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...” Schummer (2015).

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.

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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.

Reference:

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