FLEXIBILITY OF DIAGNOSTIC CATHETERS

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Summary: *The diagnostic catheter is an intravascular catheter, which is usually used to inject the contrast media and/or fluids to the body. The cardiovascular system contains tight angulations in the tortuous vessels which can cause device failure. In this study the flexibility of one diagnostic catheter was investigated according to the Food and Drug Administration's recommendation. The catheter was bended around 16 gauges with different radius. The radius decreased from 10 mm to 2.5 mm in 0.5 increments. 9 bending points were selected on the diagnostic catheter: from 120 mm to 280 mm with 20 mm increments. The catheter was measured on all bending points. We concluded that between the diameter decrease and the deflection there is a linear dependency and they are independent from the placement of the measurement point (so from the distance measured from the tip).*

Keywords: *diagnostic catheter, flexibility, susceptibility to bend*

1 Introduction

Intravascular catheters are either single or multilumen tubular devices which are introduced partially or implanted completely to the cardiovascular system for diagnostic or therapeutic reason. One of the species of these catheters is called diagnostic (or also known as angiographic catheter) which is used for introducing the contrast media and/or fluid but can also be used for measuring pressure, taking blood sample, cross-sectional imaging of the lumen arteries wall or evaluation of different properties of the artery wall and/or the atherosclerotic plack [1, 2, 3, 4, 5].

During their usage in the tortuous vessel they go through narrow segments and this can cause the failure of the devices [6]. Between 1983 and 2012 fifteen diagnostic catheters' failure was published. These failures were fracture, kinking and knotting [7].

For the testing of the flexibility and kinking of the catheters the Food and Drug Administration (FDA) suggested to do such an analysis by which it is possible to prove that through an anatomically relevant radius the catheter does not kink. One way for this can be that we bend the catheter onto gauges with smaller and smaller radius till the catheter kinks or the lumen collapses [6]. This method is published by Macha D.B. et al. [8] and by a Premarket Notification (510k) [9].

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In the Premarket Notification (510k) diagnostic analysis of catheters' bending and kinking were reported, 10, 40, 120 and 250 mm from the distal tip (it introduced to the patient [1]) [9] while Macha D.B. et al. made the test on three analysis point [8]. However, the flexibility of the catheter might change along itself [10].

Our aim was to determine the flexibility of the diagnostic catheter and study how the flexibility changes along the catheters by a testing method recommended by FDA. In our study we present the first step of this measurement series where a diagnostic catheter was analyzed. We determined the bending points, the diameter decrease and the deflection on the bending points, finally theirs dependence on the distance from the tip, and theirs correlation.

2   Materials and methods

Measurements were done on a FR6-type diagnostic catheter with an initial diameter of 1.67 mm (Fig. 1). The bending points were placed 120-280 mm from the distal peak, with spaces of 20 mm; thus on one catheter there were 9 bending points placed. Bending points were choosen this way not that the distal end (it can have several types of shape for the catheters) has an influence on the measurements.
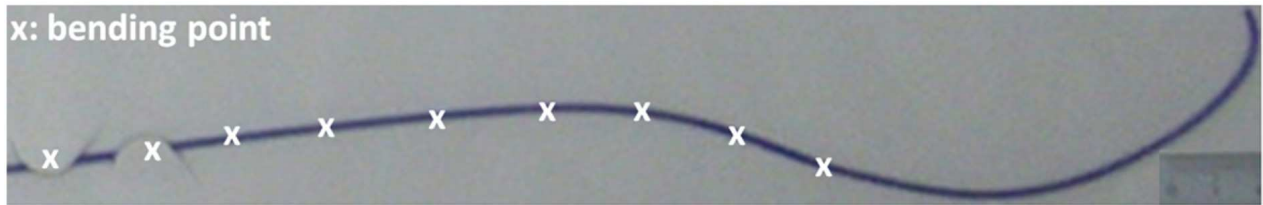

