Polymers in Drug Coated Balloon Angioplasty and its Coating Morphology

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***Abstract*— The ideal characteristics of an angioplasty balloon is its strength, flexibility, and biocompatibility. Though these balloons have been in the market for some time, major concern prevails due to the drug loss that occurs during angioplasty. This study provides the first set of experimental data on the difference in mechanical response of the polymer at various stages of manufacturing.**

***Keywords*—Angioplasty, Tensile testing, Confocal laser scanning, Pebax.**

I. INTRODUCTION

MANUFACTURING of the angioplasty balloons takes place in various stages, starting from polymer granules which is heated and extruded into a tube. These tubes are then blow moulded into angioplasty balloons with the help of heated jaws and compressed air [1]. Analysis of these polymer materials at different stages of manufacturing is important to understand the adhesion behaviour between the balloon, and the drug coating and the drug transfer pattern. Other than the properties of the polymers there are various drug related parameters like thickness of the drug coating, crystalline structure of the drug, the properties of the excipient used along with the drug that can cause a huge difference in the drug transfer [2]. Thus, adding a layer of coating can also alter the mechanical response of the Drug Coated Balloons. In this research, both the polymer films (comparable to the extruded tubes) and balloon materials are analysed for its mechanical and surface properties, with and without the coating matrix to understand the changes in properties during the manufacturing process and the drug fragmentation during release.

II. EXPERIMENTAL METHODS

Mechanical analysis on both the films and balloon material were performed by micro-tensile and bulge testing to understand the change in properties at various stages of manufacturing. Here the materials of analysis are Polyamide composites. The experiments were performed in both dry and wet conditions trying to mimic the in vivo conditions. Considering the material to be hyper-elastic, nonlinear data fitting was performed using Finite Element Modelling (FEM). Apart from analysing the mechanical response, fibre orientation during the manufacturing process and change in coating morphologies during experiment are understood by observing it under the laser microscope during and after the testing.

III. RESULTS AND DISCUSSION

Results from mechanical tests provided information on strength, stiffness and elastic properties of the polymer films and the balloon material. Fig 1 shows the stress-strain curves from the preliminary ring tests (Left) and strain vs pressure response from the bulge simulation (Right) of the balloon material. With FEM it was possible to reproduce the mechanical behaviour of the balloon materials and compare it with the hyper elastic theoretical models. The morphology of the balloon and the polymer films with and without coating matrix were recorded under laser microscope as in Fig 2. The thickness of the balloon ranged between 43µm and 63µm, whereas the thickness of the polymer films ranged between 60µm and 120µm. The polymer films were opaque while the balloon material was transparent to the monochromatic laser light at 406 nm. Change in surface roughness was also observed which maybe one of the influential parameters for change in mechanical properties. This observation along with further analysis helps in understanding the fragmentation of the coating and its release pattern

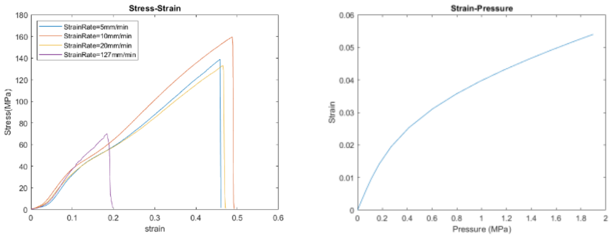

Figure 1: Circumferential stress-strain curves (Left), Pressure-Deflection analysis (Right)

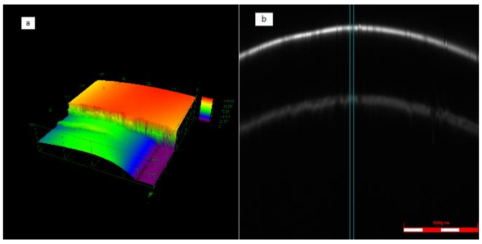

Figure 2: Surface charcterization of the balloon material under confocal laser microscope

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