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Mechanical Testing of Infusion and Drug-Delivery Medical Devices in the United States: A Narrative Review of Methods, Standards, and Gaps

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Abstract: Mechanical testing is fundamental to establishing the safety and performance of infusion and drug-delivery medical devices (IDDs) within the United States regulatory framework. These systems, including infusion pumps, tubing assemblies, connectors, vascular access devices, and intravascular catheters, depend on mechanical integrity to maintain functional reliability under clinically relevant loading and environmental conditions. This review examines mechanical testing practices for IDDs in the United States through the perspectives of FDA regulatory expectations, FDA-recognized consensus standards, and representative experimental literature. Prevailing methodologies, including tensile and bond strength testing, fatigue and cycling loading assessment, burst pressure and leakage evaluation, environmental conditioning, and simulated-use protocols, are synthesized and critically analysed. The review identifies substantial methodological variability in test configurations, boundary conditions, environmental parameters, and definitions of mechanical failure. Inconsistent procedural reporting and limited disclosure of test implementation strategies emerge as recurrent limitations that constrain reproducibility and cross-study comparability. These challenges reflect the inherent flexibility of performance-based regulatory and standards frameworks rather than regulatory absence. Strengthening procedural transparency, clarifying failure criteria, and expanding system-level and interface-focused evaluation strategies represent practical opportunities to enhance the interpretability and translational relevance of mechanical testing evidence while preserving the innovation-enabling character of the U.S. device evaluation paradigm.

Keywords: Mechanical testing; infusion and drug-delivery devices; bench performance testing; FDA regulatory science; Quality Management System Regulation (QMSR).

INTRODUCTION

Infusion and drug-delivery medical devices (IDDs) such as hospital and ambulatory infusion pumps, insulin pumps/patch pumps, on-body injectors, and related fluid-path delivery assemblies are integral to the healthcare infrastructure of the United States, as these help with the controlled delivery of therapeutic agents in acute, chronic, and critical care settings. Following the consistently high number of safety and performance-related complaints associated with infusion pump systems, the U.S. Food and Drug Administration (FDA) initiated the Infusion Pump Improvement Initiative (2010). This was aimed at enhancing regulation, promoting design changes, and raising awareness of the risks associated with using infusion pumps (U.S. Food and Drug Administration, 2010).

Mechanical integrity is directly connected to functional reliability: U.S.-based studies of infusion pump recalls indicate that defects and failures in device performance and component integrity can lead to clinically significant risks and outcomes (Gao *et al.*, 2019). In line with this, a large U.S. hospital safety data reported medication errors associated with infusion pumps across 132 Pennsylvania hospitals, which indicates clinical malfunction and usage risk trends in the clinical settings (Taylor & Jones, 2019).

Mechanical performance testing is incorporated into the U.S. regulatory framework as part of a broader category of non-clinical bench performance testing expectations that support determinations of device safety and performance across a variety of premarket pathways (e.g., 510 (k), PMA, De Novo). The bench testing guidance by the FDA outlines the information that the FDA expects such as a description of the test setup, pre-determined acceptance criteria, results, deviations, and analysis plans in test report summaries, protocols, and complete reports contained in premarket submissions (U.S. Food and Drug Administration, 2019). Targeting infusion pumps specifically, the FDA's Total Product Life Cycle (TPLC) guidance emphasizes risk mitigation across the product life cycle and identifies factors that manufacturers should consider throughout device development and post-market use. Thus, anchoring the significance of high-quality and rigorous evidence to address known and emerging risks in infusion pump systems (U.S. Food and Drug Administration, 2014).

The use of voluntary consensus standards such as standards devised by International Organization for Standardization (ISO), Advancing Standards Transforming Markets International (ASTM), International Electrotechnical Commission (IEC),

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and the Association for the Advancement of Medical Instrumentation (AAMI) which the FDA relies on, may be used by manufacturers to demonstrate conformity with established performance and safety benchmarks in regulatory submissions. The FDA's guidance on the appropriate use of voluntary consensus standards describes how manufacturers may rely on recognized standards and how conformity to those standards should be documented in pre-market submissions. In addition, the FDA maintains a publicly accessible database of FDA-recognized consensus standards, for which manufacturers may submit a Declaration of Conformity when applicable (U.S. Food and Drug Administration, 2018). In infusion pump evaluation, AAMI TIR101:2021 (Fluid delivery performance testing of infusion pumps), which is recognized by the U.S Food and Drug Administration, provides technical guidance intended to support clinically relevant assessment of fluid delivery performance under varying use conditions. The document offers a structured framework for considering test conditions, performance metrics, and use-related factors without imposing test requirements (U.S. Food and Drug Administration, 2022).

