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ORIGINAL RESEARCH

Are All Wires Created the Same? A Quality Assurance Study of the Stiffness of Wires Typically Employed During Endovascular Surgery Using Tension Dynamometry

Arindam Chaudhuri [a,c,*], **Frederic Heim** [b,c], **Nabil Chakfe** [c]

[a] Bedfordshire — Milton Keynes Vascular Centre, Bedfordshire Hospitals NHS Foundation Trust, Bedford, UK
[b] Université de Haute-Alsace, Laboratoire de Physique et Mécanique Textiles, Mulhouse, France
[c] Geprovas, Batiment d'Anesthesiologie, Strasbourg, France

Objective: There have only been a few studies on the stiffness and load bearing characteristics of guidewires used to deliver devices during endovascular procedures, particularly endovascular aneurysm repair. The aim of this study was to compare the load bearing characteristics of typical stiff and floppy wires, including in the context of consistency for each wire type.

Methods: Two sets of stiff guidewires (Lunderquist Extra-Stiff and Amplatz Super Stiff [0.035" × 260 cm]), were compared with a floppy hydrophilic guidewire (Radifocus Stiff M [0.035" × 260 cm]). Radial stiffness was defined as the force (newtons [N]) needed to deform the wires on an electromechanical dynamometer. Tests were repeated with three runs on three sets of the same wire to check for consistency. Data were logged on proprietary dynamometric software and peak load values assessed per wire. Peak deformation forces (PDFs) from straight configuration to midwire deformation at 15 mm was translated into Microsoft Excel for statistical analysis in Minitab 19 for Windows.

Results: There was good agreement within each wire set, with no difference in PDFs from runs for each wire ($p >$ .10). Mean ± standard deviation PDFs were 7.83 ± 0.23 N for the Lunderquist, 9.87 ± 0.92 N for the Amplatz, and 7.84 ± 0.52 N for the Radifocus wires. The Amplatz wire exhibited the greatest resistance to deformation *vs.* both the Lunderquist and Radifocus wires ($p <$ .001, one way analysis of variance). Both Amplatz and Radifocus wires had non-linear deformation characteristics.

Conclusion: This study confirmed that the represented hydrophilic wire is more deformable than the stiff wires. The Amplatz wire has complex construction features that yielded surprising baseline stiffness characteristics. The linear stiffness characteristics of the Lunderquist wire possibly contribute to it being the preferred choice for large endograft delivery.

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INTRODUCTION

Endovascular aneurysm repairs (EVARs) are undertaken with device delivery over wires of varying stiffness, and guiding wires to achieve an optimal target position. Typically, very stiff wires are used to deliver large aortic endoprostheses during EVAR or thoracic EVAR,[1,2] or even to test device deliverability,[3] while wires perceived as being slightly less stiff can be used to delivery auxiliary devices such as an iliac branch endoprosthesis.[4] More than one wire may be necessary to "stiffen" the aorto-iliac system and reduce tortuosity.[5] In contrast, "floppy" hydrophilic wires are typically used as negotiating wires, with the understanding that they are not stiff enough to support delivery of substantial endoprosthesis systems. This paper is a continuation of studies that have examined mechanical wire properties, one of which has examined floppy wires that have been tensioned as for use as pull through wires.[6]

Although a few studies have examined the stiffness of guidewires,[7,8] there is no comparative analysis of the mechanical properties of these wires, and no literature on any quality assurance analysis of any single class of wire.

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* Corresponding author. Bedfordshire-Milton Keynes Vascular Centre, Bedfordshire Hospitals NHS Foundation Trust, Kempston Road, Bedford MK42 9DJ, UK.

E-mail address: a.chaudhuri@ntlworld.com (Arindam Chaudhuri).

Twitter: @vascularis

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Therefore, this study sought to examine the stiffness properties of each type of wire for consistency in mechanical characteristics, and also to quantify the differences between each type to see if there is a mechanical basis that informs current understanding of wire choice for device delivery.

METHODS

System set up/apparatus

Three types of 0.035” × 260 cm wires were assessed: the Lunderquist Extra-Stiff Wire Guide (Cook Aortic Interventions, Bloomington, USA; hereafter referred to as the “Lunderquist”); Amplatz Super Stiff (Boston Scientific, Hemel Hempstead, UK; hereafter referred to as the “Amplatz”), and the Radifocus Guidewire M Stiff (Terumo UK, Bagshot, UK). The wires were assessed with a pretensioning load of 1.96 newtons (N; equivalent to a 200 gf gravitational tensioning force) applied to remove any slack. This created consistent baseline tensioning that is significantly lower than what might be used to tension a pull through wire, for instance,[6] and is relevant to creating consistency in the test platform and also in eliminating any confounders from the resting elasticity/plasticity aspects of each wire.

