Topology analysis of polymer tube sections using micro-computed tomography images

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Abstract

Coronary artery disease (CAD) is a significant cause of mortality in developed countries. Heavily resistant lesions remain a challenge in interventional cardiology. To exert high forces to the vessel wall, the rated burst pressure (RBP) of the device must be high. The catheter shaft topology play a major role in the pressure resistance of the product. Hence, the topology must be quantified to control and optimise the pressure resistance. It is hypothesized that the shaft topology of a percutaneous transluminal coronary angioplasty (PTCA) catheter can be quantified by using micro-computed tomography (μCT) images. An image processing algorithm is proposed to evaluate: (1) the homogeneity of the tube topology, (2) deviations from the specifications, and (3) differences between plain and necked tubes. The evaluation showed statistically significant differences. Although, the algorithm is not optimised towards computations effectiveness, it is concluded that the algorithm is capable of quantifying the catheter shafts topology accurately enough to assess the shape of the tube, measure real deficiencies to the specification limits, and to evaluate different tube morphologies.

1 Introduction

Coronary artery disease (CAD) is prevalent in the worldwide elderly population. In the United States, 15.5 million people (year 2016) have coronary artery diseases [1]. However, the mortality due to CAD has gradually declined over the last few decades. Among other reasons, the reduction is caused by the timely percutaneous coronary intervention (PCI) with balloon catheters [2]. Heavily resistant coronary lesions remain a challenge in interventional cardiology [2]. The inability to fully dilate a lesion can lead to adverse effects, e.g. restenosis [3]. For a successful dilatation of a resistant lesion, a high force must be applied to the vessel wall [3]. To exert high forces, the rated burst pressure (RBP) of the device must be high [2, 3]. The cardiovascular system consists of very thin structures [4]. Therefore, the crossing profile of the balloon catheter must be as small as possible. The smaller the crossing profile, the better peripheral coronary arteries can be reached. Designing a balloon catheter with a high RBP, within the size limitations, e.g. small crossing profile, is challenging. It is crucial to understand topology of the thin polymer materials of a percutaneous transluminal coronary angioplasty (PTCA) catheter to overcome the challenges [5]. The catheter shaft is a polymer tube, that is beside the balloon especially crucial for a high RBP [6]. A rupture of the catheter shaft may lead to the inability to deflate the ballon [7].

The standard procedure to quantify the topology of polymer tubes is to measure the inner- and outer diameter. The outer diameter is measured with a micrometer or a two-axis laser. The inner diameter is measured with precision mandrels. The current practice can only be applied on a short endsection of the tube. Positions in the middle of the tube cannot be measured, making it difficult to quantify the topology along the tube. The topology may be assessed by a laser-ultrasonic method, which measures the wall thickness along a seamless tube at one angle of that tube [8]. The method is restricted to tubes with wall thicknesses of about 30 mm and high tolerances [9]. Medical images, e.g. computed tomography are used in the medical field to measure airways wall thicknesses [10]. Micro-computed tomography (μCT) may be used to measure the topology of polymer tubes used in PTCA catheters as well.

The aim of this work is to quantitatively analyse the topology of polymer tube sections based on the outer- and inner diameter along the catheter shaft tube axis. We hypothesize that the shaft topology of a PTCA catheter can be quantified accurately by using μCT images. High resolution μCT images from catheter shaft tubes are theoretically sufficient to analyse their topology. Noise present in the raw images and the image processing algorithm itself, e.g. deviation of edge detection, may introduce some inaccuracies. However, to control the accuracy of the image processing algorithm an own algorithm is proposed, to evaluate the tube topology.

In this report we present an image processing approach to quantify the topology of a PTCA catheter shaft. μCT images of a polymer tube are the basis for this analysis. In the remainder of the report the topology of two tube samples, plain and necked, are analysed. The deviation to the specification limits for both data sets is investigated. Based on the results of the algorithm, the capabilities to analyse the tubes are evaluated.

2 Material and Methods

Images were acquired with a μCT System (Skyscan1172, Hamamatsu, Japan). The inner- and inter image resolution is 1.66 µm. The two tubes samples are made out of Grilamid L 25 and have specified outer- and inner diameters as shown in table 1. One of the samples is a plain tube, that is as received by the supplier. The other sample underwent a necking process, which enhances some of the material properties, e.g. yield stress, stress at break, and E-modulus. Each data set consists of 2452 images.

