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FLEXIBILITY OF GUIDEWIRES

Abstract: The guidewire is a flexible medical device, which subserves the navigation and positioning of devices for angiography and angioplasty. In our study we present a method for the determination of guidewires' bending stiffness and flexibility (reciprocal of the bending stiffness) improved by our research group. With this method the flexibility can be detachedly defined, it is quantitative and by this new technique different guidewires can be compared. We characterized the bending stiffness, which value does not change at the first 15 mm of the guidewires' distal end (this part is inserted into the patient). The deflection of guidewires was performed by a tensile test machine. We examined three guidewires. As for the reliability of our method, we drew conclusions from the coefficients of variation. Our three coefficients were between 0.8-0.13 so our methodology is reliable; it is suitable for the objective determination and comparative analysis of the flexibility of guidewires.

1. Introduction

The guidewire is a relevant part of the intervention. It is a flexible device, onto which the catheter or the dilator is lead, helping their introduction and emplacement into the blood vessels. The guidewire reaches and traverses the stenosis, and delivers the intervention devices to the desired location [1, 2]. The distal end enters the patient; the proximal end stays outside. The end of the distal part is the so-called tip [1].

The intervention occurs through the femoral artery, or as an alternative through the radial artery, the brachial artery or travelling through the axillary artery. The guidewire has to go traverse a tortuous vessel part till the stenosis [3, 4]. During this way several problems might appear, e.g. difficult removal, breakage of the wire(s), device or device fragments can remain, tip breakage can occur and the positioning can also be difficult [5]. The origin of these problems can be the flexibility, stiffness and kinking resistance. The distal end of the guidewire reaches the stenosis traversing the tortuous vessels, this is why this part has to be resistant against kinking, bending and knocking [6-8].

In our previous work we determined the kinking resistance of guidewires [9]; this time we present a measuring technique for the flexibility analysis of guidewires. We used the experiences from our earlier experiments on flexibility analysis of stents [10].

The equipment for flexibility analysis applied in the standards can be seen in Fig. 1a. After the tests there should be no defects or damage visible either at the distal end, or at the other parts of the guidewire, furthermore in case of coated guidewires, flaking should not be occurred on the coating [1]. If we want to compare flexibility, it is necessary to have an objective measurement technique but this analysis gives a subjective result.

Based on the FDA Guidance the tip flexibility can be described with the force which is needed for the deflection of 45° and 90° of the tip, 5, 10, 20 mm from the tip [11]. J. Schröder applied a similar method for the determination of the stiffness of the guidewire. He examined the deflection force for the 45° with spring balance, 50 mm from the fixation (Fig. 1b) [12]. The disadvantage of these two methods is that the force necessary for the deflection changes along the guidewire.

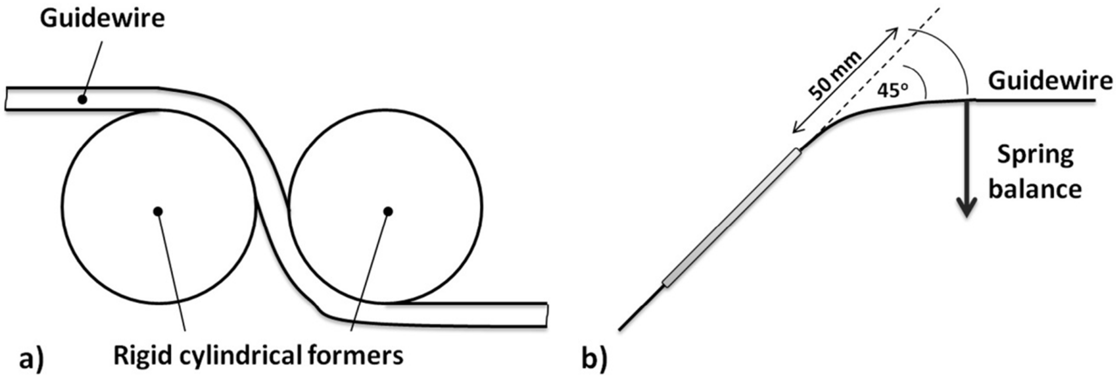

Fig. 1. a) Flexibility analysis based on the ISO 11070 standards [1] and b) stiffness analysis on behalf of J. Schröder [12]

It can be seen that the standard for the determination of the flexibility of the guidewire does not contain an objective measuring method which is independent from the measuring distance between the tip and the grip. To compensate this lack we created our measurement technique in which we defined the bending stiffness of the distal end of the guidewire. This value is independent from the distance from the tip on the first 20 mm of the distal end. We described the flexibility of the guidewire with this value. In our measurement technique we applied the FDA Guidance and J. Schröders' method for the easy and practical implementation.

