◆ EXPERIMENTAL INVESTIGATION ◆

Guidewire Stiffness: What's in a Name?

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Purpose: To measure the stiffness of commonly used ''stiff'' guidewires in terms of their flexural modulus, an engineering parameter related to bending stiffness.
Methods: Eleven different intact stiff guidewires were selected to undergo a 3-point bending test performed using a tensile testing machine. Testing was performed on 3 new and intact specimens of each guidewire at 10 locations along the wire's length, excluding the floppy tip. The flexural modulus (in gigapascals, GPa) was calculated from the results of the bending test.
Results: The flexural modulus of the plain Amplatz wire was 9.5 GPa compared to 11.4 to 14.5 GPa for the ''heavy duty'' wires. Within the Amplatz family of guidewires, the flexural modulus was 17 GPa for the ''stiff,'' 29.2 GPa for the ''extra stiff,'' 60.3 GPa for the ''super stiff,'' and 65.4 GPa for the ''ultra stiff.'' The Backup Meier measured 139.6 GPa and the Lunderquist Extra Stiff 158.4 GPa.
Conclusion: The Instructions for Use of some endovascular devices specify a wire type selected from a range of undefined ''stiffness'' descriptors. These descriptors have little correlation with the measured flexural modulus. Two guidewires with the description ''extra stiff'' can have a 5-fold difference in flexural modulus. We recommend that guidewire catalogues and packaging include the flexural modulus and that device manufacturers amend their Instructions for Use accordingly.

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When delivering endovascular devices, the choice of support guidewire should be guided by the Instructions for Use (IFU) if specific types of guidewires are recommended. Otherwise, the operator's experience and the available stock dictate the selection. To our knowledge, there is no accepted nomenclature to describe the stiffness of guidewires, yet the names of a number of guidewires contain adjectives such as ''stiff,'' ''super stiff,'' ''extra stiff,'' and ''ultra stiff,'' without any apparent scientific meaning. These terms are also used across different groups of wires, an example being the Amplatz Extra Stiff and Lunderquist Extra Stiff wires. Meaningful nomenclature for stiffness is therefore required.

The flexural modulus is an engineering parameter related to a wire's resistance to bending. This measure is rarely displayed on the guidewire packaging or within the catalogue. The aim of this study was to measure the stiffness of some commonly used ''stiff'' guidewires as reflected by the flexural modulus.

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TABLE
Guidewires According to Increasing Stiffness

Guidewire	ΔF/ΔD, N/mm	E_f, GPa
Amplatz	0.218±0.028	9.5±0.6
Fixed Core Heavy Duty	0.262±0.007	11.4±0.3
Rosen Heavy Duty	0.283±0.016	12.3±0.7
Newton Heavy Duty	0.289±0.016	12.5±0.7
Rosen Heavy Duty	0.334±0.013	14.5±0.6
Amplatz Stiff	0.393±0.021	17.0±0.8
Amplatz Extra Stiff	0.674±0.021	29.2±0.9
Amplatz Super Stiff	1.39±0.021	60.3±0.9
Amplatz Ultra Stiff	1.51±0.027	65.4±1.2
Backup Meier	3.22±0.057	139.6±2.5
Lunderquist Extra Stiff	3.66±0.033	158.4±1.5

Data are presented as the means ± standard deviation.

METHODS

Guidewires

A search was made in the printed and electronic catalogues of guidewire manufacturers for adjectives suggestive of stiffness, including ''heavy duty.'' This list, which was not intended to be exhaustive but rather provide a sample of stiff guidewires, was augmented by a radiologist's knowledge of any other stiff wires. The standard diameter of guidewire used in endovascular aneurysm repair (EVAR) is 0.035 inches, and all guidewires selected were of this diameter.

The search found 9 guidewires identified as either ''stiff'' or ''heavy duty'' from the catalogues (Table): Fixed Core Heavy Duty (Cook Inc., Bloomington, IN, USA), Rosen Heavy Duty (Cook Inc.), Newton Heavy Duty (Cook Inc.), Rosen Heavy Duty (Boston Scientific, Natick, MA, USA), Amplatz Stiff (Cook Inc.), Amplatz Extra Stiff (Cook Inc.), Amplatz Super Stiff (Boston Scientific), Amplatz Ultra Stiff (Cook Inc.), and the Lunderquist Extra Stiff (Cook Inc.). The Backup Meier (Boston Scientific) was added because it is a stiff guidewire frequently used during EVAR. The Amplatz (C.R. Bard, Inc., Murray Hill, NJ, USA) was used as a comparator within the Amplatz family.

