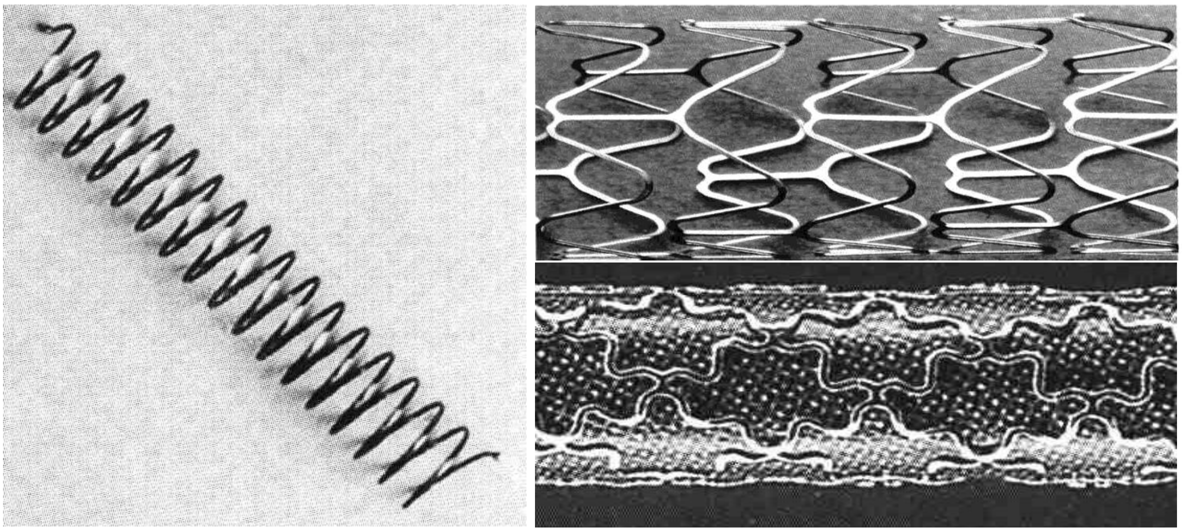
Cardiovascular stents are inserted into an artery in order to dilate a blockage and restore blood flow to vital organs.

1.1 Geometric Risk Factor

Several studies (e.g. 1, 2) have established that the risk of susceptibility to arterial disease is dependent on patient-to-patient variations including blood rheology, artery geometry and wall compliance; as well as differences in the endothelial growth around an embedded stent. This is known as the 'Geometric Risk Factor' (GRF) and its significance warrants consideration in the design process of stents. In other words, the GRF is a class of noise factors specific to the design of devices implanted in the body.

1.2 Stent design

Stent design initially developed solutions for structural support but the importance of designing for blood flow characteristics is now recognised (3) as the overriding concern as flow is a key contributing factor in the re-blockage (restenosis) of a stented artery. Therefore stent pattern features and strut detail are now designed with fluid flow in mind (fig 1).



(a) Early stent design **(b) Contemporary stent designs**

Figure 1. Stent design examples

The result is that stent design has developed away from the relatively dense simple helical-type designs to more open and sophisticated forms made from thinner material that are less disruptive to the blood flow.

The role of Wall Shear Stress (WSS) in restenosis has received a lot of attention (4) and to this end, Computational Fluid Dynamics (CFD) has emerged as a vital design tool. It is interesting that WSS cannot be measured *in vivo* as yet, which restricts direct validation of simulation results. Another constraint is that the ratio of overall size to important detail is large for a stent, about 30, and this limits the discretisation of the full CFD stent model for a given resource. Therefore full stent models can be unsatisfactory, as they do not fully resolve the recirculation regions around stent struts and limits the degree of confidence in finding an optimum design.

2 SIMULATION MODELS

Modelling a general artery of 3mm diameter as an idealised cylinder is a reasonable first approximation. The Geometric Risk Factor can be represented by two noise factors, namely, the degree of stent embedding into the artery wall and also inflow conditions to the stent. A CFD mesh of this model was generated and simulated in CFX 5.4 (5).