2. Our bending stiffness measurement method

The principle of the method can be seen in the Figure 2a. We gripped the guidewire into the lower jaw of the tensile-testing machine, then approaching the upper jaw to the lower one with constant speed we buckled the guidewire with the polymer sheet gripped into the upper jaw. The bending speed was adjusted to 10 mm/min. The distance (L) between the grip and the load point was 5 mm every time. Our measurements were performed by Zwick 5000 universal tensile test machine.

From the standard force – deflection pairs we defined the bending stiffness (IE) with the undermentioned formula:

$$IE = \frac{FL^3}{3f}\,[Nmm^2] \tag{1}$$

, where ‘F’ is the standard force, ‘L’ is the distance between the grip and the load point and ‘f’ is the rate of the deflection.

For all measurements three standard force – deflection pairs were chosen from the standard force-deflection curve’s rising part which is appears as linear part of it (Fig. 2b). The determined average of the bending stiffness is the bending stiffness for the given gripping point.

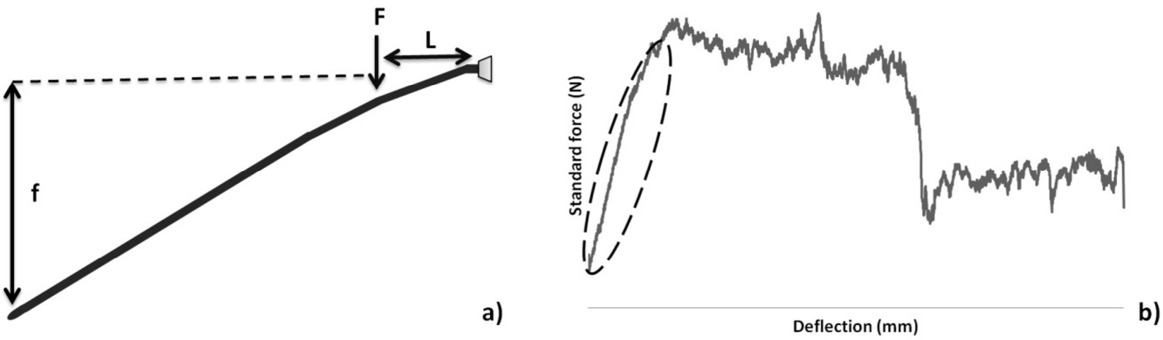

Fig. 2. a) Schematic figure of the bending stiffness analysis (F: Standard force (N), L: distance between the grip and the load point (mm), f: rate of the deflection (mm)) b) Standard force-deflection curve, at the rising, linear part (dashed lines)

The measurement was carried out on three guidewires. The stereomicroscope pictures of the distal end of the examined guidewires can be seen in Figure 4. The ability for support of the guidewire marked with 1 is moderate based on the manufacturer’s description, however the ability for support is light for the guidewires marked with 2 and 3. The distal end of the guidewires marked with 1 and 2 is straight, but the distal end of the guidewire marked with 3 was J Tip (Fig. 4).

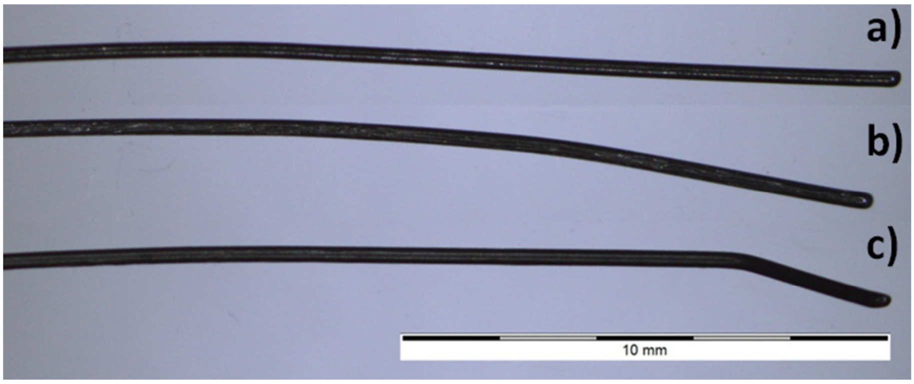

Fig. 4. The first 20 mm of the distal ends of the examined guidewires, stereomicroscopic photo a) straight, moderate guidewire b) straight, light guidewire c) J Tip, light guidewire

For the straight guidewires with distal end (samples nr. 1-2) we adjusted the distance for 5 mm between the grip and the tip. For the J Tip guidewire with distal end the measured a distance of 5 and 10 mm was determined from the start of the fracture of the J, so the distance altered to 8.3 and 13.3 between the grip and the tip.

