Original Article

Different mechanical properties in Seldinger guide wires

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Abstract

Background and Aims: Most central venous catheters are placed using Seldinger guide wires. EN ISO 11070 is the guideline for testing guide wire flexing performance and tensile strength, and we can safely assume that guide wires in use meet these requirements. Unfortunately, EN ISO 11070 guidelines do not reflect the clinical requirements and we continue to see mechanical failures and their associated complications.

Material and Methods: This *in vitro* study was performed in an accredited laboratory. With regard to flexing, we: (1) Established the minimum flexing performance needed to meet clinical requirements, (2) developed flexing performance tests which mimic clinical requirement, and (3) evaluated the mechanical properties of various guide wires relative to these requirements. With regard to tensile strength, we used the testing method prescribed in ISO 11070, but did not end the test at 5 Newton (N). We continued until the guide wire was damaged, or we reached maximum tractive force. We then did a wire-to-wire comparison. We examined two basic wire constructions, monofil and core and coil.

Results: Tensile strength: All wires tested, except one, met EN ISO 11070 requirements for 5 N tensile strength. The mean of the wire types tested ranged from 15.06 N to 257.76 N. Flexing performance: None of the wires kinked. The monofil had no evidence of bending. Two core/coil wires displayed minor bending (angle 1.5°). All other wires displayed bending angles between 22.5° and 43.0°.

Conclusion: We recommend that: (1) Clinicians use guide wires with high-end mechanical properties, (2) EN ISO 11070 incorporate our flexing test into their testing method, raise the flexing requirement to kink-proof, (3) and raise the tensile strength requirement to a minimum of 30 N, and (3) all manufacturers and suppliers be required to display mechanical properties of all guide wire, and guide wire kits sold.

Key words: Central venous cannulation, complications, flexing/bending/kinking characteristics, guide wire, mechanical properties, tensile strength

Introduction

Central venous catheter (CVC) insertion is part of daily routine in modern medicine. Of approximately 16 million CVC insertions per year globally, 66% are inserted by Seldinger technique (market data B. Braun: www.cvc-partner.com).[1] The literature is rife with statements about guide wire failings, inappropriate handling, and particularly difficult clinical situations.

The reported complication rate is approximately 5-19% and is related to the experience of the operator and different clinical situations.[2] Known complications related to the guide wire often occur, when force is applied to the wire.[3] Known guide wire associated complications are knotting of the straight part, kinking with an acute angle, separation of the spiral wire and the core wire even with fragmentation of the core wire, fragmentation, and embolization.[4-8]

Given the extent to which the Seldinger technique is used, it is extremely beneficial to understand the root cause of the problems and to search for solutions. In our clinic, we decided to collect all used guide wires over a period of 4 weeks, and examine them for bending and kinking. Of the 330 used in that period, 39 displayed significant bending, and 5 had kinked [Figure 1].

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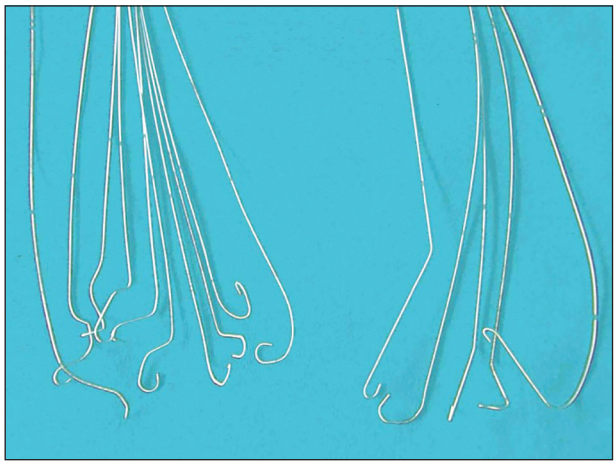

Figure 1: A sample of kinked guide wires

There had also been recent fatalities after perforation of the vessel wall. On an inspection of the guide wires used in these cases, we determined that the wire had kinked under pressure from the dilator. Once the wire kinked, the dilator could not follow the course of the vessel and its forward movement perforated the vessel wall.[9,10]

