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SHORT REPORT

Quantifying the Functional Stiffness of Pullthrough Wires Used for Endovascular Aneurysm Repairs Using Comparative Tension Dynamometry

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

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

Objective: There are only few studies on the stiffness of guidewires used to deliver devices during endovascular procedures, particularly abdominal/thoracic endovascular aneurysm repair. In certain situations, tensioned pullthrough wires are also used, but no studies have examined their effective/functional stiffness. The objective of this study was to assess the radial stiffness characteristics of pullthrough wires compared with standard stiff wires.
Methods: Two types of stiff guidewires (Lunderquist Extra-Stiff and Amplatz Super Stiff; 0.035″ $\times$ 260 cm), were compared with a floppy guidewire (Radifocus Stiff M; 0.035″ $\times$ 260 cm) in two configurations: standard (non-tensioned) and pullthrough (tensioned). Radial stiffness was defined as the peak deformation force (PDF; newtons [N]) needed to deform the wires on an electromechanical dynamometer; data were logged on proprietary dynamometric software and peak load values assessed per wire. Three experimental runs were performed on three fresh sets of each wire per configuration. PDFs from straight configuration to midwire deformation at 15 mm were translated into Microsoft Excel for statistical analysis in Minitab 19 for Windows.
Results: Mean $\pm$ SD PDFs were 7.83 $\pm$ 0.23 N for the Lunderquist and 9.87 $\pm$ 0.92 N for the Amplatz. This was 7.84 $\pm$ 0.52 N for the Radifocus wire in standard configuration, which increased to 15.48 $\pm$ 0.33 N when the Radifocus wire was in pullthrough configuration. This was significantly higher than both the Lunderquist and Amplatz Super Stiff wires ($p < .001$, one way analysis of variance).
Conclusion: This study affirmed that a pullthrough wire becomes functionally more rigid than typical stiff wires used for endovascular procedures, and it is this stiffness that allows device delivery.

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INTRODUCTION

Endovascular aneurysm repairs (EVARs) are undertaken with device delivery over wires of varying stiffness. Occasionally, particularly in cases with tortuous aorto-iliac anatomy, "pullthrough" wires (PTWs), which are typically floppy hydrophilic wires, are used for device delivery, with the tensioned PTW acting as the substitute for the stiff wire that would have been employed originally. Although a few modern studies have examined the stiffness of guidewires,[1,2] there is no analysis of the mechanical properties in a floppy wire that is then "stiffened" in pullthrough configuration. Therefore, this study sought to examine the mechanical properties of such pullthrough wires and compare them with conventional stiff wires, in order to understand the underlying mechanical basis that eventually allows/supports device delivery.

MATERIALS AND METHODS

System set up/apparatus

Three types of 0.035″ $\times$ 260 cm guidewires were assessed: the Lunderquist Extra Stiff Wire Guide (Cook Aortic Interventions, Bloomington, IN, 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 first two wires were assessed in standard configuration with only a pre-tensioning load of 1.96 newtons (N) applied to remove any slack that might confound the results, as described previously;[2] the Radifocus Stiff wire was assessed in standard (hereafter referred to as the

* 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).
@vascularis

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Radifocus) and pullthrough (hereafter referred to as the Pullthrough) configurations, the latter with a predetermined additional tensile load of 38.30 N. This load was selected based on prior experimental studies looking at representative tensions used on a PTW bench test validated in terms of being able to support endovascular device delivery.[3]

Wires were set up on a frictionless tensor apparatus, specifically an electromechanical dynamometer (MTS Insight 50kN; MTS Systems, Eden Prairie, MN, USA). A test segment of wire was selected at 18.5 cm length between frictionless supports as suitable for mounting in the test platform. The wires were subjected to a central deformation of 15 mm at a displacement rate of 13 mm per minute to avoid slippage (Supplementary Figure S1 and Video S1), and the peak force noted to achieve the deformation was logged into a data logging system (MTS TestWorks 4 on Windows 7; MTS Systems) as a curvilinear plot. The peak deformation force (PDF) was then assessed for each wire as representative of radial stiffness. Each experiment from a non-deformed to a fully deformed state was defined as a run. Runs were undertaken with three sets (each set given a 1—2—3 designation) of each wire configuration (Lunderquist, Amplatz, Radifocus, and Pullthrough) to assess consistency. These were denoted as runs A, B, and C. Fresh wires were used for each run. This approach has been described in a recent prior study assessing wire radial stiffness.[2]

Supplementary video related to this article can be found at https://doi.org/10.1016/j.ejvsvf.2022.05.001

The following is the supplementary data related to this article:

Analysis

Data outputs were exported from the MTS Insight data logger into Microsoft Excel and statistically analysed within Minitab 19 for Windows (Minitab, Philadelphia, PA, USA). Continuous variables are presented as mean $\pm$ standard deviation. Distribution identification analysis was used to affirm the uniformity of mean PDFs for suitability of comparison. One way analysis of variance (ANOVA) was used for comparison of intraclass and interclass outcome differences. The threshold of statistical significance was $p < .05$. Regression analysis was used to correlate the effect of tension on change in PDFs for the PTW.