Design verification and design validation activities are governed by the Quality System Regulation (21 CFR Part 820) under the FDA's design control paradigm. The forthcoming Quality Management System Regulation (QMSR), effective February 2, 2026, will align U.S. quality system requirements more closely with ISO 13485 (U.S. Food and Drug Administration, 2024a). This transition further elevates the need for transparent, reproducible mechanical and bench testing practices that can withstand both regulatory scrutiny and scientific evaluation, particularly as device architecture evolves.

Despite this extensive standards-and-guidance architecture, the peer-reviewed literature explaining how mechanical tests are implemented in practice with IDDs (with sufficient procedural transparency to enable reproducibility and cross-study comparability) is sparse. This is not merely a "lack of papers," but a structural aspect of the field: many of the methods are codified in standards, test protocols, and manufacturer verification documentation as opposed to the open literature. Concurrently, in those cases where experimental studies are available, there can be a significant methodological variation in test conditions, measurement approaches, and definitions of performance. These are issues that become more consequential as IDD technologies contain miniaturized mechanisms and complex polymeric/ multi-material structures and drug-device interactions that can induce scale-dependent failure modes and degradation pathways.

Accordingly, this article presents a narrative review of the mechanical testing of infusion and drug-delivery medical devices in the United States. This review focuses on mechanical and structural evaluation within the U. S. regulatory and engineering context; software algorithms, electronic control systems, and user-interface elements are outside the scope except where they directly influence mechanical performance or structural integrity. Consistent with the regulatory-science nature of this topic, evidence identification prioritized FDA guidance documents, FDA-recognized consensus standards, and representative peer-reviewed experimental and safety studies rather than exhaustive retrieval of empirical trials. Sources were identified through targeted searches of PubMed/MEDLINE, IEEE Xplore, Web of Science, and Google Scholar, supplemented by review of FDA guidance materials, the FDA Recognized Consensus Standards database, and relevant regulatory provisions. By synthesizing these sources, the review (i) maps prevailing mechanical and bench-testing approaches relevant to IDDs, (ii) identifies methodological and reporting gaps that limit interpretability and comparability, and (iii) highlights actionable opportunities to strengthen procedural transparency and harmonization to support safer and more reliable drug-delivery technologies.

UNITED STATES REGULATORY AND STANDARDS FOR MECHANICAL TESTING OF INFUSION AND DRUG DELIVERY MEDICAL DEVICES

The infusion and drug-delivery medical device (IDD) testing in the United States is regulated by a multi-layered system, which incorporates federal regulations, FDA guidance, and voluntary consensus standards. This framework is used throughout the entire drug-delivery pathway, including infusion pumps, tubing and connectors, vascular access devices, and intravascular catheters. This aligns with the FDA's system-level risk-based evaluation approach.

Pre-market Regulatory Pathways and the Role of Bench Evidence

The U.S. Food and Drug Administration reviews IDDs using one of a variety of premarket

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pathways, which are most often Premarket Notification (510 (k)), Premarket Approval (PMA), or De Novo classification, based on the risks of the device and the availability of predicates. In all pathways, a non-clinical bench test is one of the fundamental components of the evidence that supports the claim of safety and performance of the device. The FDA guidance titled "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions" describes the information that the FDA expects manufacturers to include in submitting bench testing information These include the objectives of the test, test protocols, test conditions, predefined acceptance criteria, test results, deviations, and test analysis methods (U.S. Food and Drug Administration, 2019). Mechanical testing, such as evaluation of structural integrity, resistance to mechanical loading, durability, leakage, and interface robustness, falls squarely within this non-clinical bench testing paradigm when such characteristics are relevant to identified device risks. In the case of infusion pumps, the Infusion Pumps Total Product Life Cycle (TPLC) guidance of the FDA also places the bench testing in a broader lifecycle framework encompassing design, verification, validation, and postmarketing surveillance (U.S. Food and Drug Administration, 2014). Though the TPLC guidance does not prescribe detailed mechanical test procedures, it highlights the necessity of extensive evidence to cover the known failure modes and performance risks associated with infusion systems, a fact that underlines the importance of mechanical testing within a risk-based evaluation program.

Quality System Regulation and Design Controls.

The implementation of mechanical testing activities is present in the manufacturer-directed quality system as needed under the Quality System Regulation (QSR), specifically Section 820.30 (Design Controls) of Title 21 of the Code of Federal Regulations (CFR Part 820) (U.S. Food and Drug Administration, 2024a). Manufacturers do so under the design control requirements of 21 CFR §820.30, whereby manufacturers are required to establish and maintain design verification and design validation procedures. For instance, ensuring design outputs satisfy design input requirements, and that devices are within the requirements and intended use of the user (U.S. Food and Drug Administration, 2025). The mechanical integrity test, which encompasses tensile strength, fatigue resistance, burst pressure, and interface integrity, is usually applied to verify design and, in certain instances, design validation. Notably, the QSR specifies what manufacturers have to demonstrate but does not prescribe how individual mechanical tests should be performed, leaving methodological decisions to manufacturers within a risk-based framework. The FDA has finalized a transition from the QSR to the Quality Management System Regulation (QMSR), which will be enforced on February 2, 2026, and will allow U.S. requirements to more closely align with ISO 13485 (U.S. Food and Drug Administration, 2024b). While this transition does not fundamentally change expectations for mechanical testing, it further emphasizes documented, reproducible verification and validation practices within a comprehensive quality management system.

