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Development and testing of a synthetic fibre reinforced three-leaflet heart valve

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Introduction

Commercially available heart valve prostheses are either mechanical or biological. Mechanical valves damage the red blood cells, that implies the patient follows a lifelong anticoagulant therapy. Biological prostheses, mostly porcine, have durability problems. Synthetic valves are the future valve generation. However the prototypes made up to now, the polyurethane valves, have still durability problems. It is believed that considerable improvement can be achieved by using fibre reinforced composite material for the leaflets.

Materials and Manufacturing

The stented three-leaflets valve prosthesis (fig.3) consists of a stent, which supports the three leaflets. The stent is made of nylon 6, while the leaflets are constructed of a flexible, fibre reinforced, synthetic material. In the stentless prototype (fig.2) the leaflets are directly made inside a piece of the aorta. The matrix consists of EPDM rubber, a copolymer of ethylene and propylene, which has good biocompatibility. The matrix is reinforced with polyethylene (PE) fibres, which are thin and strong. The PE fibres are placed on the EPDM rubber, using a computer controlled winding machine. Different fibre layouts are possible in order to reinforce the composite material in the areas where the highest stresses occur.

Numerical simulations

In the design, extensive use is made of a finite element model of the valve. The leaflets (and the aorta in the stentless) are subdivided into a large number of elements, with the appropriate material behaviour. The finite element model is shown in fig. 4 and 5. The numerical simulation not only gives us the geometry of the leaflets during the cardiac cycle, but also the strains and stresses in the material. These results can be used to optimize the fibre layout such that the stresses in the leaflets will be as low as possible.

Conclusions

The procedure of manufacturing a three-leaflet valve prosthesis, with fibre reinforced leaflet, is very flexible. It is possible to apply the fibres so that the same functionality as in the natural valve is obtained. Prototypes of valves have been tested, showing good opening and closing behaviour. FEM models with fibre reinforcement show lower stresses than the model without fibres.