Experiment 1 (background)

Wire assessment: intraclass. A summative analysis of the PDFs was undertaken to validate consistency for each wire type before proceeding to comparison of the wires themselves. This has already been described as undertaken for the wires in standard configuration,[2] and this time an additional consistency check was undertaken for the pullthrough wire.

Experiment two (focused)

Wire assessment: interclass. PDFs were effectively comparable between the following configurations: (1) stiff and floppy wire (standard configuration); (2) floppy wire in standard and pullthrough configurations; and (3) stiff wires (standard configuration) *vs.* floppy wire (pullthrough configuration). The results are presented in summative fashion below.

RESULTS

Experiment 1

Wire assessment: intraclass. There was no significant difference in the PDFs over runs A — C for the Lunderquist, Amplatz, or Radifocus wires, as described previously ($p > .1$, ANOVA).[2] There was some variance within the Pullthrough wire sets ($p < .001$, ANOVA); the uniformity of the PDF values for the Pullthrough wire was subsequently affirmed by distribution identification analysis (Fig. 1). The overall results were thus pooled together for cumulative analysis and comparison.

Experiment 2

Wire assessment: interclass. The mean PDF for each group of wires was 7.83 $\pm$ 0.22 N (Lunderquist), 9.87 $\pm$ 0.92 N (Amplatz), 7.84 $\pm$ 0.52 N (Radifocus), and 15.47 $\pm$ 0.33 N (Pullthrough), indicating a significantly higher stiffness/resistance to deformation in the Pullthrough wire once the tensile load had been applied ($p < .001$, ANOVA).

Regression modelling indicated this resultant stiffness correlated with significant gain in rigidity from the Radifocus standard configuration by tensioning (r^2_{adjusted} = 96.9%). This was appreciable in the deformation trends (Fig. 2A) and in the range of peak deformation forces (Fig. 2B).

The overall results indicating the PDFs are presented in Table 1.

DISCUSSION

Severe angulation along the length of the aorta and the iliac arterial segments can hamper the tracking and delivery of endovascular devices over stiff guidewires during EVAR or thoracic EVAR,[4,5] including failure to obtain retrograde wire

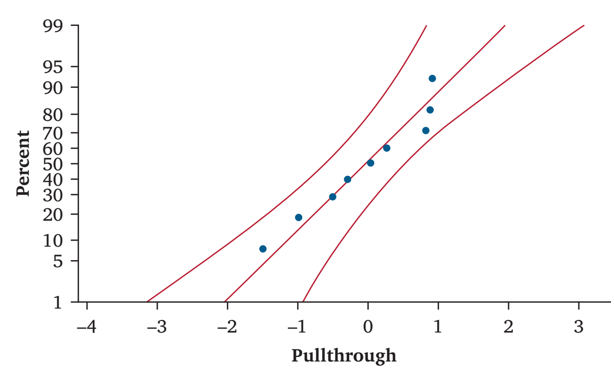

Figure 1. Individual distribution identification analysis assessing variance between mean peak deformation force values for the pullthrough wires.