FDA-Recognized Voluntary Consensus Standards

The U.S. regulatory system in relation to medical device review is highly characterized by the Voluntary Consensus Standards Program of the FDA, which was granted in Section 514 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §360d) (U.S. Food and Drug Administration, 2020). Within this program, the FDA acknowledges standards that have been established by other organizations like the International Organization of Standardization (ISO), ASTM International, the International Electrotechnical Commission (IEC), and the Association of Advancement of Medical Instrumentation (AAMI). The FDA has a publicly accessible list of accepted consensus standards that can be referenced by manufacturers in premarket submissions. FDA guidance on the Appropriate Use of Voluntary Consensus Standards in Premarket Submissions makes it clear that voluntary consensus standards may be applied to demonstrate compliance with performance benchmarks and, in most cases, this may be done with a "Declaration of Conformity". However, it is important to remember that the manufacturers are still not relieved of the burden to ensure that the testing is sufficient to address risks unique to the device (U.S. Food and Drug Administration, 2018). It is important to note that most standards applicable to IDDs are performance-based or non-prescriptive, including performance requirements or acceptance criteria, but they provide little or no detail on the conduct of mechanical tests in practice.

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Standards Applicable to Infusion and Drug-Delivery Systems.

Within the FDA-recognized standards ecosystem, various standards apply to different components of the IDD system. The IEC 60601-2-24 is concerned mostly with infusion pumps and controllers and provides performance and safety requirements that outline the key constituents of an infusion pump and controller. Besides, AAMI TIR101:2021 (Fluid Delivery Performance Testing of Infusion Pumps) offers a clinically focused paradigm of defining the infusion accuracy and performance, and has been officially accepted by the FDA (U.S. Food and Drug Administration, 2022). Mechanical test methods based on ASTM and ISO standards of tensile strength, fatigue, burst pressure, and leakage, and material durability are often utilized in the evaluation of tubing, connectors, vascular access devices, and intravascular catheters. Such standards are often implemented on a component level and integrated with system-level strategies on the entire drug-delivery pathway. The FDA does not require any standards or test procedures. Instead, the manufacturers can choose the right standards or even other methods if the evidence, which will be obtained, will suffice to make the claims related to safety and performance (U.S. Food and Drug Administration, 2020b, 2020d).

Implication to Mechanical Testing Practice.

Taken together, the U.S. regulatory and standards framework establishes clear expectations regarding evidence while allowing substantial methodological flexibility. It is innovative and flexible to the architecture of different devices, but it also puts a lot of burden on the manufacturer and investigators to explain why they chose a certain methodology and to report how the standards are applied (Graham & Estes, 2009). This flexibility, as the following sections of this review will show, has significant implications for consistency, transparency, and comparability within the group of mechanical testing studies of IDDs (Teli *et al*., 2024). The situation where regulatory and standards are clearly understood is the key to a critical evaluation of the practice of testing nowadays and to finding the prospects of better rigor and harmonization.

Figure 1 presents a conceptual framework illustrating the relationship between the U.S. regulatory and standards environment, prevailing mechanical testing practices for infusion and drug-delivery medical devices (IDDs), and the translational gaps identified in this review.

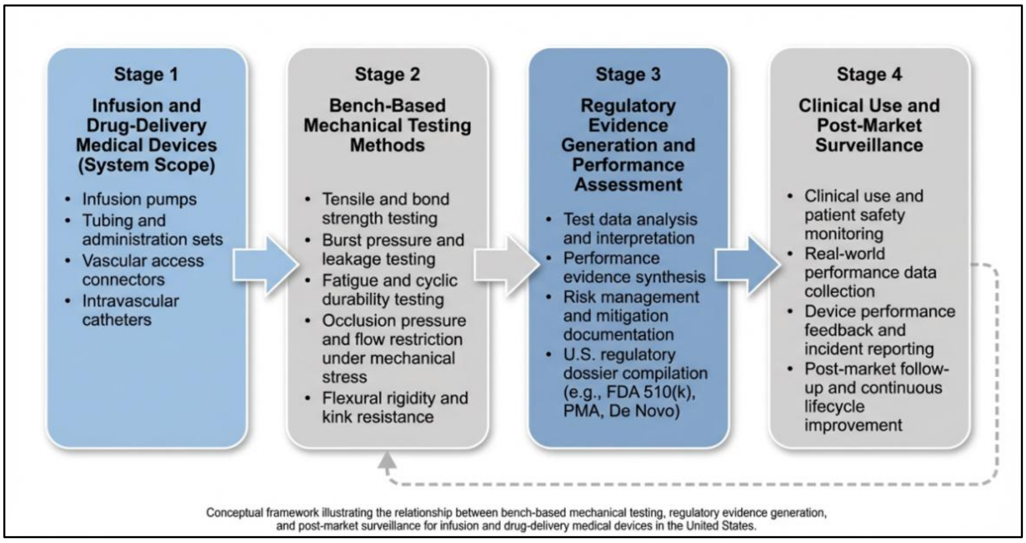

Figure 1: Conceptual Framewrok illustrating the relationship between bench based mechanical testing regulatory evidence gernation and performance assessment and clinical use and post market surveillance

MECHANICAL TESTING METHODOLOGIES OF INFUSION AND DRUG-DELIVERY MEDICAL DEVICES.