For all three guidewires we determined the standard force – deflection curve and from that we determined the bending stiffness for both of their grip. We calculated the coefficient of variation (CV) based on the average and deviation values of the bending stiffness of guidewires.

The rate of the coefficient of variation points to the fact that our method is reliable: the smaller the coefficient of variation is, the more reliable our method is. In the literature the acceptable level is not categorized in a standard way but on the basis of the data, smaller values than 0.2 refer to a sufficient reliability.

3. Bending stiffness and the flexibility of the examined guidewires

As for the guidewire marked with 1 the determined standard force-deflection curves can be seen in the Figure 5. The curve, what corresponds to the distance between the grip of 5 mm and the tip, is lighter. As for the distance of 10 mm, is darker.

Table 1 contains the bending stiffness values calculated from the linear part of the curve. It can be seen that the bending stiffness are similar at the two gripping points, so the bending stiffness of the distal end can be well described by their average, which is 0.553±0.043 Nmm^2. Its coefficient of variation is 0.08 (Table 1). The flexibility is 1.817±0.151 $N^{-1}mm^{-2}$.

For the guidewire marked by 2 the standard force – deflection curves can be seen in Figure 6. The average of the bending stiffness for the two gripping points is 0.234±0.024 Nmm^2, the coefficient of variation is 0.1 (Table nr. 1). The flexibility is 4.308±0.224 $N^{-1}mm^{-2}$.

The curves for the guidewire marked by 3 can be seen in Figure 7. The bending stiffness of this guidewire is 0.167±0.022 Nmm^2, the coefficient of variation is 0.13 (Table 1). The flexibility is 6.081±0.462 $N^{-1}mm^{-2}$.

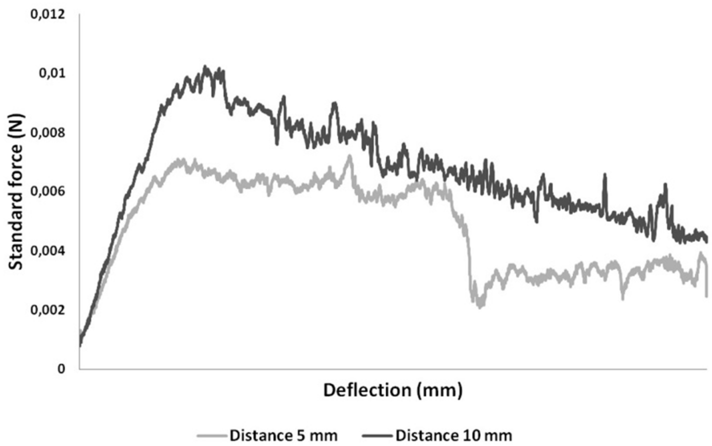

Fig. 5. Standard force – deflection curves of straight, moderate guidewire with distal end at different grip-tip distances

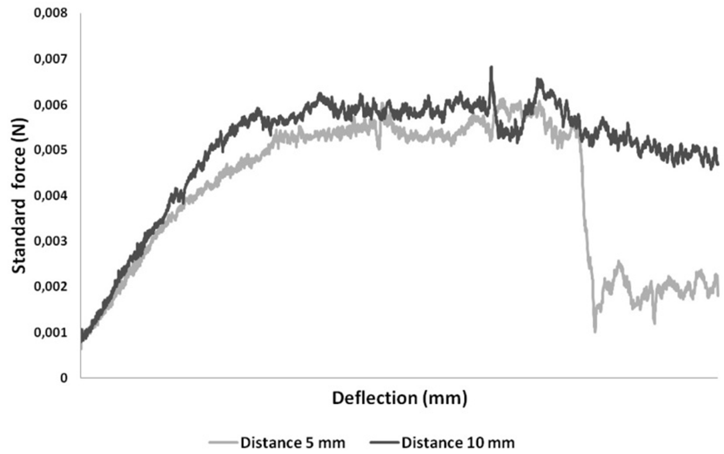

Fig. 6. Standard force – deflection curves of straight, light guidewire with distal end at different grip-tip distances