2.1 Full 3D model

For a full 3D model, straight or curved entry tubes were used to determine the inflow conditions. Thus meshing the flow domain of the full 3D model (fig 2), for a given computer resource, severely limits the number of elements available to represent the stent geometry. This is because there is a relatively large difference between overall artery size and the important stent features; which in practical terms does not allow sufficient discretisation of the flow domain near to the artery wall.

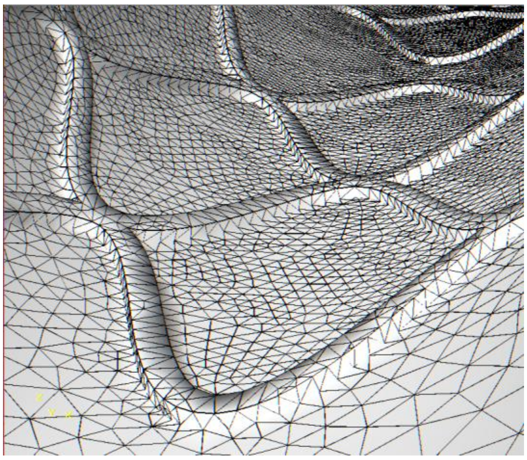


Figure 2. CFD mesh detail for full 3D stent model (slotted tube design)

2.2 Partial 3D model

Taking a partial CFD 3D stent model based on a 1/6 segment of the full 3D model (fig 3) can improve discretisation of the important small stent features. This is possible due to the repeating nature of the stent pattern.

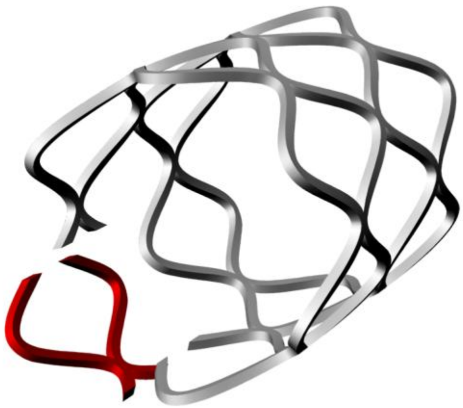
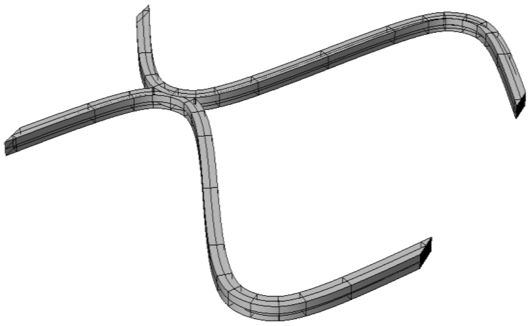
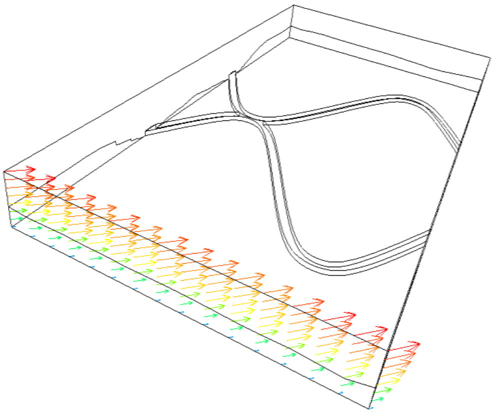


Figure 3. Partial model of stent cut from a full stent (slotted tube design)

The CFD partial model developed from such a thin segment is considered to be flat (fig 4) and the effects of this approximation are considered to be negligible. Inflow conditions can be simply represented as the angle of the inlet flow.



(a) stent geometry



(b) flow domain

Figure 4. Partial models of a stent

The resulting discretisation of the partial model (fig 5) is greatly improved around the stent geometry for the same computer memory resource as for the full model.