In the United States, mechanical testing of infusion and drug-delivery medical devices (IDDs) encompasses a range of bench-based experimental methods that are aimed at evaluating the structural integrity, durability, and functional robustness of devices and components under simulated conditions of use. Mechanical testing methods are employed throughout the drug-delivery pathway, encompassing infusion pumps, tubing systems, connectors, vascular access devices, and intravascular catheters. Rather than being

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explicitly prescribed by regulation, the choice of specific test approaches is typically informed by FDA guidance and recognized consensus standards.

Bench-Based Mechanical Testing in IDD Evaluation

FDA guidance on non-clinical bench performance testing emphasizes that bench studies should be structured to cover both device-specific risk factors as well as to augment assertions of safety and performance in premarket submissions (U.S. Food and Drug Administration, 2019).

Within this framework, mechanical testing serves multiple fundamental purposes: (i) verification of structural integrity, (ii) assessment of resistance to mechanical loading, (iii) evaluation of durability under repeated or sustained stresses, and (iv) confirmation that components maintain functional performance under expected clinical conditions. In the case of IDDs, the tests are especially applicable due to continuous or prolonged mechanical stress imposed during usage, and these include pressurization, bending, torsion, cyclic loading, and contact with fluids.

The Infusion Pumps Total Product Life Cycle (TPLC) guidance by the FDA places these bench testing activities within a broader product life cycle framework, emphasizing the importance of testing strategies that consider both device performance and potential degradation over time. (U.S. Food and Drug Administration, 2014).

Tensile and Pull-Out Testing

Tensile tests are commonly used in assessing the mechanical integrity such as tubing, catheter shafts, connectors, hubs, and bonded or welded joints of IDD components subjected to axial loading (Esqueda Hernández, 2022). Practically, tensile tests are used to determine ultimate tensile strength, elongation at break, and resistance to disconnection or pull-out at interfaces (Amstutz *et al*., 2021a). Common tensile testing standards on polymers and elastomeric materials used in IDDs are ASTM D638 (plastics) and ASTM D412 (rubber and elastomers), both of which are FDA-recognized consensus standards and specify allowable ranges of test speeds and specimen configurations (ASTM International, 2021, 2022a; U.S. Food and Drug Administration, 2022). It is important to note that these standards stipulate acceptance parameters and broad principles of tests, but give substantial latitude on test parameters, such as crosshead speed, specimen geometry, and conditioning. Consequently, tensile tests reported in peer-reviewed articles on IDD components often show significant differences in execution, even when nominally the same standard is used (Amstutz *et al*., 2021a; Gillis *et al*., 2018; Gorski, 2024; International Organization for Standardization, 2013). From a critical perspective, the definition of failure also differs depending on the studies and test protocols. Mechanical failure can be characterized as initial yield, complete fracture, or loss of functional integrity (e.g., connector separation or leakage), with limited justification provided in many reports for the selected criterion. This inconsistency makes it hard to compare tensile performance across devices and studies (U.S. Food and Drug Administration, 2022).

Fatigue and Cyclic Durability Testing

Fatigue testing is used to evaluate the ability of IDD components to withstand repeated or cyclic mechanical loading representative of clinical use, such as repeated pressurization of infusion tubing, bending of catheters, or cyclic mechanical actuation under simulated use conditions (Hartquist *et al*., 2021; U.S. Food and Drug Administration, 2019). The fatigue performance is of special importance when dealing with long-term or ambulatory infusion systems, where devices may be subjected to thousands or millions of load cycles (Marrey *et al*., 2018).

Consensus standards addressing fatigue behaviour of polymeric and elastomeric components (such as ASTM D7791 on plastics fatigue testing) offer generic recommendations on the concept of the test and reporting, but do not provide clinically specific loading profiles of IDDs (ASTM International, 2022b). In reality, fatigue test protocols for IDDs are commonly designed by manufacturers or researchers in a custom manner, reflecting the expected use conditions (U.S. Food and Drug Administration, 2018, 2019). Nevertheless, peer-reviewed reports often do not give much information about loads, the number of cycles, and the choice of waveforms or the argument of fatigue limits adopted. Fracture, leakage, loss of stiffness, or performance deviation may be considered a failure, and this also adds to the heterogeneity of the methodology.