Three-Point Bending Tests

The 3-point bending test is a standard method for determining flexural properties.

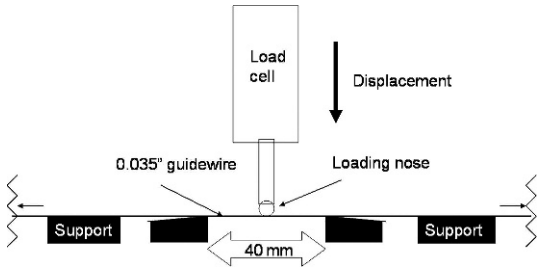

Figure 1 ◆ Diagram of the tensile strength testing machine. The full length of the wire is supported at regular intervals along its length by low-friction supports.

A guidewire was placed in a mechanical testing machine (model M5; Nene Instruments Ltd, UK) supported horizontally at 2 points 40 mm apart (Fig. 1), but able to move freely. A semicircular loading nose placed at a point midway between the supports was displaced downward at a constant speed of 20 mm/min, and the reaction force experienced by the loading nose was measured continuously by means of an attached 50-N load cell. The maximum deflection was set to 5 mm and measured by the tensile strength testing machine. Because of the long length of the guidewire, low-friction supports were provided to keep the guidewire horizontal during the measurement. Only intact and unused guidewires were tested; cutting the guidewires into short segments would have disrupted the structural integrity of the wire and produced inaccurate results. At the start of each batch of tests, the load cell was calibrated using a selection of weights from 100 to 1000 grams. Three specimens of each guidewire were tested at 10 separate points along their length. The first 60 cm from the floppy tip was not tested since the aim was to test only the stiff portion of the guidewires.

Analysis

The flexural modulus E_f, given in gigapascals (GPa), is represented by[1]:

$$E_f = \frac{L^3 F}{48 I D} \qquad \text{(Eqn.1)}$$

where L is the distance between the supports, F is the force, D is the deflection, and I is the second moment of area of the wire about the

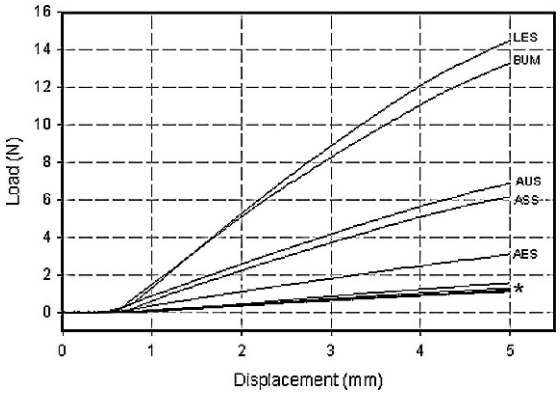

Figure 2 ◆ Displacement and force data for one test of each guidewire. The curves (*) for all of the heavy duty, Amplatz, and Amplatz stiff guidewires were so similar that they appear superimposed. AES: Amplatz extra stiff, ASS: Amplatz super stiff, AUS: Amplatz ultra stiff, BUM: Backup Meier, LES: Lunderquist extra stiff.

neutral plane. For a guidewire with a circular cross section, I is determined by the equation:

$$I = \frac{\pi d^4}{64} \qquad \text{(Eqn.2)}$$

where d is the guidewire diameter.

A graph of the applied force was plotted against the mid-span displacement for each test (Fig. 2). The ratio F/D was determined at the initial linear portion of the curve (i.e., where the deformation is linearly elastic) by calculating the gradient $\Delta F/\Delta D$ in N/mm. The initial flat portion of the curve was ignored as this represented the movement of the loading nose before contact with the wire. The gradient ($\Delta F/\Delta D$) was determined over the first 0.3 mm of deflection from the computed linear regression curve. For each guidewire type, the mean and standard deviation of the gradient and flexural modulus were calculated from the 30 measurements generated.