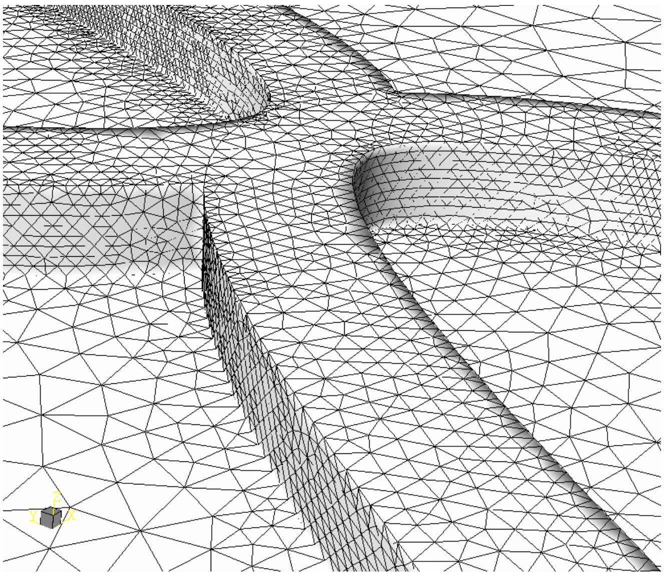


Figure 5. CFD mesh detail for partial 3D stent model

2.3 Performance measures

In CFD the performance of a stent is most commonly assessed by means of colourful qualitative output, typically using WSS values. Such qualitative measures are not suitable for driving a design optimisation algorithm. Therefore we have developed two quantitative measures but the detailed presentation of these measures is outside the scope of this design paper. In short, one measure processes the elemental values of WSS in relation to the mean value as a measure of the dispersion of WSS values about the norm (Equation 1).

WSS NORM EQUATION (1)

The other measure is based on the power dissipated by the fluid as it passes through the fluid domain and is expressed by Equation 2.

$$N_{diss} := \iiint_V \mathbf{P} : \nabla \vec{U} dxdydz \qquad (2)$$

Where: $\vec{U}$ is the velocity vector field. $\mathbf{P}$ is a stress tensor, V is the volume of the flow domain.

3 RESULTS

A comparison of WSS across the stented artery surface is shown in Figure 6.

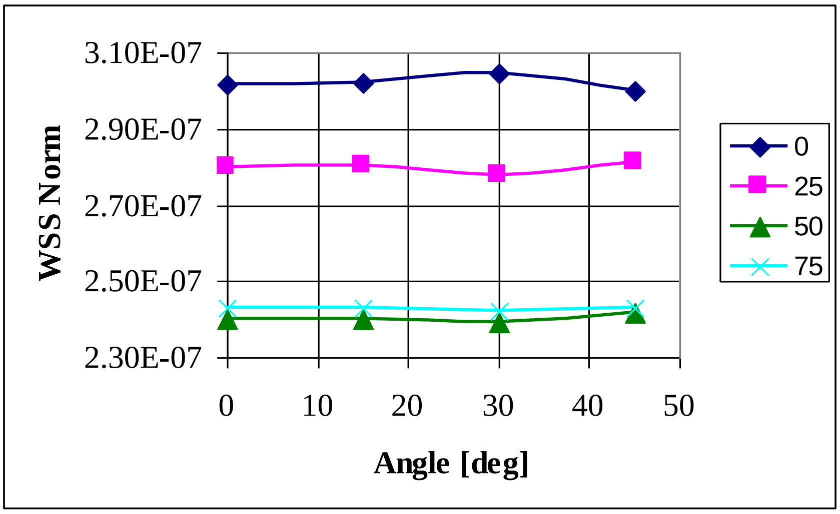


Figure 6. WSS versus noise factors for slotted tube and ?coil designs

- Comments on data precision etc.

A comparison of dissipated energy across the stented artery surface is shown in Figure 7.