Wires (in intact and unused condition) were set up on a frictionless tensor apparatus, namely an electromechanical dynamometer (Insight 50 kN; MTS Systems, Eden Prairie, MN, USA) (Fig. 1A). A test segment of wire of 18.5 cm length that would be representative of a section that would carry an endovascular device was selected for mounting in the test platform. The wires were subjected to a central deformation of 15 mm (Fig. 1B and Supplementary Video S1) and the forces noted to achieve the deformation were logged in a data logging system (MTS TestWorks 4 on Windows 7; MTS Systems) as a curvilinear plot; each plot was also assessed visually to see if the deformation force evolution trends were linear or curvilinear. Peak deformation force (PDF) was then assessed for each wire. PDF assessment was preferred to assessment of flexural modulus (FM) as this is a recognised technique that looks at the active effect of loading;[9] FM is useful for assessing deformation resistance in stiff wires as in other studies that examined reaction to loading,[7] and thus may not produce meaningful results for floppy wires, which are included in the current study. Each experiment from the non-deformed to a fully deformed state was defined as a run.

Experiment 1

Wire assessment (intraclass). Runs were undertaken with three sets (each set given a 1—2—3 designation) of each wire configuration (Lunderquist, Amplatz, and Radifocus) to assess consistency. These were denoted runs A, B, and C. Fresh wires were used for each run.

Experiment 2

Wire assessment (interclass). PDFs were summated and compared between each wire type. The results are presented in summative fashion below.

Analysis

Data outputs were exported from the MTS Insight data logger into Excel and statistically analysed within Minitab 19 for Windows (Minitab LLC, Philadelphia, USA). Capability analysis was used to affirm uniformity of distribution of mean PDFs for suitability of comparison. One way analysis of variance (ANOVA) was used for the comparison of intraclass and interclass outcome differences.

RESULTS

Intraclass

There was no significant difference in the PDFs over runs A − C for the Lunderquist ($p = .73$), Amplatz ($p = .15$), and Radifocus ($p = .11$). These results are presented in Table 1

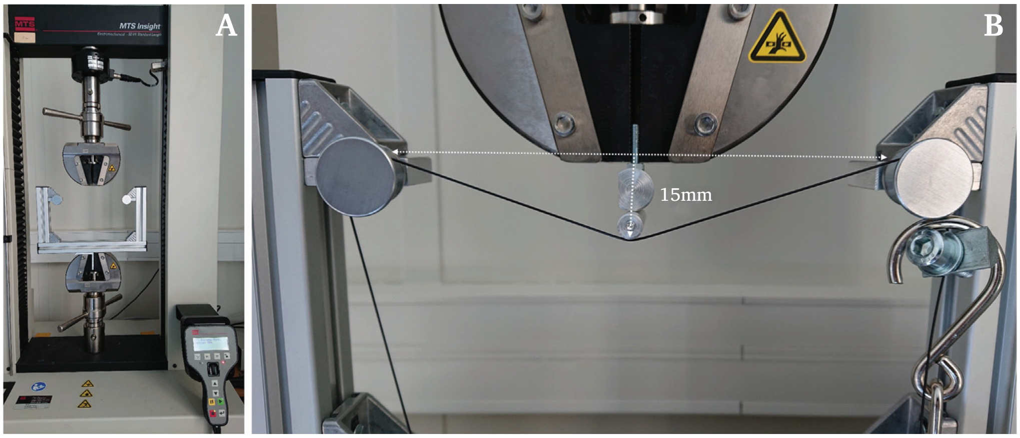

Figure 1. (A) The test platform position and (B) a test wire loaded in the deformed position (Amplatz); the dotted lines indicate the starting position (horizontal arrowed line, which indicates the 18.5 mm test segment between the round low friction supports) and the 15 mm vertical distance traversed to create the index central deformation.

Table 1. Results of individual test runs (A, B, C) with the three sets (1, 2, 3) of each wire class, indicating the peak deformation force (PDF) at each run, indicating the intraclass and interclass trends

Assessment/comparison				***p* value**	**Comments**
Intraclass assessment (PDF − newtons)					
	Wire class				
	Lunderquist			.731	Agreement
Run	1	2	3		
A	7.97	7.77	7.80		
B	7.88	7.70	7.90		
C	7.37	8.23	7.85		
	Amplatz			.146	Agreement
Run	1	2	3		
A	8.20	9.05	9.77		
B	9.26	10.66	10.65		
C	9.70	10.49	11.03		
	Radifocus			.106	Agreement
Run	1	2	3		
A	7.24	6.99	7.95		
B	7.99	7.54	8.46		
C	8.24	7.73	8.44		
Interclass comparison (PDF − newtons)					
Grouped					
Amplatz	**9.87 (0.92)**			$< .001$	Highest PDF noted for Amplatz wire
Lunderquist	7.83 (0.22)				
Radifocus	7.84 (0.52)				
Individual					
Amplatz *vs* Lunderquist				$< .001$	—
Amplatz *vs* Radifocus				$< .001$	—
Lunderquist *vs* Radifocus				.96	—

Data are presented as mean ± standard deviation. PDF = peak deformation force(s).

with the uniformity of the values affirmed by capability analysis (Fig. 2). The results within each wire class were thus pooled together for cumulative analysis and comparison, as indicated in the methods.