RESULTS

The gradients and flexural modulus values are presented in the Table for the 11 wires according to increasing flexural modulus (stiffness). The mean gradients varied from 0.218 to 3.66 N/mm. The flexural modulus (Fig. 3) of the plain Amplatz wire was 9.5 GPa compared to 11.4 to 14.5 GPa for the ''heavy duty'' wires. Within the Amplatz family of guidewires, the flexural modulus was 17 GPa for the ''stiff,'' 29.2 GPa for the ''extra stiff,'' 60.3 GPa for the ''super stiff,'' and 65.4 GPa for the ''ultra stiff.'' The Backup Meier measured 139.6 GPa and the Lunderquist Extra Stiff 158.4 GPa.

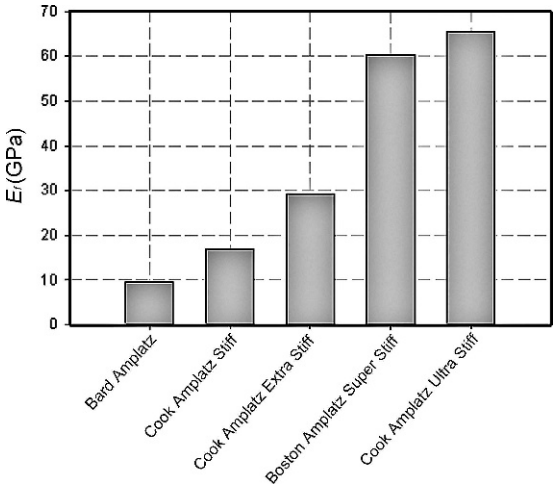

Figure 3 ◆ The flexural modulus for the Amplatz guidewires.

DISCUSSION

A support guidewire has two principal purposes during endovascular procedures. Firstly, it must allow safe delivery of the endovascular device to the deployment site and prevent trauma to the vasculature en route. Secondly, the guidewire should also prevent significant distortion of the device during delivery such that the components function normally at deployment. The key guidewire property that facilitates these purposes is stiffness. If a wire is chosen that is not sufficiently stiff, then vascular trauma may occur as a device is tracked through the vascular tree.

Factors that influence the choice of guidewire during EVAR include the available stock, individual experience, accepted practice in the profession, medical literature, advice from product specialists, and information in the stent-graft's IFU. The available stock in a large group practice will, of necessity, not include all marketed guidewires.

The importance of guidewire choice is illustrated by the Medical Device Alert for an abdominal aortic stent-graft issued in 2009 by the UK regulator, the Medicines and Healthcare Products Regulatory Agency (MRHA).[2] The problem identified was ''the potential for serious injury or death of the patient due to difficulty releasing or inability to release the suprarenal stent during graft deployment.'' Referencing the choice of guidewire, the alert stated ''it is important to ensure that the manufacturer's recommended model and length of stiff guidewire is used and advanced beyond the end of the dilator tip (to the thoracic aorta) to provide maximum support for the inner cannula.''

If we accept that the stiffness of guidewires is a key property for endovascular use, then it would be valuable if there were an easy way for physicians to compare wires from different manufacturers. However, to our knowledge, there is no accepted nomenclature for guidewire stiffness, which makes it difficult for manufacturers to offer clear advice on the required stiffness of the delivery wire and leaves physicians unclear as to whether alternative wires are of suitable stiffness.

The IFU for endovascular devices vary in how specific they are with respect to guidewire choice. For example, the IFU for the W.L. Gore Excluder recommend the use of a ''super stiff'' guidewire but give no examples of such wires.[3] In the absence of accepted nomenclature for guidewires, the term ''super stiff'' has no scientific meaning. There is no defined property of a guidewire or stratification of guidewires to allow physicians to be confident that their choice of guidewire is consistent with this requirement of the IFU. The only wire of which we are aware that contains the descriptor ''super stiff'' is the Boston Scientific Amplatz Super Stiff wire. It could therefore be argued that any use of the Gore Excluder endograft on a wire other than the Boston Scientific Amplatz Super Stiff wire contravenes the IFU and therefore represents off-label use, with potentially important consequences. The MHRA issued a device alert in 2010 warning users that the off-label use of devices ''exposes users and patients to unknown and therefore unacceptable risks and may have legal and ethical implications.''[4]