The failures noted above (in the literature and our clinic) are mechanical failures, yet these guide wires met the requirements of EN ISO 110701, the guideline for testing guide wire flexing performance and tensile strength (www.iso.org). Unfortunately, EN ISO 11070 guidelines do not meet the clinical requirements, and we continue to see mechanical failures and their associated complications. Therefore, we designed equipment and tests to mimic clinical flexing requirements. Because we are unable to measure the actual tensile force exerted in clinical situations, we designed a wire-to-wire comparison of tensile strength. The logic is that all things being equal, the higher the tensile strength, the less likely the wire would fail because of "excess" force — As excess force on one wire may not be excess force on the next.

Material and Methods

We studied seven different types of guide wires usually used for CVC insertions, all with core and wire construction and one monofil wire, Radifocus, usually used in angiography. The Radifocus has a nitinol alloy construction with a polyurethane polyamide elastomeric coating and is known for its extraordinary mechanical properties.

The guide wires tested are shown in Table 1. The Braun NK1 was a prototype, which was never launched.

Table 1: Types of guide wires tested

Type	Diameter (inch/mm)	Length (cm)	Quantity tested for tensile strength	Quantity tested for kinking behaviour[a]
Accoat[b]	0.035/0.89	70	6	Test 1: 6/Test 2: 6
Braun N[b]	0.035/0.89	70	6	Test 1: 6/Test 2: 6
Braun S[b]	0.035/0.89	70	6	Test 1: 6/Test 2: 6
Arrow[b]	0.035/0.89	68	6	Test 1: 6/Test 2: 6
Edwards[b]	0.035/0.89	60	0	Test 1: 6/Test 2: 6
Braun NK1[b]	0.035/0.89	70	6	Test 1: 6/Test 2: 6
Braun NK2[b]	0.035/0.89	50	6	Test 1: 6/Test 2: 6
Radifocus[c]	0.035/0.89	150	6	Test 1: 6/Test 2: 6

[a]Insertion angle Test 1 = 20°, Test 2 = 50°, [b]Core and coil wire, [c]Monofil angiography wire

Definitions

Kinked wire

The coils do not hold their original spacing, which causes the core wire to lose its mechanical integrity. Because of this definition, a monofil can never fall into this category.

Bent wire

The wire does not kink, but it does exhibit a permanent alteration or bend.

Test for tensile strength

Testing for tensile strength was carried out according to the method described by EN ISO 11070 Annex H (1999).[11]

Guide wires with a diameter between 0.750 and 1.150 mm have to withstand a tractive force of 5 Newton (N). One end of the guide wire is secured to a split-tapered clamp, which is attached to the moving crosshead of the tensile splitting apparatus. Pneumatic grips attached to the fixed head should grip the guide wire approximately at its central point and at least 150 mm from the split-tapered clamp [Figure 2]. Then, a tensile force at a rate of 10 mm/min is applied in the direction of the main axis of the guide wire.

The EN ISO test is stopped at 5 N or at disruption of the union of core wire and coil, whichever occurs first. We continued the test procedure until disruption was audible or maximum tractive force was applied. Tractive force (N) and changes in guide wire length (mm) were continuously recorded.

Test for flexing behavior based on clinical requirements

The construction of the testing apparatus [Figure 3] consists of a fixed aluminum plate and a movable journal bearing which allows vertical movement. Movement in a vertical direction simulates the advancement of the dilator into tissue. The dilator (taken from Certofix TRIO SB 730 Set, FA B. Braun AG, 34209 Melsungen, Germany, diameter: 7 French)

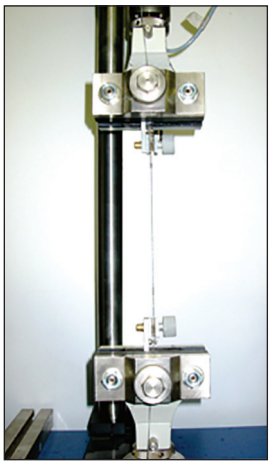

Figure 2: Testing for tensile strength: One end of the guide wire is secured to a split-tapered clamp attached to the moving crosshead of the tensile splitting apparatus. Pneumatic grips attached to the fixed head should grip the guide wire approximately at its central point and at least 150 mm from the split-tapered clamp [Figure 3]