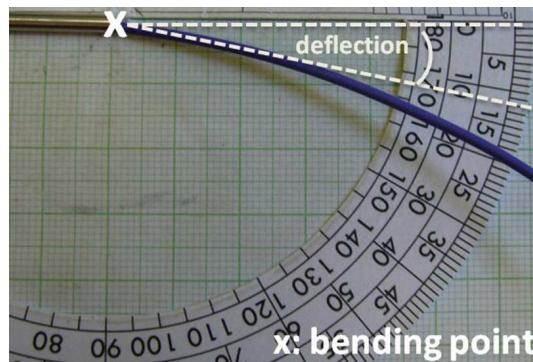Figure 1: The analysed section of the catheter
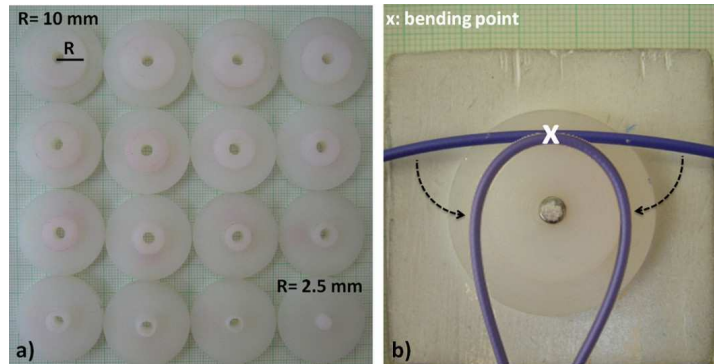

Figure 2: Measure of deflection   Figure 3: a) The gauges and b) the bending process

First the diameter and the deflection of the diagnostic catheter was measured at the bending point which was at the closest part to the tip (120 mm from it). These values were considered as references. For the measurement of the diameter micrometer (Mitutoyo®) and caliper (Workzone®) were used. The deflection was measured by goniometer as shown on Figure 2. The bending was carried out with gauges (Fig. 3a). 16 gauges were applied for the tests from which the greatest radius was 10 mm, the smallest 2.5 mm and their radius decreased from the greatest to the smallest by 0.5 mm.

After assigning the reference values the bending point was placed onto the gauge and the catheter was bended onto the gauge with the greater diameter (Fig. 3b), then it was held in the same state during 5 seconds.

The bending was helped by hand making sure that the catheter is still in contact with the rim of the gauge, lie on it. This process required increasing force because of the radius decreasing, but it was not measured in this study; it did not address the recommendation of the FDA. In this case only the behaviour of the diagnostic catheter was investigated. After 5 seconds the catheter were released and its diameter and deflection were measured on the bending point. The bending was carried out for all gauges (from the greatest to the smallest diameter) measuring everywhere the diameter and the stoop after the bending. The bending was carried out for all bending point gradually away from the tip.

From the measured values the diameter decrease (mm and %) and the deflection (degree) were determined caused by the gauge with the given diameter. For the evaluation of the results statistic methods were applied (average, deviation, correlation).