Interclass

The mean PDF for each group of wires was 7.83 ± 0.22 N (Lunderquist), 9.87 ± 0.92 N (Amplatz), and 7.84 ± 0.52 N (Radifocus) (Fig. 3A). The highest PDFs needed to achieve the fully deformed configuration on the test platform were noted for the Amplatz wire and was statistically significant compared with both the Lunderquist and Radifocus wires ($p < .001$, ANOVA; Table 1). There was no significant difference in the PDFs between the Lunderquist and the Radifocus wires ($p = .96$, ANOVA; Table 1). Visual assessment of the plots demonstrated linear characteristics in the deformation force evolution trends for the Lunderquist, while those for the other two wires were appreciable as curvilinear (Fig. 3B).

DISCUSSION

This study indicated good agreement within each class in terms of consistent deformation/stiffness characteristics and affirms qualitative robustness from a manufacturing

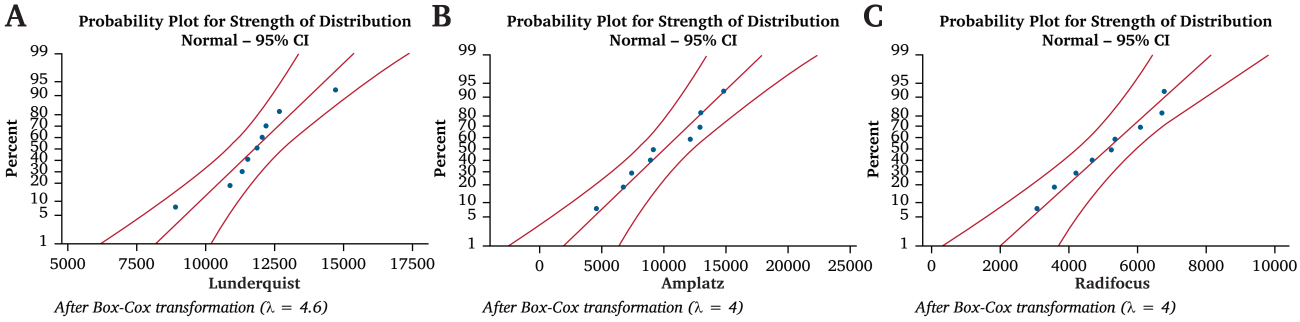

Figure 2. Individual distribution identification analyses indicating minimal variance between mean peak deformation force (PDF) values for (A) Lunderquist, (B) Amplatz, and (C) Radifocus wires. CI = confidence interval.

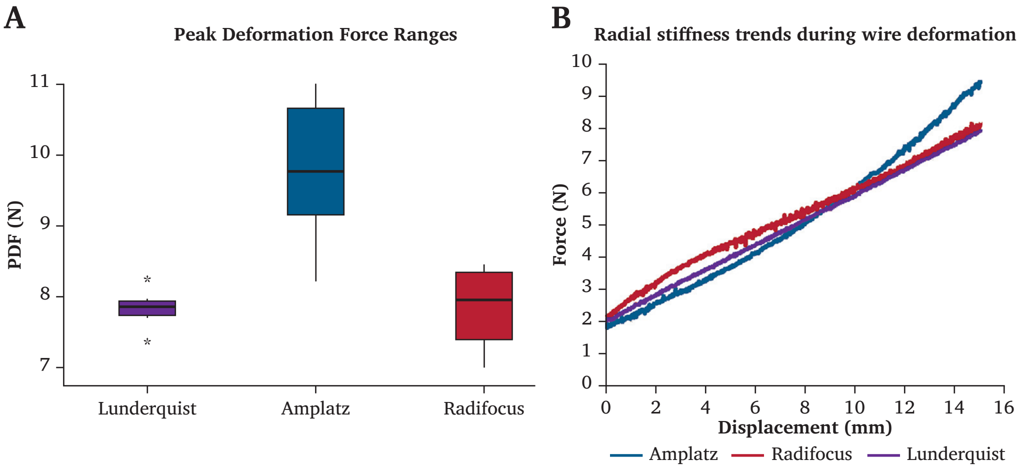

Figure 3. Representative interclass comparisons. (A) Boxplot indicating the range of peak deformation forces (PDFs) achieved for each three wire type. (B) Composite graph indicating typical PDFs for each wire configuration during deformation, with additional emphasis on the dip below and then the rise of the Amplatz characteristic above the curves of the other wires. N = newtons.

