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Design and implementation of a medical device test stand for micro-catheters and guide-wires

Abstract: The use of catheters and guide-wires in minimally invasive therapeutic approaches is an important part of clinical practice. In the neurovascular field, the unique nature of cerebral blood vessels necessitates very thin-walled and flexible catheters. The blood vessels in question are highly branched and at the same time can be less than one millimetre in diameter. This results in high demands on micro-catheters and guide-wires for successful endovascular therapy. The interaction of these surgical tools and the vessel wall is of especial interest. Depending on the catheter stiffness, this interaction can be friction, punctual collision or straightening. The work aims to design and implement a test setup for evaluation of these interactions with the vessel wall. For this purpose, a standardized vessel course with representative characteristics is necessary. Furthermore, by implementing suitable measuring equipment, an endovascular intervention can be simulated.

Keywords: Test setup, catheter, guide-wire, straightening, force

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1 Introduction

When using the catheter or guide-wire, collisions and friction with the inner walls of the cardiovascular arteries and veins during feed are unavoidable. This may result in injuries to the blood vessel. In medicine, such damages or leaks are

called perforations. These can lead to blood loss or hematomas [1] or serious intracranial bleeding.

In principle, two types of injuries occur during such a minimally invasive procedure. First if the catheter or guide-wire tip (distal end) is too rigid, the vessel can be punctured. Second if the catheter shaft or guide-wire shaft is rigid, vessels can be injured during insertion by straightening the vessel and wall detaching from the surrounding tissue. For this reason, various catheter shapes and constructions are available depending on the use case and to meet anatomical requirements. In order to compare the tool-wall interaction for different catheters and guide-wires directly, this article describes a test setup that enables the recording of the deformation of a standardized curved vascular model.

2 Methods

Based on the analysis of tool-wall interactions in actual patients a dedicated test setup was designed.

Figure 1: Test setup

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Figure 1 shows the experimental setup. The arterial course was mimicked by a PEBAX tube with an inner lumen diameter of 3mm and an outer diameter of 4mm. The PEBAX tubing was attached to a pegboard prepared with graph paper as a back-ground. This allowed displacements to be clearly detected visually. The PEBAX tube was fixated in three defined curves, with radii of 35mm each, with the help of springs. The structure and the course of the curves were based on common standards and guidelines (ISO 10555, DIN EN 13868:2002-11, DIN EN ISO 11070:2019-04, ASTM F2394-07). For example, the determination of the curve radius was based on ASTM F2394-07 "Standard Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System" [2].

The springs have a stiffness of $k=0.16$ N/mm. During the feed of a tool, the curved path gets deformed. These displacement can be recorded with a camera fixated above the setup. The graph paper in the background allows the measurements of deformation in millimetres and, in combination with the springs, the tube material and the dimensions of interaction forces.

Several test runs are performed with a guide-wire (Terumo Guide Wire M 0.035"). First, the force required to push the guide-wire through the defined arterial course is determined. Second, the displacement is recorded. For insertion force recording, the proximal end of the guide-wire was firmly connected to the force gauge. The force gauge (Sauter FC 10 digital tensile force gauge) has a measuring range of up to 10 N and readability of 0.01 N. For each curve, the contact surface between guide-wire and inner wall ascends requires an increased force for further feed, which was read in the maximum range.

3 Results

Ten tests were performed using the presented test setup. The guide-wire (Terumo Guide Wire M 0.035") was inserted into the PEBAX tube and advanced as uniformly as possible. In each case, at the curve exits, of the three curve radii (see Figure 2), an increased force was recorded on the force gauge. These values were listed in Table 1.

In Figure 2, two image sections of two video sequences were superimposed. On the one hand, an image section without inserted guide-wire and on the other hand with inserted guide-wire. For a better comparison, points at the apex of the curve were marked and compared.

Figure 2: Point of force absorption, displacement in mm

Table 1: Spring deformation force

	FG1 [N]	FG2 [N]	FG3 [N]
Test 1	0,55	1,11	1,13
Test 2	0,5	1,01	1,05
Test 3	0,6	1,16	0,98
Test 4	0,64	1,08	1,02
Test 5	0,59	1,11	1,03
Test 6	0,61	1,21	1,02
Test 7	0,6	1,21	1,03
Test 8	0,62	1,32	1,13
Test 9	0,63	1,17	1,11
Test 10	0,63	1,2	1,07
ø	0,6	1,16	1,06

Due to the stiffness of the guide-wire, the course of the tube was straightened. To counteract the straightening, the three springs (spring stiffness: 0.16 N/mm) were attached at the apex of each curve. Table 2 shows the displacement of the PEBAX tube due to the guide-wire.