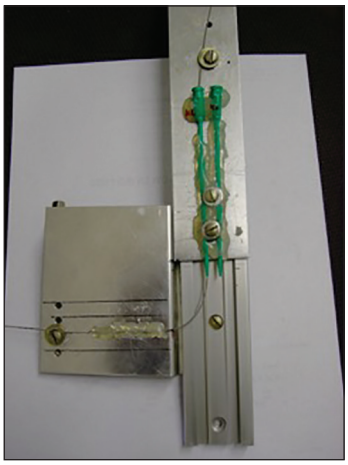

Figure 3: The testing machine for kinking consists of a movable journal bearing which allows a vertical movement. a = Kinking Test 1; b = Kinking Test 2. For kinking Test 2, the dilator was fixed 2 cm closer to the distal end of the guide wire. Furthermore, a force transducer measuring the vertical movement was connected to this bearing. Movement in a vertical direction simulates the advancement of the dilator into the tissue. On the aluminum plate, a metal tube (diameter 1.3 mm, length 5 cm) was installed at a right angle position to the vertically movable journal bearing. In the start position of the bearing, the tip of the dilator was situated 3 cm above the level of the horizontal tube on the aluminum plate. For the measurement of the kinking behavior, the journal bearing was moved downward 3 cm with a defined velocity of 1.3 cm/s

was fixed to the journal bearing as shown in Figure 3. A force transducer, measuring the vertical movement, was also connected to this bearing. On the aluminum plate, a metal tube (diameter 1.3 mm, length 5 cm) was installed at right angle to the vertically movable journal bearing.

The flexing tests were performed at two dilator positions on the journal bearing [Tables 3 and 4]. For flexing Test 2, the dilator was fixed 2 cm closer to the distal end of the guide wire than in Test 1, resulting in a greater flexing angle [Table 4]. The guide wire was inserted through the dilator and the metal tube. Screws, 3 cm from the J-tip, fixed the wire to the aluminum plate and onto the test apparatus. This allowed free movement of the dilator over the fixed wire.

In the start position, the tip of the dilator was situated 3 cm above the level of the horizontal tube on the aluminum plate. For measurement, the journal bearing was moved downward 3 cm with a defined velocity of 1.3 cm/s. Thereafter, the screws were released, and the journal bearing was slowly lifted until the guide wire was released. The distal part of the wire was then carefully removed. A digital scan of the guide wire was then generated.

Data analysis and statistics

We measured tensile strength in N. We measured flexing angles by first scanning the wires with CanoScan 5000 F, and then analyzing the results with the assistance of the Adobe Illustrator 10 (Adobe Systems Incorporated, 345 Park Avenue San Jose, CA 95110-2704). Within each wire type, standard deviation and mean were determined. Concerning flexing behavior, we compared variables using nonparametric Mann-Whitney U-test for independent samples. Analysis of variance (ANOVA) was used to test the type of the guide wire for significant differences. Significant differences between the types were analyzed by a *post-hoc*-analysis (Tukey's honestly significant difference [Tukey's HSD]). Probability value was defined as 5% ($P < 0.05$). All analyses were performed using SPSS 11.5.1 (Chicago, Illinois, SPSS Inc., USA).

Table 2: Tensile strength in Newton: Means of the three subgroups after Tukey's HSD

Type	Subgroup I	Subgroup II	Subgroup III
Accoat	15.06 N		
Braun NK1	17.09 N		
Braun N	24.44 N	24.44 N	
Arrow	26.34 N	26.34 N	
Braun S		31.43 N	
Braun NK2		35.89 N	
Radifocus			257.76 N
Significance	0.102	0.092	1.000

See also data analysis and statistics section, HSD = Honestly significant difference, N = Newton

Results

Tensile strength

All guide wires, except one of the six Braun NK1 prototypes, met EN ISO 11070 requirements for tensile force of 5 N. One-way ANOVA showed statistically significant differences. After *post-hoc* analysis of means by Tukey's HSD, three subgroups could be defined [Table 2]. The mean of the wire types tested ranged from 15.06 to 257.76 N.