3 Results and Discussions

The catheter's diameter decreased at each bending point while its leaning increased by the decrease of the bending radius. In Fig. 4 the diameter decrease can be seen dependently on the bending radius from 120, 160, 200, 240, and 280 mm from the tip. In Fig. 5 at the same points the caused bending can be seen dependently on the bending radius. The curves follow each other randomly, independently from the distance measured from the tip. Thus it can be concluded that the diameter decrease and the deflection are both independent from the distance measured from the peak.
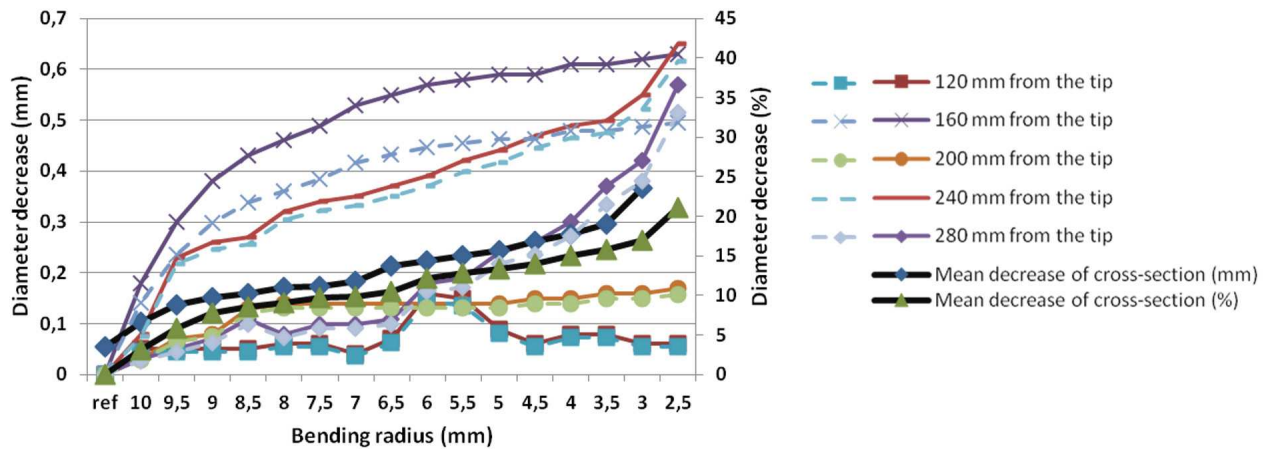

Figure 4: The diameter decrease at the given radius

Due to the independent of distance the values of the 9 bending points were averaged, and their relationship were investigated. The average deflection changed linearly depending on the bending radius (Fig. 5), furthermore linear correlation was between the average diameter decrease and the average deflection (Fig. 6).

4 Conclusions

By the flexibility measurement method recommended by the FDA it the present work it has been concluded that the flexibility of the catheter at the section of 120-280 mm of the catheter (where the values express the distance measured from the tip) was independent from the distance, furthermore linear correlation can be observed between the diameter decrease and the deflection; they were dependent from each other.

In the near future examination will be carried out on further samples for giving more detailed results.
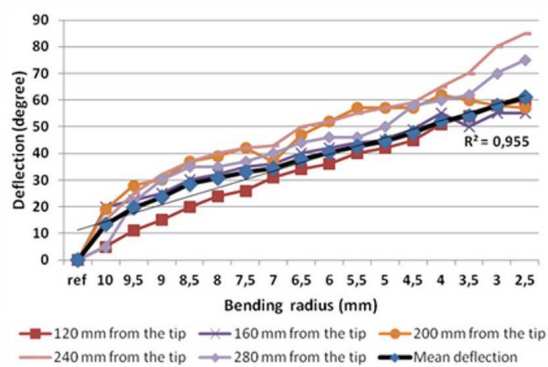
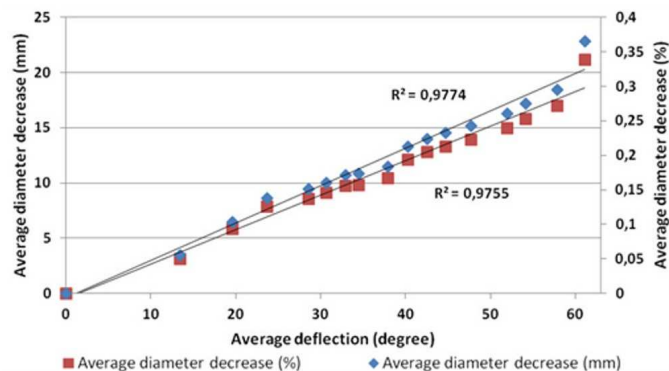Figure 5: The caused deflection at the given radius

Figure 6: Correlation between the average diameter decrease and the deflection

5 Acknowledgment

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