standpoint. The interclass studies confirmed that minimal force was required to achieve the index deformation in the Radifocus wire, reflecting its floppy designation. The Amplatz wire needed a higher PDF to achieve the 15 mm deformation, indicating that it was the stiffest wire examined here, but the tensioning characteristics of the Lunderquist lay within a narrower range (Fig. 3A) and showed a linear slope (Fig. 3B), suggesting it will bend less readily.

Interestingly, even company websites offer little information on the quantification of the mechanical characteristics of such guidewires, including aspects of stiffness. While wire stiffness units have been applied in some studies, these are not necessarily intuitive enough, and resistance to deformation has been used, as applied in this study, by some manufacturers as an index.[9] The results are in contrast to other studies, such as that by Harrison *et al.*,[7] with lower forces needed to achieve an index deformation in this study; this may be due to the difference in experimental setup given that in this study the peak force needed to attain a fixed deformation (15 mm) was used, whereas in the study by Harrison *et al.*[7] there were different load configurations used over a different length (40 cm) and deformation (5 mm), and the tests were for reaction to loading. Both approaches are valid in terms of set up but perhaps not necessarily directly comparable. The Amplatz Super Stiff wire was somewhat paradoxically "stiffer" in the present study, and it is interesting to note that some authors have used this as a pull through wire.[10] Its stiffness has also been confirmed in other studies.[11] Other aspects, such as supporting the wire with a sheath, were not examined owing to the limitations of the test platform and the consideration of Newton's third law in that tension will be uniform throughout. Although there are other wire types that can be employed and thus analysed, three commonly used representative wires were chosen to maintain study simplicity.

The limitations of this study, given the above bench constraints, are to be considered. The characteristics were considered without the application of sheaths or endovascular devices, and do not include the possible effect of the curvilinear aspects of aorto-iliac geometry. Another consideration may be the length of the test segment, and further tests are needed to double check whether length is a confounding variable in this set up; nevertheless, the test lengths were all matched and thus the test segments were all equivalent and comparable in terms of analysis. Furthermore, wires represent a complex interplay of materials used in their manufacture; specifically, the Lunderquist is made of stainless steel coated with polytetrafluoroethylene (PTFE).[1] The Amplatz is also stainless steel coated with PTFE with a flat wire coil and an inner core,[12] which yields complex elasticity—plasticity characteristics, as noted in the initial dip and then upturned slope of its curve(s) (Fig. 3B). The Radifocus M Stiff is a polyurethane (with tungsten) jacketed nitinol based guidewire, with the "M" referring to a proprietary hydrophilic coating designation,[13] which probably contributes to similar complex elasticity—plasticity features, which graphically indicates that the wire deforms early and then "settles in" (Fig. 3B). It is likely that this early deformability does not allow the delivery of large endoprostheses but is acceptable in delivery devices in straighter and smaller arteries, for example the femoropopliteal segment. Furthermore, this is the "stiff" variant of the floppy wires from this portfolio, compared with the Radifocus M Standard,[14] which was not tested. The former has a contrasting purported "reinforced superelastic Nitinol core" with "good torque control and stiffness", which is required for a navigating wire, as indicated by the manufacturer,[13] and so this variant of the Radifocus M was chosen. Assessment of the contribution of individual components of these guidewires was beyond the scope of this study. The Lunderquist demonstrated more linear deformation characteristics, as is notable in Fig. 3(B), implying a more predictable response to external forces, and this may be what contributes to it being the favoured wire for the delivery of large endoprostheses.

This study also indicates excellent matched stiffness characteristics *within* each wire class, and complex characteristics in some wires such as the Amplatz and the Radifocus, particularly given that prior studies have only looked at multiple segments in a single wire,[8] which is a method to qualify a single wire, rather than the *class* of wire. Such results may also provide a realistic assessment of wires that may challenge and prompt re-examination of the marketed concepts of stiffness, which may then generate a new classification system from this perspective.

Conclusion

This study provides quantitative insights into the biomechanical basis for the "stiffness" characteristics of a mixed group of commonly used guidewires that is accepted as a given by endovascular operators. From a quality standpoint, the results also support consistent stiffness characteristics for each wire type.

FUNDING

None.

CONFLICT OF INTEREST

None.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvsvf.2021.06.006.

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