Burst Pressure and Leakage Test.

Burst pressure testing is an important technique for determining how fluid-path components, including tubing, connectors, catheters, and reservoirs, can resist internal pressurization without rupture

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(ASTM International, 2018; International Organization for Standardization, 2023b). Leakage testing complements burst testing by evaluating integrity under sub-burst pressures that correspond to normal or worst-case operating conditions (International Organization for Standardization, 2023b; van Heeren *et al*., 2022). Commonly used standards of pressure testing are ISO 8536-8 and component-related ASTM and ISO standards addressing pressure resistance and leakage (International Organization for Standardization, 2023a). In the case of the polymeric tubing and the catheter systems, pressure testing methods are usually based on material standards or derived from internal manufacturer protocols (ASTM International, 2018; U.S. Food and Drug Administration, 2019). The guidance by the FDA does not insist on the use of a particular burst or leakage test, but rather anticipates that the dangers of pressure be handled with relevant bench evidence (U.S. Food and Drug Administration, 2010; U.S. Food and Drug Administration, 2019). Very importantly, the test conditions, including pressure rate, dwell time, test medium (air or liquid), and temperature, have not been adequately reported in the literature, although the factors have been known to affect the measured burst strength and leakage behaviour (Amstutz *et al*., 2021b; ASTM International, 2018). This is not very transparent, which constrains reproducibility and cross-study comparison (Reyes & Van Heeren, 2019; U.S. Food and Drug Administration, 2019).

Environmental Conditioning and Simulated Use tests.

Environmental conditioning is often incorporated in the mechanical testing of IDDs to reproduce clinical conditions such as exposure to fluids, high temperatures, and prolonged dwell time (ASTM International, 2020; International Organization for Standardization, 2023b). Depending on the type of device and its intended use, testing can be performed in ambient air in a laboratory or fluid immersion at physiological temperature (typically around 37 °C) (Amstutz *et al*., 2021b; International Organization for Standardization, 2023a). Although some standards suggest that specimens should be conditioned before testing, the decision on which environment to use and for what duration to use in conditioning is often at the discretion of the test designer (U.S. Food and Drug Administration, 2018). Therefore, reported studies are inconsistent about the type of tests performed, be it dry or wet, room temperature or body temperature.

Simulated use testing, which combines mechanical loading with fluid flow, pressurization, plus the operation of the device, is highlighted in the FDA infusion pump guidance as a method of system-level testing. Nevertheless, simulated use protocols are hardly ever standardized and are frequently described at a high level in published studies, limiting insight into how closely test conditions reflect real-world clinical use (Giuliano *et al*., 2021; U.S. Food and Drug Administration, 2014).

Summary and Critical Observations.

Across the mechanical testing approaches discussed, including tensile and bond strength evaluation, fatigue and cyclic loading assessment, burst pressure and leakage testing, environmental conditioning, and simulated-use protocols, a coherent methodological landscape is observed in the evaluation of IDDs. These testing strategies collectively aim to characterize device integrity, durability, and performance under conditions intended to approximate clinical use and expected loading environments. Mechanical testing methods are applied at both component and subsystem levels, reflecting the modular architecture of many IDDs, including tubing assemblies, connectors, vascular access devices, and catheter structures. The selection and configuration of test parameters, boundary conditions, and environmental factors are typically guided by FDA-recognized consensus standards and FDA-guidance documents, which emphasize performance evaluation within a risk-based and use context framework. Taken together, these methodologies illustrate the central role of non-clinical bench and mechanical testing in establishing device performance expectations before clinical deployment. The variability in how such methods are implemented and documented, along with their implications for interpretability and comparability, is examined in detail in the following section

Table 1 summarizes commonly employed mechanical testing methods for infusion and drug-delivery medical devices (IDDs), including infusion pumps, tubing, connectors, vascular access devices, and intravascular catheters. The table outlines typical device applications, frequently reported performance metrics, and recurring sources of methodological variability or reporting gaps observed across the peer-reviewed literature and standards-informed testing practices.

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Table 1 Common Mechanical Testing Methods for Infusion and Drug-Delivery Medical Devices and Associated Methodological Variability