Table 2: displacement

	$\Delta mm1$	$\Delta mm2$	$\Delta mm3$
Test 1	2,5	3,5	2,5
Test 2	1,0	4,5	2,5
Test 3	2,2	3,0	2,8
Test 4	2,2	3,3	2,5
Test 5	2,1	2,6	2,5
Test 6	2,2	3,0	2,8
Test 7	1,9	3,4	2,3
Test 8	1,9	3,4	2,6
Test 9	2,0	3,1	2,6
Test 10	1,9	3,1	2,6
σ	2,0	3,3	2,6

4 Discussion

The ability of the guide-wire or micro-catheter to be guided through blood vessels depends on different factors. Various tool-vessel wall interactions act during advancement, which in total result in the advancement force F_G . When a guide-wire or micro-catheter tip collides with a vessel wall, a point contact occurs, referred below as the contact force F_K . In addition, frictional forces F_R arise when there is contact between the outer wall of the catheter or guide-wire and the inner wall of

the blood vessel. Both act in the opposite direction to the feed force F_G . This friction is highly depended on vascular curvature and the stiffnesses of the tool and vessel path.

According to Yin et al. [3], in addition to the forces mentioned, a viscous friction force F_{VZ} acts in the opposite direction or in the direction of the feed, depending on the direction of blood flow. Since the flow velocity of the blood, (about 200 to 300 mm/s) is significantly higher than the advancing velocity of the catheter (about 2 mm/s), the advancing force decreases or increases. However, this force can be classified as low in qualitative terms compared to the frictional force F_R between the catheter or guide-wire and the inner vessel wall. The acting forces are illustrated in figure 3.

$$F_G = F_K + F_R \pm F_{VZ} \quad (1)$$

Figure 3: Forces acting during cutter feed: a: viscous tensile force, b: frictional force, c: collision force [3]

The publication by Guo et al. also deals with the quantitative recording of force variables. A robot was developed that can automatically take over the work of the person treating the patient and can control the feed force and angle. A fiber-optic force sensor was used to measure the contact force. The range of values for the contact force was [0; 0.04 N] during an experimental procedure. The average feed force was 1.5 N [4].

According to Zakaria et al. who developed a mechatronic catheter navigation system, the critical value of the contact force is 0.12 N [5]. In their automated catheter navigation, a direct collision between the catheter and the inner vessel wall is assumed when this force is reached. The catheter is considered to be "stalled". No further advance in the selected direction is performed. In this case, the catheter advance is then aborted, the catheter is rotated (change of inclination angle) and thus the direction of advance is changed.

Lubricant in the blood vessel influences the guidance of the catheter or guide-wire significantly. The frictional forces that arise at the inner walls are assumed, to be very low. According to a study by Takashima et al, the friction

coefficient between the catheter and the inner vessel wall at an angle of $<75^\circ$ is <0.017 [6]. From this, it can be assumed that a low advancement force is generally required for minimally invasive therapy.

In the tests carried out, the recorded feed force peaks (see Table 1) were on average $F_{G1}=0.6$ N, $F_{G2}=1.16$ N and $F_{G3}=1.06$ N at the first, second and third curve, respectively. At the respective curves, the guide-wire had to change the direction, thus causing an increased force to be applied to the feed. The force values recorded correspond to the data from the literature sources listed above.

The guide-wire used for the test series (Terumo Guide Wire M 0.035") straightens the course of the artificial artery during the advance. Depending on the stiffness of the guide-wire, the displacement is larger or smaller. The three curve radii are also connected by means of three identical spiral springs (spring stiffness 0.16N/mm). This experimental setup is intended to simulate the integration of the arteries in the tissue.

In the test series, the displacement is on average 2.0 mm, 3.3 mm and 2.6 mm in curve 1, 2 and 3 respectively (see Table 2). Considering the spring stiffness, the contact force is between 0.32 N and 0.53 N. Compared to the study of Zakaria et al., the recorded values are slightly increased. For a further experimental setup, the test series should be carried out in a water bath or with less stiffer springs.

5 Conclusion

In this paper, a test rig was developed to characterize the mechanical interaction of vessel walls and guide-wires or micro-catheters. A guide-wire was pushed through the test stand in ten test series. The experiment aimed to determine and

quantify a contact force on the vascular phantom and the resulting effect (displacement). When the guide-wire is advanced and collides with a direct phantom wall, forces of up to a maximum of 1.16 Newtons are generated on the blood vessel based on the measurement results. This result applies analogously to an actual invasive therapy where a guide-wire or catheter is inserted into the human blood vessel. The next step was to quantify the contact force. In the interaction between artificial artery material (PEBAX), spring selection and experimental conditions without fluid, forces of 0.32 N to 0.53 N were recorded. Compared to the literature, these values are slightly increased and can be optimized in the following experimental setups by adjusting the parameters.

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