Table 3: Kinking Test 1: Means in the four subgroups after Tukey's HSD

Type	Subgroup I	Subgroup II	Subgroup III	Subgroup IV
Braun NK1	0.00			
Radifocus	0.00			
Braun NK2	0.00			
Edwards		8.25		
Arrow		11.83	11.83	
Braun S		11.92	11.92	
Braun N			14.92	
Accoat				25.17
Significance	1.000	0.080	0.207	1.000

See also data analysis and statistics section, HSD = Honestly significant difference

Table 4: Kinking Test 2: Means in the four subgroups after Tukey's HSD

Type	Subgroup I	Subgroup II	Subgroup III	Subgroup IV
Radifocus	0.00			
Braun NK1	0.50			
Braun NK2	0.50			
Edwards		24.58		
Arrow		25.17		
Braun S		27.33	27.33	
Braun N			29.25	
Accoat				38.25
Significance	0.999	0.118	0.487	1.000

See also data analysis and statistics section. HSD = Honestly significant difference

Flexing properties

Flexing performance

None of the wires kinked. The monofil displayed no evidence of bending. Two core/coil wires displayed minor bending, (angle 1.5°) and all other wires displayed bending angles between 22.5° and 43.0°. The applied insertion angle (Test 1: 20°, Test 2: 50°) had an influence on the resulting bending angle of the guide wire. This was significant in the guide wires of Accoat, Braun N, Braun S, and arrow [Table 5].

Discussion

Central line insertion is a daily routine in anesthesiology and the management of critically ill patients. Even though materials and insertion technique have improved dramatically over the last few years, serious complications are still being regularly reported in the medical literature. Problems can emerge from inappropriate handling, material defects or differences in quality. Our study focused on the mechanical properties.

We do not have it in our power to produce error-proof humans. We do have it in our power to produce and use high-end guide wires which can actually neutralize many of the human errors associated with CVC and other procedures. The primary purpose of this study was to test and compare the mechanical properties of core and coil Seldinger wires used in commercially available CVC kits. We also tested a type of

Table 5: Results of kinking Test 1 and 2

Type	Accoat	Braun N	Braun S	Arrow	Edwards	Braun NK1	Braun NK2	Radifocus
Kinking Test 1								
Mean	25.16	14.92	11.92	11.83	8.25	0.00	0.00	0.00
SD	2.44	2.87	1.83	3.53	1.75	0.00	0.00	0.00
SEM	0.99	1.17	0.75	1.44	0.72	0.00	0.00	0.00
95% confidence upper	22.60	11.90	9.99	8.13	6.41	0.00	0.00	0.00
5% confidence lower	27.73	17.93	13.84	15.54	10.09	0.00	0.00	0.00
Minimum	23.00	11.00	9.50	7.50	5.00	0.00	0.00	0.00
Maximum	29.50	19.50	15.00	17.00	9.50	0.00	0.00	0.00
Kinking Test 2								
Mean	38.25	29.25	27.33	25.17	24.58	0.50	0.50	0.00
SD	3.66	0.94	1.51	0.82	1.83	0.77	0.77	0.00
SEM	1.49	0.38	0.61	0.33	0.75	0.32	0.32	0.00
95% confidence upper	34.41	28.27	25.75	24.31	22.66	−0.31	−0.31	0.00
5% confidence lower	42.09	30.23	28.91	26.02	26.50	1.31	1.31	0.00
Minimum	32.50	28.00	25.50	24.00	22.50	0.00	0.00	0.00
Maximum	43.00	30.50	29.50	26.00	26.50	1.50	1.50	0.00
Comparison kinking Test 1/kinking Test 2								
Mann–Whitney-U	0.000	0.000	0.000	0.000	0.000	12.000	12.000	18.000
Wilcoxon-W	21.000	21.000	21.000	21.000	21.000	33.000	33.000	39.000
Z	−2.887	−2.887	−2.882	−2.892	−2.903	−1.483	−1.483	0.000
Asymptotic significance (two-tailed)	0.004	0.004	0.004	0.004	0.004	0.138	0.138	1.000
Exact significance (one-tailed)	0.002	0.002	0.002	0.002	0.002	0.394	0.394	1.000