Mechanical Test Type	Typical Device Applications	Commonly Reported Performance Metrics	Frequently Observed Methodological Variability or Gaps
Tensile & Bond Strength	Catheter shafts, luer connectors, tubing-to-hub joints, adhesive bonds	Peak force at failure (N), elongation at break (%), and elastic modulus	Inconsistent crosshead speeds (strain rates), variable use of bollard vs. serrated grips, and limited reporting of gauge length and alignment controls
Burst Pressure	Multi-lumen catheters, infusion tubing, administration sets, syringes	Maximum internal pressure before failure (kPa or psi), failure location	Variability in pressure ramp rates; inconsistent environmental conditioning (dry vs. aqueous immersion, temperature control)
Fatigue & Cyclic Loading	Peristaltic pump tubing, vascular access ports, and long-term indwelling catheters	Cycles to failure, changes in mechanical integrity over time	Lack of standardized worst-case cycle counts; inconsistent loading frequencies, waveforms, and termination criteria
Kink Resistance & Flexibility	Peripheral and central venous catheters, kink-resistant tubing	Minimum kink radius (mm), flexural rigidity, force required to induce occlusion	Absence of standardized mandrel diameters or fixtures; variability in kink detection methods (visual inspection vs. flow-based criteria)
Occlusion Pressure & Flow Restriction Under Mechanical Stress	Infusion tubing, volumetric infusion pumps, syringe delivery systems	Occlusion pressure thresholds, time to occlusion alarm activation	Inconsistent back-pressure settings; variability in fluid properties and test compliance; limited transparency in test setup and data windowing

METHODOLOGICAL GAPS AND SOURCES OF VARIABILITY IN MECHANICAL TESTING OF INFUSION AND DRUG-DELIVERY MEDICAL DEVICES.

Despite the existence of FDA guidance and FDA-recognized consensus standards, the current practice of mechanical testing of infusion and drug-delivery medical devices (IDDs) in the United States exhibits persistent methodology gaps that limit the reproducibility, cross-study comparison, and translational applicability (Hartquist *et al*., 2021; van Heeren *et al*., 2022). These gaps do not arise from regulatory absence but rather from the performance-based and non-prescriptive nature of the prevailing framework, which affords flexibility while providing limited procedural standardization (U.S. Food and Drug Administration, 2014, 2018, 2019, 2024a).

Non-Prescriptive Standards and Procedural Latitude.

FDA guidance on the appropriate use of voluntary consensus standards explicitly recognizes that standards are intended to define performance expectations rather than mandate specific test procedures (U.S. Food and Drug Administration, 2018). Although this methodology favors innovation and the ability to accommodate both diverse architectures of devices, it also enables manufacturers and researchers to have broad discretion in matters of test parameters, fixtures, loading profiles, environmental conditions, and the definition of failures (U.S. Food and Drug Administration, 2018, 2019). Due to this, mechanical tests that are formally conducted to the same standard can vary significantly in implementation, making meaningful comparisons of results between devices or studies impossible (Reyes & Van Heeren, 2019; U.S. Food and Drug Administration, 2019). This procedural latitude is especially impactful in the case of IDDs, in which even minor geometrical, material, or interface design variations can result in nonlinear mechanical behaviour, which is sensitive to test conditions (Amstutz *et al*., 2021b; Hartquist *et al*., 2021).

Variability in Test Parameters and Boundary Conditions.

In peer-reviewed literatures and standards-informed testing techniques, there is a significant difference in the experimental designs in terms of the basic mechanical parameters (U.S. Food and

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Drug Administration, 2019). Tensile tests of tubing, connectors, or catheter components may be conducted at crosshead speeds spanning quasi-static to highly dynamic regimes, despite the recognized rate-dependence of polymeric and elastomeric materials (ASTM International, 2016; Jenket *et al*., 2019; Upadhyay *et al*., 2021). Fatigue tests similarly differ in applied load amplitudes, cycle counts, waveform selection, and run-out criteria (ASTM International, 2017). Consensus standards such as ASTM D638 and ASTM D412 permit broad ranges of test speeds and specimen configurations, leaving investigators to determine what constitutes clinically relevant loading (ASTM International, 2016, 2021). Nonetheless, numerous studies published fail to support such decisions and to explicitly associate them with the conditions of intended use, which leaves the question of whether the presented findings have any clinical implications.

Boundary conditions, such as grip design, fixture compliance, alignment, and interface constraints, are frequently underreported despite their well-established influence on measured mechanical responses and observed failure modes. Variations in gripping mechanisms or fixture stiffness can alter local stress distributions, introduce unintended bending or shear components, and produce measurement artifacts that affect estimates of strength, stiffness and deformation behaviour. Similarly, misalignment or uncontrolled interface constraints may lead to premature failure, non-representative fracture patterns, or exaggerated variability in reported mechanical properties. These effects are particularly consequential for polymeric and multi-material device components, whose mechanical behaviour is highly sensitive to loading configuration and constraint conditions. Failure to clearly document boundary conditions therefore complicates interpretation of test results, limits reproducibility, and undermines meaningful comparison across studies (Christ & Swanson, 1976; Jenket *et al*., 2019).

Environmental Conditioning and Physiological Relevance.