In figure 1, a block diagram of the proposed image processing algorithm is depicted. The algorithm consists of the following sequence: (I) To reduce noise in the image it was filtered with a gaussian filter ($\sigma_G = 2.5$), and (II) cropped to the region of interest (ROI). To find the edges of the outer diameter

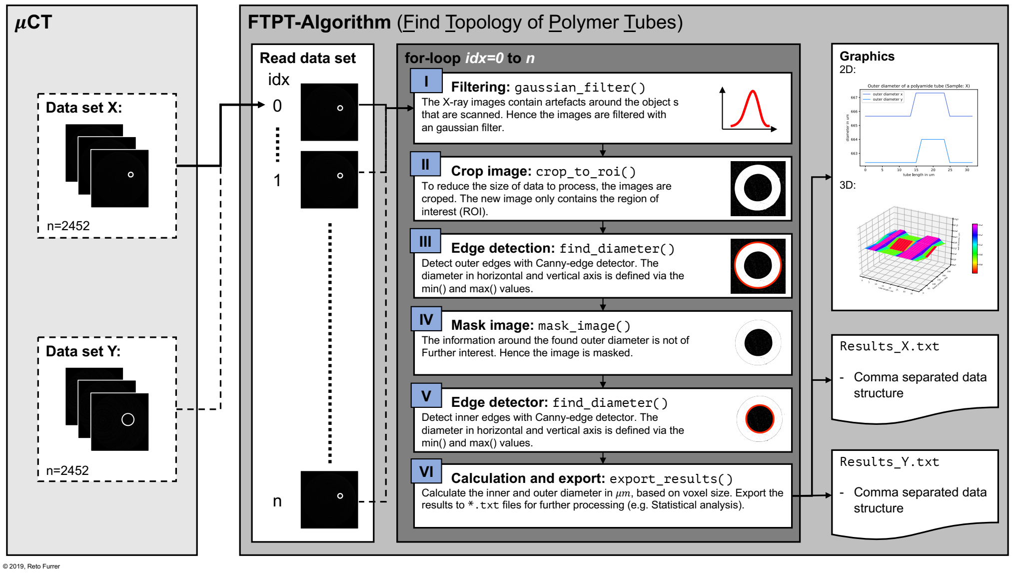

Figure 1: Overview of the proposed algorithm to analyse the topology of polymer tubes.

(III) a Canny-edge detection ($\sigma = 2.5$) was applied. After successful detection of the outer diameter, the information outside the border is removed (IV) by a masking of the image. The procedures (III to IV) was repeated to find the inner diameter (V). Finally, the results of the above are transformed into SI-units (VI), i.e. μm. To evaluate the topology of the tube, the homogeneity of the diameters, the deviation from the specification limits and the difference between plain and necked tubes were analysed.

Homogeneity of the topology: The homogeneity is defined as the differences of the diameters on two perpendicular axes, i.e. the horizontal and vertical axis of the image. If the difference deviated from zero, we assumed that the algorithm found an ellipse. An ellipse with a center point (x_0,y_0) and the major axis (a) and minor axis (b) is defined with equation 1.

$$\frac{(x - x_0)^2}{a^2} + \frac{(y - y_0)^2}{b^2} = 1 \tag{1}$$

If the difference is zero ($a = b$) the algorithm detected a circle. For each image it was analysed, whether the inner- and outer diameter in horizontal direction of the image differed from the diameters in vertical direction.

Deviation from tube specifications: For each image the detected inner- and outer diameters were averaged, i.e. the average from the horizontal and vertical diameter was calculated. The average diameters were compared to the specification limits of the inner- and outer diameter of the tube as defined in table 1.

Topology differences between plain and necked tubes: The detected mean diameters and the mean wall thickness of each image were analysed. The detected measures of the plain tube sample were compared to the measures of the necked tube.

Statistical analysis: Descriptive statistics of the homogeneity of the diameter in the horizontal and the vertical direction, the difference of the detected diameters to the specification limits, and the differences between the plain and necked tube topology are calculated. The Wilcoxon-sign rank test was applied to analyse the differences. All analyses were performed using the software `R` (R Foundation for Statistical Computing, Austria), and significance levels were set at $p = 0.05$.

3 Results

The two analysed data sets consisted of a consecutive series of images which allowed a reconstruction of the topology of the surfaces along the tube. The results are set out in table 1.

Table 1: Specification limits and results of the topology analysis. The significance level for the Wilcoxon signed-rank test was defined as $p = 0.05$. The interquartil range (IQR) is the difference between 1st Qu. and 3rd. Qu.