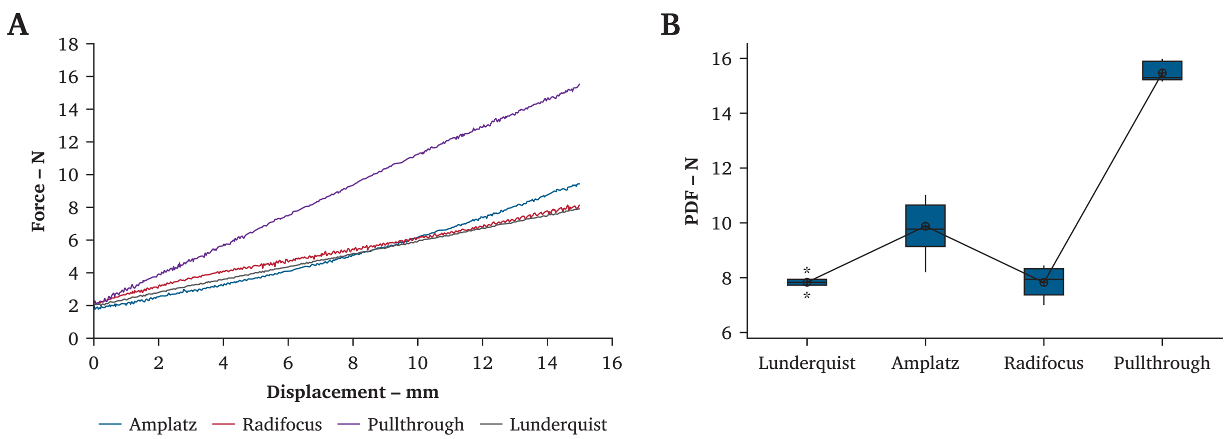

Figure 2. (A) Composite graph indicating typical deformation trends for each wire configuration, emphasising the linear graph slope and high peak deformation force (PDFs) needed for the Pullthrough wire during deformation. (B) Box plot indicating the range of PDFs across the four wire configurations.

access when a frozen elephant trunk repair has been undertaken,[6] often creating anatomical constraints beyond the instructions for use of the proposed endoprosthesis,[7] and in such cases even strategies such as the use of double stiff wires do not work. Thus pullthrough wires have been applied for thoracic and aorto-iliac interventions,[4,5] and femorofemoral pullthrough configurations[8] have also been successfully applied, precluding the need for brachial access. Such wires have also been colourfully described as body floss wires,[9] or as creating a clothes line effect,[10] the latter being particularly reflected in the present experiments. Previous studies support the assessment of radial stiffness,[2] which the authors' felt approximates the clinical scenario more realistically, particularly as radial stiffness is what prevents lateral deviation and supports linear tracking of endovascular devices along the guidewire.

It is interesting to note that some authors have used the Amplatz Super Stiff wire (which was somewhat paradoxically "stiffer" in the current study)[2] as their pullthrough wire.[4] The decision was made not to examine the Lunderquist or the Amplatz wires in the pullthrough configurations because this does not reflect the authors' practice and the results presented bear this out as well; tortuous anatomy is negotiated typically with a floppy hydrophilic wire, which can be easily tensioned for device delivery and therefore the comparisons of the standard configurations against only the Radifocus Stiff M Guidewire in Pullthrough configuration represents a clinically relevant and applicable scenario. In the authors' clinical experience it makes no sense to change the PTW for another wire. The results with the Amplatz in a previous study,[2] however, seem to support other authors using it in pullthrough configuration; it would therefore be interesting to quantify experimentally how it becomes functionally stiffer as well, but that was beyond the scope of this study. Similarly, some modern ultra low profile EVAR devices such as the Alto, or its previous iteration, the Ovation iX (Endologix, Irvine, CA, USA), actually contain dedicated channels to create PTWs in cases of difficult cannulation; these are typically with 0.018″ wires and therefore open up considerations for assessing functional stiffness aspects in narrower gauge PTWs (used here only to deliver 6—7 F guide sheaths), but these were outside the scope of this study.

Other aspects such as supporting the wire with a sheath were not examined owing to the limitations of the test platform, and sheaths probably add little to the stiffness of

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, and the intraclass and interclass comparisons

Assessment/comparison				Remarks
Intraclass assessment (PDF, newtons)				
	Wire class			Averages
	Lunderquist			7.83±0.22
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			9.87±0.92
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			7.84±0.52
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	
	Pullthrough			15.48±0.33)↑
Run	1	2	3	
A	15.21	15.31	15.84	
B	15.16	15.26	15.92	
C	15.24	15.38	15.97	
Interclass comparison				***p* value**
PTW *vs.* all others				<.001

Data are presented as mean ± standard deviation.

the system that a device is being tracked over and, in fact, take the racing line of the PTW itself, with the clinical application of sheaths typically being to avoid catastrophic aortic cheese wiring. Another consideration may be the length of the test segment; nevertheless, the test lengths were all matched and thus the test segments were all equivalent and comparable in terms of analysis.[2] It must be also borne in mind that wires in standard or pullthrough configurations represent a complex interplay of materials used in their manufacture, as discussed in a previous study;[2] thus, assessing the contribution of individual components of these guidewires was beyond the scope of this study and would be clinically unrealistic. Similarly, other floppy wires, including the standard Radifocus GW M Standard (Terumo UK) or the Laureate Hydrophilic GW (Merit Medical, South Jordan, UT, USA) could also be assessed in PTW configuration, but this was outside the scope of the study.

This study provides insights into the biomechanical basis for the stiffness that is gained by a typical floppy hydrophilic wire when tensioned by operators in pullthrough configuration, thus allowing both tracking and delivery of endoprostheses over tortuous anatomy. The study also quantitatively confirms that a floppy wire becomes functionally stiffer than the designated standard stiff wires used at EVAR.

FUNDING

None.

CONFLICTS OF INTEREST

None.

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APPENDIX ASUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvsvf.2022.05.001.

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