Environmental conditioning represents a persistent source of methodological inconsistency in the mechanical testing of IDDs. Although FDA guidance emphasizes that bench testing should reflect conditions representative of intended clinical use, published studies frequently vary in their selection and reporting of environmental parameters, including test media., temperature, and specimen conditioning protocols (U.S. Food and Drug Administration, 2019). IDD components may be evaluated under ambient laboratory conditions, fluid immersion, or elevated temperatures approximating physiological environments such as 37 °C, each of which can influence measured behaviour (Amstutz *et al*., 2021b; International Organization for Standardization, 2023b). However, the rationale for selecting specific environmental conditions, conditioning durations, or test media is often insufficiently explained, and critical details are inconsistently disclosed across studies (Hartquist *et al*., 2021). This variability constitutes a significant methodological gap because polymeric materials and bonded interfaces, which are common in IDDs, exhibit temperature-and environment-dependent mechanical responses. Inconsistent environmental conditioning can therefore produce non-comparable results and obscure clinically relevant degradation mechanisms. Despite these know effects, environmental parameters remain underreported in many experimental investigations, limiting reproducibility and cross-study interpretation(Amstutz *et al*., 2021b; ASTM International, 2018; Jenket *et al*., 2019)

Inconsistent Definitions of Mechanical Failure.

A further source of heterogeneity lies in how mechanical failure is defined and interpreted (Reyes & Van Heeren, 2019; U.S. Food and Drug Administration, 2019). Depending on the study or test protocol, failure may be defined as initial yield or onset of plastic deformation, complete fracture or rupture, leakage onset, or loss of functional performance (e.g., flow deviation, disconnection) (International Organization for Standardization, 2021, 2023b). FDA bench testing guidance emphasizes the importance of predefined acceptance criteria, but does not dictate how failure thresholds should be selected (U.S. Food and Drug Administration, 2019). In practice, many studies report ultimate strength or burst pressure without contextualizing whether these endpoints correspond to clinically meaningful failure modes (ASTM International, 2018; Hartquist *et al*., 2021). The absence of harmonized failure definitions complicates efforts to compare mechanical robustness across devices and may obscure early indicators of functional degradation that precede catastrophic failure (Jenket *et al*., 2019; U.S. Food and Drug Administration, 2014).

Limited Procedural Transparency in Peer-Reviewed Studies.

Another general finding in the literature of IDD is that the disclosure of procedure remains sparse,

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even where studies cite the FDA-approved consensus standards (Hartquist *et al*., 2021). Most of the publications refer to standards by name without indicating which sections or test options were used, how deviations were handled, or whether alternative methods were employed (U.S. Food and Drug Administration, 2018). This is contrary to the expectations of the FDA regarding regulatory submissions, as they need to be supported with detailed protocols and reporting to support review (U.S. Food and Drug Administration, 2019). The resultant lack of links between regulatory documentation and published literature restricts reproducibility and prevents the potential of independent investigators to engage critically or replicate reported studies (Reyes & Van Heeren, 2019; U.S. Food and Drug Administration, 2019).

Implication

All these methodological gaps weaken the external validity of mechanical testing research and make it difficult to replicate and extrapolate laboratory bench-level research results to clinical practice (U.S. Food and Drug Administration, 2014, 2019). The inconsistency in test execution, coupled with insufficient reporting, makes it difficult to discern whether observed differences in mechanical performance reflect true device characteristics or artifacts of experimental design (U.S. Food and Drug Administration, 2019). These challenges magnify as IDD technologies, evolve toward greater miniaturization, multi-material integration, and prolonged use durations, thus, features that introduce complex mechanical behaviours not readily captured by legacy

OPPORTUNITIES FOR HARMONIZATION AND IMPROVED MECHANICAL TESTING PRACTICES

The identified methodological variability in the previous sections does not reflect the weaknesses in the regulatory framework of the U.S. but highlights the opportunities in enhancing the way in which mechanical testing of infusion and drug-delivery medical devices (IDDs) is designed, reported, and interpreted in practice. Notably, all suggested enhancements should preserve the methodological flexibility inherent in performance-based regulatory and consensus standards frameworks, while improving transparency, reproducibility, and clinical relevance.

Enhancing Procedural Transparency Without Prescriptive Mandates.

In the FDA guidance on non-clinical bench performance testing, documentation of test protocols, acceptance criteria, and deviations of the test is critical in regulatory submissions and is to be clearly documented (U.S. Food and Drug Administration, 2019). This level of procedural transparency is, however, not usually reflected in the peer-reviewed literature (Hartquist *et al*., 2021). A key opportunity lies in improving reporting practices, rather than imposing new test requirements. Journals and investigators could adopt reporting norms that require explicit disclosure of test parameters (e.g., loading rates, pressurization rates), environmental conditions (temperature, immersion media), conditioning and specimen preparation, and preset failure standards (U.S. Food and Drug Administration, 2018, 2019). Such disclosure would bring published studies into closer agreement with FDA expectations for regulatory evidence without being selective on the methods of test.

Clarifying Failure Definitions Associated with Functional Performance.