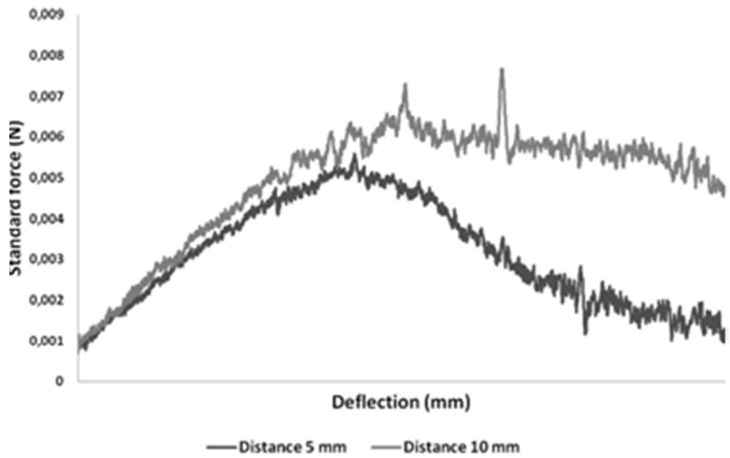

Fig. 7. Standard force – deflection curves of J Tip, light guidewire with distal end at different grip-tip distances

Tab. 1. Bending stiffness values calculated from standard force – deflection pairs

Guidewire	Grip-tip distance (mm)	Strain (mm)	Standard force (N)	IE (Nmm^2)	Average IE (Nmm^2)	Distal end IE (Nmm^2)	Coefficient of variation
Straight Moderate	10	0.284	0.004	0.603	0.586±0.033	0.553±0.043	0.08
		0.352	0.005	0.606			
		0.512	0.007	0.548			
	5	0.235	0.003	0.542	0.520±0.019		
		0.338	0.004	0.513			
		0.387	0.005	0.506			
Straight Light	10	0.488	0.003	0.271	0.243±0.025	0.234±0.024	0.10
		0.765	0.004	0.233			
		0.989	0.005	0.224			
	5	0.444	0.003	0.245	0.226±0.024		
		0.574	0.003	0.233			
		0.891	0.004	0.199			

J Tip Light	~10	0.550	0.003	0.201	0.176±0.023	0.167±0.022	0.13
		0.924	0.004	0.171			
		1.337	0.005	0.155			
	~5	0.470	0.002	0.181	0.158±0.022		
		0.844	0.003	0.156			
		1.415	0.004	0.138			

4. Conclusion

The bending stiffness and flexibility measurement method worked out by us is reliable, since the coefficient of variation is smaller than 0.2 in for all three guidewires.

Our method can be applied for determining the bending stiffness and the flexibility of straight and J Tip guidewires with distal end since the measured values of coefficient of variation is small in both cases.

Among the examined guidewires there were samples with moderate support as well as light support. From our results it can be seen that the stiffness of guidewires with moderate support is bigger (smaller flexibility) than the stiffness of the light support guidewires.

From the results it can be seen that our method is suitable for objective determination of flexibility of guidewires

References

1. ISO, Sterile single-use intravascular catheter introducers, ISO 11070:1998, International Organization for Standardization.
2. Walker C.: Guidewire Selection for Peripheral Vascular Interventions. “Endovascular Today” 2013, Vol. 5, pp. 80 – 83.
3. Morgan R.A., Walser E.: Handbook of Angioplasty and Stenting Procedures, London: Springer-Verlag, 2010.
4. Kern M.J.: The Interventional Cardiac Catheterization Handbook, Philadelphia: Elsevier Health Sciences, 2012.
5. DrugCite 2013, Most common guide wire reports to the FDA. Available from: <http://www.drugcite.com/?q=GUIDE+WIRE&a=&s=> [18 November 2013].
6. ScholarlyBrief: Sinusitis: New Insights for the Healthcare Professional: 2013 Edition, Atlanta: ScholarlyEditions, 2013.
7. Mullins C.E.: Cardiac Catheterization in Congenital Heart Disease: Pediatric and Adult. Chichester: John Wiley & Sons, 2008.
8. Lanzer P.: *Catheter-Based Cardiovascular Interventions.* A *Knowledge-Based Approach.* Berlin: Springer-Verlag, 2012.
9. Pelyhe L., et al.: Kinking resistance of guidewires. “Materials Science Forum” 2013, Vol. 729, pp. 476 – 481.
10. Szabadíts P., et al.: Examination method of uncoated Coronary Stents. “Periodica Polytechnica – Mechanical Engineering” 2010, Vol. 54, pp. 77 – 82.
11. FDA Guidelines: Coronary and Cerebrovascular Guidewire Guidance, January 1995.
12. Schröder J.: The mechanical properties of guidewires: Part I: Stiffness and Torsional Strength. “Cardiovasc Intervent Radiol.” 1993, Vol. 16, pp. 43 – 46.