The IFU for the W.L. Gore TAG indicate that a ''0.035-inch (0.89 mm) Medi-tech Amplatz Super Stiff Guidewire or equivalent, 250 cm or longer'' is required for device replacement.[5] No information is offered as to how one might determine that another wire is the equivalent of the Medi-tech Amplatz Super Stiff Guidewire. Indeed, since 2010, the Medi-tech Amplatz Super Stiff Guidewire has been rebranded as the Boston Scientific Amplatz Super Stiff Wire.

The Medtronic Endurant IFU are much less specific; under ''materials required,'' it states ''In addition to guidewires used for accessing the vessel, 0.035 inch (0.89 mm) diameter guidewires or equivalents must be used to maximally support the Endurant Delivery System into the aortic vasculature.''[6] The Medtronic Talent Thoracic stent-graft IFU are similarly vague in stating under ''Materials Recommended for Device Implantation'' that ''Stiff 0.035-inch diameter guidewires to support the Captivia Delivery System in the aortic vasculature should be used.''[7]

The various instructions for Zenith grafts make different recommendations for the delivery guidewire. The IFU for the Zenith Fenestrated graft[8] (William A. Cook Australia Pty. Ltd.) and the Zenith TX2 thoracic graft[9] (Cook Ireland Ltd.) recommend the use of ''.035inch extra, stiff wire guide, 260cm: for example: Cook Amplatz Ultra-Stiff Wire Guides (AUS). Cook Lunderquist Extra-Stiff Wire Guides (LES)''. The IFU for the Zenith Flex[10] (Cook Ireland Ltd.) also recommend the use of ''.035inch extra, stiff wire guide, 260cm: for example: Cook Lunderquist extra stiff wire guide.''

From these IFU, a physician could reasonably question the definition of an extra stiff wire, and depending on which instructions were consulted, the interventionist may consider only the LES to be an extra stiff wire or may also consider the AUS to be an extra stiff wire. To add to the confusion, one could also reasonably ask if the Amplatz Extra Stiff wire, which our results show has a lower flexural modulus than the AUS, is also an extra stiff wire guide. Although the LES and AES are both extra stiff wires, they have a 5-fold difference in flexural modulus.

Our investigation indicates that the absence of accepted nomenclature with respect to

guidewire stiffness is confusing, and companies use descriptive terms for wires without any scientific basis for their choice. Without prior experience or without handling a series of wires, a physician will struggle to interpret the relevance of the range of descriptors used. We recommend that manufacturers label guidewires with specific quantitative information about guidewire flexibility, which might be either its flexural modulus or some simpler unit that is based on this property. We also recommend that regulatory and licensing authorities responsible for approving medical devices should demand, where possible, that manufacturers provide specific rather than generic lists of ancillary components such as guidewires.

Physicians should read the IFU for all endovascular products and consider how to respond to a specific guidewire recommendation. Options include ordering and using the specified guidewire or using an alternative guidewire and accepting that this is off-label use. Another option is for a physician who wishes to use an alternative guidewire to defer using the product until the manufacturer confirms that their product may be used with this guidewire.

Limitations

None of the guidewires tested was made of nitinol, and all the measurements were performed at room temperature. It is possible that the flexural modulus may not be the same at 37°C, but the difference is likely to be small. Equations 1 and 2 are usually applied to homogeneous structures, while the guidewires are constructed with a solid inner wire core and a separate outer coil of fine wire. The equations may not be strictly applicable, and the true flexural moduli may be slightly different than those presented. However, all tests were conducted in the same way on guidewires of the same diameter, so the flexural stiffness is therefore comparable.

Conclusion

The descriptors of stiffness in guidewire names have little correlation with the measured flexural modulus. Two guidewires with the description ''extra stiff'' can have a 5-fold difference in flexural modulus. We recommend that guidewire catalogues and packaging include the flexural modulus and that device manufacturers amend the IFU accordingly.

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