Balloon folding pattern, an underestimated parameter in stent design?

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Introduction

Neointimal hyperplasia after (drug-eluting) stent implantation is correlated with non-uniform stent strut distribution. This observation is related to the local drug concentrations and gradients and the protrusion of the tissue between the struts of the stent (prolapse), resulting from inhomogeneous strut placement. For that reason efforts should target optimization of the uniformity of the stent strut distribution upon stent deployment. We hypothesize that the folding pattern of the delivery balloon is a contributor to the non-uniform strut distribution.

Methods

We developed an innovative computer tool combining the general purpose finite element solver ABAQUS with open-source dedicated pre- and postprocessing design software pyFormex [1-3]. This tool allows us to study the inflation of balloons and expansion of stents to predict and optimize stent strut distribution during the procedure. The procedure was applied to a commercially available and widely used drug-eluting stent, which was expanded virtually with both a tri- and six-folded balloon configuration. The tri-folded scenario was compared with micro-CT images at the end of the transient expansion phase for model validation.

Results

An excellent correspondence between the simulations and the micro-CT images of the real expansion was observed (see Fig. 1). For the tri-folded balloon (which is actually combined with this stent), a non-uniform strut distribution pattern was observed (strut angle varying from 49° to 71°), whereas a six-folded balloon results in a homogeneous strut distribution (strut angle equal to 60°).

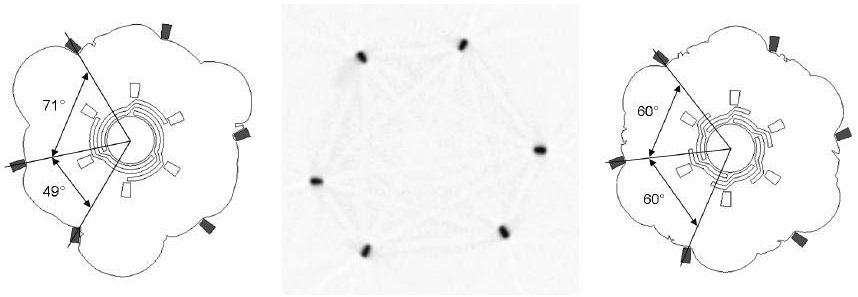

Fig. 1. For the tri-folded balloon, a non-uniform stent strut distribution was observed (left panel: simulation; center panel: experiment), whereas a six-folded balloon (right panel: simulation) results in a homogeneous strut distribution.

Conclusions

The balloon folding pattern is a major factor contributing to non-uniform stent strut distribution during free stent expansion. Our virtual tool allows to assess the most appropriate balloon folding for a specific stent design to minimize stent strut non-uniformity attributable to balloon unfolding. Currently the developed virtual design tool is being extended to study the interaction between the stent and patient specific blood vessels in detail.

References

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