The guidance on bench testing given by the FDA emphasizes that a predetermined acceptance criterion is essential, but does not specify how failure is to be determined (U.S. Food and Drug Administration, 2019). There is an opportunity to be more explicit in defining mechanical failure in terms of functional performance, especially in the case of IDDs, where the onset of degradation can be determined before disastrous failure (U.S. Food and Drug Administration, 2014). For example, leakage thresholds are more clinically applicable than the ultimate burst pressure (U.S. Food and Drug Administration, 2024c). The material tensile strength may not reflect real-life hazards, but connector disengagement forces may be an improved metric, and alterations of stiffness or compliance can be a sign of future loss of performance (International Organization for Standardization, 2013, 2021). Consensus standards and technical reports (e.g., AAMI guidance documents) could provide illustrative, non-binding examples of function-linked failure criteria to guide test design without constraining innovation (Schirn, 2023).

Greater Use of System-Level and Interface-Focused Testing.

The FDA's infusion pump Total Product Life Cycle (TPLC) guidance focuses on system-level risk mitigation rather than that of a single

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component (U.S. Food and Drug Administration, 2014). Mechanical testing practice, however, is typically component-based, especially for tubing, connectors, vascular access devices, and intravascular catheters (International Organization for Standardization, 2013, 2021; U.S. Food and Drug Administration, 2019). Since most real-life failures are at interfaces, pump-tubing connections, catheter hubs, and luer fittings, more system-level and interface-based testing is a significant scope of improvement (International Organization for Standardization, 2021; U.S. Food and Drug Administration, 2024c). A combination of mechanical loading, fluid flow, pressurized, and environmental conditioning by simulated-use testing would be better suited to capture clinically relevant failure modes, which is in line with the FDA philosophy of risk-based evaluation (U.S. Food and Drug Administration, 2019).

Leveraging FDA-Recognized Standards More Transparently

The FDA encourages the use of recognized voluntary consensus standards to demonstrate conformity with performance benchmarks and streamline premarket review (U.S. Food and Drug Administration, 2018). However, many peer-reviewed studies often reference standards only by name without specifying which clauses or test options were applied, how deviations were handled, or whether alternative methods were used. A practical opportunity exists for investigators to explicitly identify which clauses or test options within a cited standard were applied, to describe any deviations or adaptations made to the prescribed methods, and to justify test parameter selections in relation to intended device use. This would not only enhance reproducibility, but also make the way performance-based standards are being operationalized in practice more transparent (U.S. Food and Drug Administration, 2018).

Aligning Mechanical Testing with Emerging Device Complexity

As IDD technologies increasingly incorporate miniaturized components, advanced polymeric materials, and multi-material interfaces, conventional mechanical testing paradigms may not fully capture emerging degradation pathways and interface-driven failure mechanisms (U.S. Food and Drug Administration, 2020c). FDA's transition from the legacy Quality System Regulation to the Quality Management System Regulation (QMSR) underscores the increasing emphasis on quality system harmonization, risk management integration, systematic approaches to device quality and performance, consistent with modern quality management expectations (U.S. Food and Drug Administration, 2026). Opportunities exist to integrate accelerated aging with mechanical testing, assess degradation-induced changes in mechanical behaviour, and evaluate the cumulative effects of mechanical, thermal, and chemical stressors. These methods are consistent with the current framework of the FDA and may be implemented without new regulatory mandates (U.S. Food and Drug Administration, 2020a).

CONCLUSIONS AND FUTURE DIRECTIONS

This review examined the mechanical testing of IDDs in the United States within the context of FDA regulatory expectations, FDA-recognized consensus standards, and representative empirical evidence. Mechanical and bench testing remain central to the non-clinical evidence framework supporting device safety and performance in U.S premarket evaluation(U.S. Food and Drug Administration, 2019). The U.S regulatory system, grounded in design controls and performance-based principles, establishes evidentiary expectations without prescribing specific test methodologies, thereby preserving flexibility across diverse device architectures and technological advancements(U.S. Food and Drug Administration, 2014, 2018, 2024c). Despite this robust regulatory and standards infrastructure, the review identified persistent methodological variability and reporting limitations in published mechanical testing studies. Differences in test parameters, environmental conditioning, boundary conditions, and failure definitions, coupled with limited procedural transparency, constrain reproducibility, cross-study comparison, and interpretation of translational relevance. These challenges do not reflect regulatory absence but rather the inherent latitude of performance-based frameworks, which place responsibility on manufacturers and investigators to justify methodological decisions and document testing practices(U.S. Food and Drug Administration, 2018). As the FDA implements the Quality Management System Regulation (QMSR), greater emphasis on systematic, well-documented verification and validation practices may further reinforce expectations for methodological rigor and traceability(U.S. Food and Drug Administration, 2024c). Future progress in mechanical testing of IDDs will depend on

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improved procedural transparency, clearer linkage between mechanical endpoints and functional performance, and broader adoption of system-level and interface-focused evaluation strategies. Strengthening these practices within the existing regulatory paradigm can enhance the reliability, interpretability, and clinical relevance of mechanical testing evidence while preserving the innovation-enabling character of the U.S. framework(U.S. Food and Drug Administration, 2014, 2019).

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