# MECHANICAL ASPECTS OF DRUG-COATED BALLOON ANGIOPLASTY DETERMINING THE EFFICIENCY OF THE COATING TRANSFER

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## Introduction

Computational modeling has been proven a powerful tool and a compelling ally of physicians to confront cardiovascular diseases. In the past decade, there has been an effort by scientists to approach Drug-Coated Balloon (DCB) angioplasty exploiting this numerical tool. Nevertheless, the vast majority of the studies have so far focused on mass transfer and drug-elution kinetics within the arterial wall, neglecting further aspects of the DCB treatment. Literature indicates that the coating transfer onto the arterial wall is to date insufficient and, as evidenced, there is a strong dependence of the coating transfer rates on the local contact pressure values [1,2]. Furthermore, the drug coating on the balloon may experience preliminary loss, during the various manufacturing processes involved. Consequently, the objective of this study is the investigation of, pre- and during-treatment, mechanical processes that could influence the coating transfer rates onto the mural arterial surface, using computational means.

## Methods

The DCB thickness was gauged in a number of bare balloons, along their longitudinal axis. An accurate replica for the angioplasty balloon was introduced into the finite element models, reproduced of shell elements on Abaqus software. The realistic folding process of the balloon was simulated, as implemented in a recent study [3], taking into account possible non-uniform balloon thickness. Subsequently, the folded balloon was inflated in peripheral arterial models. The contact pressure with the arterial wall (as an indication of the coating transfer), was evaluated, as a function of oversizing and different vessel features. Simplified models of peripheral arteries were used, considering cylindrical shapes with the addition of different stiffness areas, as occurring *in vivo*.

## Results

Our preliminary measurements on real devices suggest a varying thickness along the longitudinal axis of the balloons (thicker at the two ends). This was expected as a direct consequence of the blow molding process during the balloon forming and was implemented in the numerical models. The balloon folding simulations forecasted increased strain values at the crests and the "valleys" of the folds, suggesting a possible risk for microcracks on the coating or delamination during the folding process (Figure 1), as the strain values exceeded the calculated strains at break [4]. Moreover, the expansion of a folded balloon inside an undersized cylindrical arterial model revealed linearly-patterned areas with elevated contact pressure values, due to the irregular contact of the non-distended balloon with the arterial wall (Figure 2). These results could justify the observed drug coating transfer distribution onto the mural surface of porcine femoral arteries [1].

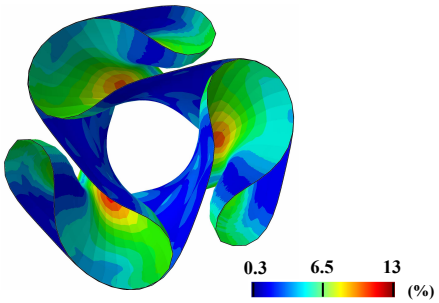


*Figure 1: Maximum principal logarithmic strain percentage at integration points of the folded and pleated balloon.*

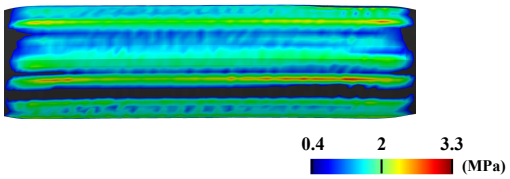


*Figure 2: Contact pressure variables at the nodes of the arterial wall during the inflation of a uniform-thickness balloon, inside a slightly undersized simplified artery (black color equals to values below 0.4 MPa).*

## Discussion

In this study, we aimed to examine the parameters that could impact the coating transfer onto the arterial wall. There are some mechanical effects that arise during the pre- and during-operation processes, which could deteriorate the coating layer. Thus, we regarded the inclusion of the folding process of the balloon as a consequential factor when approaching the DCB treatment computationally. Furthermore, the heavy fluctuation of contact pressure values between the DCB and the vessel could justify the observed inhomogeneous coating transfer on the arterial wall [1]. Effectively, our study concluded that the mechanical aspects of DCB angioplasty can justify the reduced coating transfer rates.

## References

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2. Chang et al, Sci Rep 9, 6839, 2019
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