	Wilcoxon-sign rank test						
Variable	**Median**	**1st Qu.**	**3rd Qu.**	**Min.**	**Max.**	**p-value**	**Spec. Limit**
Images of plain tube ($n = 2'452$)							
Horizontal outer diameter (μm)	669.0	667.7	669.0	665.7	1507.3	< 0.001	645 ± 25.4
Vertical outer diameter (μm)	664.0	664.0	665.7	662.3	745.3		
Mean outer diameter (μm)	666.5	665.7	667.3	664.0	1115.5	< 0.001	
Horizontal inner diameter (μm)	403.4	403.4	403.4	401.7	1354.6	< 0.001	394 ± 12.7
Vertical inner diameter (μm)	396.7	396.7	398.4	395.1	690.6		
Mean inner diameter (μm)	400.1	400.1	400.9	398.4	1019.2	< 0.001	
Wall thickness (μm)	133.2	132.8	133.2	19.9	139.4	< 0.001	251 ± 28.4
Images of necked tube ($n = 2'452$)							
Horizontal outer diameter (μm)	776.9	770.2	803.4	766.9	815.1	< 0.001	750 ± 25.4
Vertical outer diameter (μm)	766.9	737.0	776.9	722.1	776.9		
Mean outer diameter (μm)	771.9	770.2	771.9	766.9	775.2	< 0.001	
Horizontal inner diameter (μm)	654.0	647.4	683.9	644.1	723.8	< 0.001	650 ± 12.7
Vertical inner diameter (μm)	645.7	630.8	652.4	599.3	654.0		
Mean inner diameter (μm)	649.1.	649.1	650.7	645.7	650.6	< 0.001	
Wall thickness (μm)	60.9.	60.2	61.0	44.4	63.5	< 0.001	100 ± 28.4

Homogeneity of the topology The difference between the found diameters in horizontal- and vertical direction was analysed for both samples. In the plain tube sample the outer diameter in horizontal direction ($Mdn = 669.0\mu m$, $IQR = 1.7$) is significantly different ($p < 0.001$) from the diameter in vertical direction ($Mdn = 664.0\mu m$, $IQR = 1.7$). Equally for the necked tube sample, where the outer diameter in horizontal direction ($Mdn = 776.9\mu m$, $IQR = 33.2$) is significantly different ($p < 0.001$) from the diameter in vertical direction ($Mdn = 766.9\mu m$, $IQR = 39.9$).

Deviation from tube specifications The specification limits from table 1 are used for a one-sample U-test. The median outer diameter of the necked tube ($Mdn = 771.9\mu m$, $IQR = 1.7$) varies significantly ($p < 0.001$) from the specification limit. The detected median diameter ($Mdn = 649.1\mu m$, $IQR = 1.6$) of the inner lumen differs significantly ($p > 0.001$) from the specification limit. For the plain tube sample the detected median outer diameter ($Mdn = 666.5\mu m$, $IQR = 1.6$) differs significantly ($p < 0.001$) from the specification limit. The median diameter of the inner lumen ($Mdn = 400.1\mu m$, $IQR = 0.8$) is significantly different form the specification limit. The calculated wall thickness of the plain tube

($Mdn = 133.2\mu m$, $IQR = 0.4$) is compared to the specification ($251 \pm 28.4\mu m$). The difference is statistically significant ($p < 0.001$). The wall thickness of the necked tube ($Mdn = 60.9\mu m$, $IQR = 0.8$) also differs significantly ($p < 0.001$) from the specification of $100 \pm 28.4\mu m$.

Topology differences between plain and necked tubes The topology differences between plain and necked tubes are analysed based on the mean outer- and inner diameter. The outer diameters ($Mdn = 666.5\mu m$, $IQR = 1.6$ and $Mdn = 771.9\mu m$, $IQR = 1.7$) differs significantly ($p < 0.001$) from each other. The diameters of the inner lumen ($Mdn = 400.1\mu m$, $IQR = 0.8$ and $Mdn = 649.9\mu m$, $IQR = 1.6$) are also statistically significantly different ($p < 0.001$) between plain and necked samples.

4 Discussion

In this work, an algorithm to quantitatively analyse the topology along the catheter shaft tube axis has been presented. The empiric study on two samples, consisting of 2'452 images each, demonstrated that the algorithm is able to measure the outer- and inner diameter of the polymer tube samples. Unlike the standard procedures [8, 9], which are unable to quantitatively analyse the whole cross section along the tube, the proposed algorithm was able to detect differences of diameters in various directions of the tube, and reveal major changes in wall thickness along the tube. The algorithm was also able to show statistically significant deviations from the specified limits. The differences might indicate that it would not have been possible to reach the RBP of the PTCA-catheter with this particular shaft tubes or that the catheter shaft could have even smaller wall thicknesses, if it is properly controlled, while fulfilling the requirements of a high RBP.

Although the results of the μCT image analysis algorithm show that it is possible to quantify the shaft topology of a PTCA catheter accurately enough to evaluate differences of diameters and wall thicknesses, the implementation is not optimised towards computational efficiency. The image resolution is important and the acquisition of images with a high resolution is time consuming. The presented algorithm lays the foundation for future optimisations towards computation performant implementations. Furthermore, additional degrees of freedom, i.e. not only circles and ellipses, might be used to quantitatively evaluate PTCA catheter shafts. Finally, we conclude that the presented algorithm can be used to evaluate the topology of PTCA catheter tube sections. However, the image acquisition in μCT and the image processing takes a considerable amount of time. Hence, the algorithm should be used only where all other methods do not deliver enough insights.

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