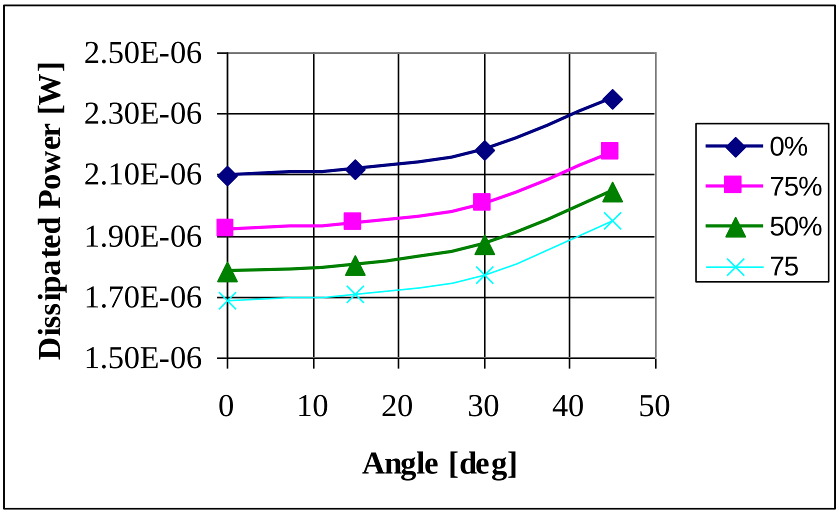


Figure 7. Dissipated power versus noise factors for slotted tube and ?coil designs

4 DISCUSSION & CONCLUSIONS

- GRF is seen to be a significant influence on fluid characteristics.
- The degree of embedding also provides information on stent strut thickness. Therefore the results indicate the significant influence of strut thickness on stent performance. This is in agreement with clinical trials of different stent designs (7).
- Limitations on stent geometry in model due to strut width versus skew which causes meshing problems.
- Ideally the relationship between performance and noise factors should be flat in order to be robust.
- More than 70 coronary stents have been approved for clinical use in Europe (6). In addition to their flow performance these stents differ in terms of their deliverablility, flexibility, retention, radiopacity and other clinical performance factors, which in practice, have to be taken into consideration.
- Geometric configuration also affects vascular injury (8)
- From Figure 8, it can be seen that mesh type is more important than mesh size generally. However, this is only in terms of calculating a global value such as dissipated power or volume. For clarifying the fluid behaviour around fine stent features small elements are vital.

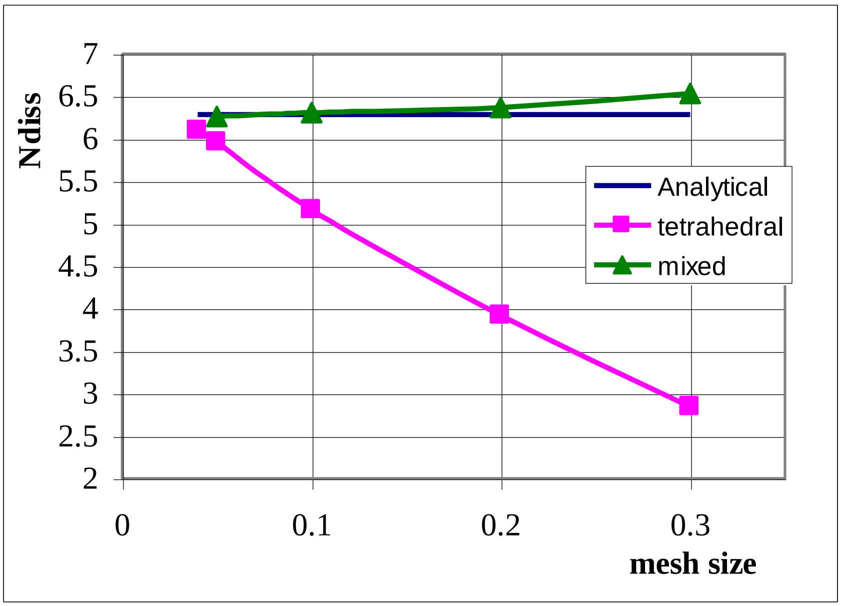


Figure 8. Dissipated power versus mesh size for different mesh types

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