SD = Standard deviation, SEM = Standard error of the mean

guide wire type routinely used in angiography. The intent of its inclusion was to give clinicians comparative information necessary to make informed decisions when faced with certain procedures and body types known to be extremely problematic, for example:

1. Patient is of small stature, especially if corpulent, and the procedure involves a large-bore catheter;
2. Patient is of small stature, especially if corpulent, and the procedure involves the right subclavian or the left internal jugular vein;
3. Patient has undergone or is believed to have undergone previous/numerous cannulations.

Tensile strength

To avoid serious complications, excessive force should not be applied to guide wires. Even the instructions for use included with the CVC kit read: "Do not apply excessive force in removing the guide wire." "Excessive force" is an extremely nebulous measurement, and in any event, the actual N rating of the guide wire in the kit is not provided. This means clinicians often do not know if they are working with an extremely robust guide wire or a marginally adequate guide wire. Hence, the human force applied successfully with unknown guide wire X, may be too much force for unknown guide wire Z. Since there is no way to measure the tensile force used in an actual clinical situation, the clinician must perform a great deal of this delicate procedure through learned behavior, through feel — which may be extremely difficult to achieve if the mechanical properties of the wires are different from kit to kit. This leads to one obvious conclusion: In order to avoid the complication caused by "excessive force" use a kit which consistently contains a guide wire with the highest possible tensile strength. The second conclusion is that the 5 N EN ISO requirement is simply not adequate to meet clinical requirements or would not continue to see the high level of mechanical failures.

In our study of tensile strength, we found three significantly different groups. In subgroup II, the mean ranged from 35 to 25 N, and overlapped with subgroup I which ranged from 24 to 26 N. We would recommend guide wires of Group II for Seldinger technique, especially those which are not in both subgroups (>27 N).

Subgroup III, the Radifocus wire, is virtually indestructible. It consists of an elastic alloy core coated with a polyurethane jacket and a hydrophilic coating. The result is an extremely pliable tip, a smooth outer coating and excellent torque control. Because of the monofil construction of this wire, the tensile strength is only influenced by the stability of the metal wire itself. This kind of the guide wire is routinely used in radiology but not for CVC procedures.

Flexing test

One critical step during the insertion of CVC via the Seldinger technique is the dilation of the puncture canal. In order to dilate the perivascular tissue, a dilator is guided over the wire. During the advancement of the dilator, a forward movement of the guide wire is prevented by immobilizing the wire with a firm grip. However, in clinical practice, the dilator may not always run exactly parallel. When this is the case, the force intended for tissue dilation often diverts to the guide wire, potentially leading to patient complications. Clinicians can avoid this result using nonkinking wires, such as the Braun NK2 or the Radifocus monofil tested in this study. This does not imply that continuing education and training should be discontinued. But, medical devices now exist that would allow us to make an immediate improvement in patient results. Not using these devices would appear difficult to justify.

To simulate this CVC insertion process, a method of testing flexing characteristics, mimicking clinical demands, was developed. Main features influencing the insertion procedure were taken into consideration for developing the test design, that is, resistances of tissue or friction by fixing the distal end of the wire, muscle force of the physician and dilation velocity by defining the sliding velocity, as well as the angle between the dilator and guide wire by testing at two different angles. The existing directive does not address these issues.

Conclusion

We recommend that:

1. Clinicians use guide wires with high-end mechanical properties, (nonkinking, high tensile strength),
2. EN ISO 11070 incorporate our flexing test into their testing method, raise the flexing requirement to kink-proof, and raise the tensile strength requirement to a minimum of 30 N, and
3. All manufacturers and suppliers be required to display mechanical properties of all guide wires and CVC kits sold.

We recommend that clinicians use the least amount of force necessary during CVC insertion/retraction, and remain alert to specific patient profiles.

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