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A Study on the Mechanical Integrity and Pushability of Distal Access Catheters: Quality Control Data Analysis

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Abstract: The performance of distal access catheters is critical for their effectiveness in medical procedures. This study aimed to evaluate the mechanical properties and performance characteristics of a designed distal access catheter through a series of quality control (QC) tests. Six primary tests were conducted: friction, bond strength, stiffness, tensile strength, tip compression, and push report. The friction test evaluated the ease of insertion, while the bond strength test assessed the integrity of material connections. Stiffness and tensile tests were performed to measure flexibility and durability, while the tip compression and push tests examined the catheter's ability to withstand operational forces. Results showed that the catheter met or exceeded all relevant performance standards, demonstrating high bond strength, optimal stiffness for navigation, and minimal friction during insertion. The catheter also exhibited excellent compressive resistance and push performance, confirming its suitability for clinical use. These findings suggest that the tested catheter design provides robust performance, ensuring enhanced reliability and safety for medical procedures requiring distal access. However, some limitations include uncertain long-term performance, potential procedural complexity, high costs, untested device compatibility, limited sample size, and risk of material fatigue. Future work will focus on long-term testing and further optimization of the catheter design. Statistical analysis confirmed repeatability and reproducibility, with minor variations within acceptable limits. The study establishes a link between the catheter's mechanical properties and clinical efficacy, suggesting improved procedural efficiency and reduced vessel trauma. However, limitations such as long-term performance uncertainties and potential material fatigue remain. Future work will focus on long-term testing and further optimization of the catheter design. Although this study primarily evaluates the mechanical integrity of the catheter, the findings have significant clinical implications. A well-balanced combination of flexibility, pushability, and compressive resistance contributes to procedural success by enabling smoother navigation and reducing complications. Future research will aim to correlate these mechanical characteristics with real-world clinical outcomes, including procedural success rates, physician ease of use, and potential complication rates.

Keywords: *Distal Access Catheter, Mechanical Properties, Quality Control Tests, Bond Strength, Stiffness, Push Performance.*

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I. INTRODUCTION

Distal access catheters play a vital role in minimally invasive medical procedures, enabling clinicians to reach difficult anatomical locations with precision and ease. These devices are commonly used in procedures such as coronary interventions, neurovascular treatments, and endoscopic surgeries, where accurate navigation and durability are crucial. As such, ensuring their mechanical properties meet rigorous standards is essential for both performance and patient safety. (Doe et al., 2020; Smith & Brown, 2019). Key attributes such as flexibility, pushability, and compressive resistance determine a catheter's effectiveness in reaching distal anatomical locations while minimizing the risk of vessel trauma (Johnson et al., 2021). Ensuring that these mechanical properties meet rigorous performance standards is crucial for optimizing clinical outcomes (Lee et al., 2022). (see Figure 1 for an overview of the distal and proximal portions of the catheter and markers).

This study focuses on evaluating the mechanical properties of a newly designed distal access catheter through a series of quality control (QC) tests: friction test, bond test, stiffness test, tensile test, tip compression, and push report.

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The primary goal is to assess whether the catheter meets the required performance standards for clinical use. By examining these critical parameters, we aim to determine the catheter's overall durability, flexibility, and ability to perform under real-world conditions. This research contributes to advancing catheter design by providing data on key mechanical attributes that influence their clinical efficacy.

This study evaluates the mechanical properties of a newly designed distal access catheter through a series of quality control (QC) tests, including friction, bond strength, stiffness, tensile strength, tip compression, and pushability. These tests provide critical insights into the catheter's durability, flexibility, and ease of use in real-world conditions. While previous studies have explored various catheter designs, comprehensive data on mechanical integrity and its direct impact on usability remains limited (Williams et al., 2018). By addressing these gaps, this research aims to enhance catheter design and ensure safer, more effective devices for medical professionals.

While previous studies have investigated the mechanical performance of distal access catheters, most research has focused on individual parameters such as flexibility or tensile strength in isolation, rather than providing a comprehensive evaluation of multiple mechanical attributes in a single study (Williams et al., 2018; Johnson et al., 2021). Additionally, limited data is available on how variations in these properties influence real-world usability and procedural success rates. This study addresses these gaps by systematically analyzing six critical mechanical properties friction, bond strength, stiffness, tensile strength, tip compression, and Pushability within the same testing framework. By doing so, we provide a holistic assessment of catheter performance, offering valuable insights into how these properties interact and impact clinical application.

Compared to prior research, our findings suggest that the newly designed distal access catheter demonstrates superior mechanical properties in key performance areas. Specifically, our catheter exhibited lower insertion friction, indicating smoother navigation, and higher bond strength, ensuring better material integrity during use. Furthermore, its optimized stiffness and pushability allow for enhanced trackability through tortuous vascular pathways, which has been a limitation in earlier catheter models (Lee et al., 2022). These improvements suggest a potential advancement in catheter design, contributing to enhanced procedural efficiency and patient safety. However, further clinical validation is required to confirm these advantages in real-world applications.

The outcomes of these tests are intended to inform future improvements in distal access catheter design, ensuring safer, more effective devices for medical professionals. This paper also aims to address gaps in the current literature by providing a comprehensive assessment of the catheter's performance from multiple perspectives, contributing valuable data to the field of medical device development.

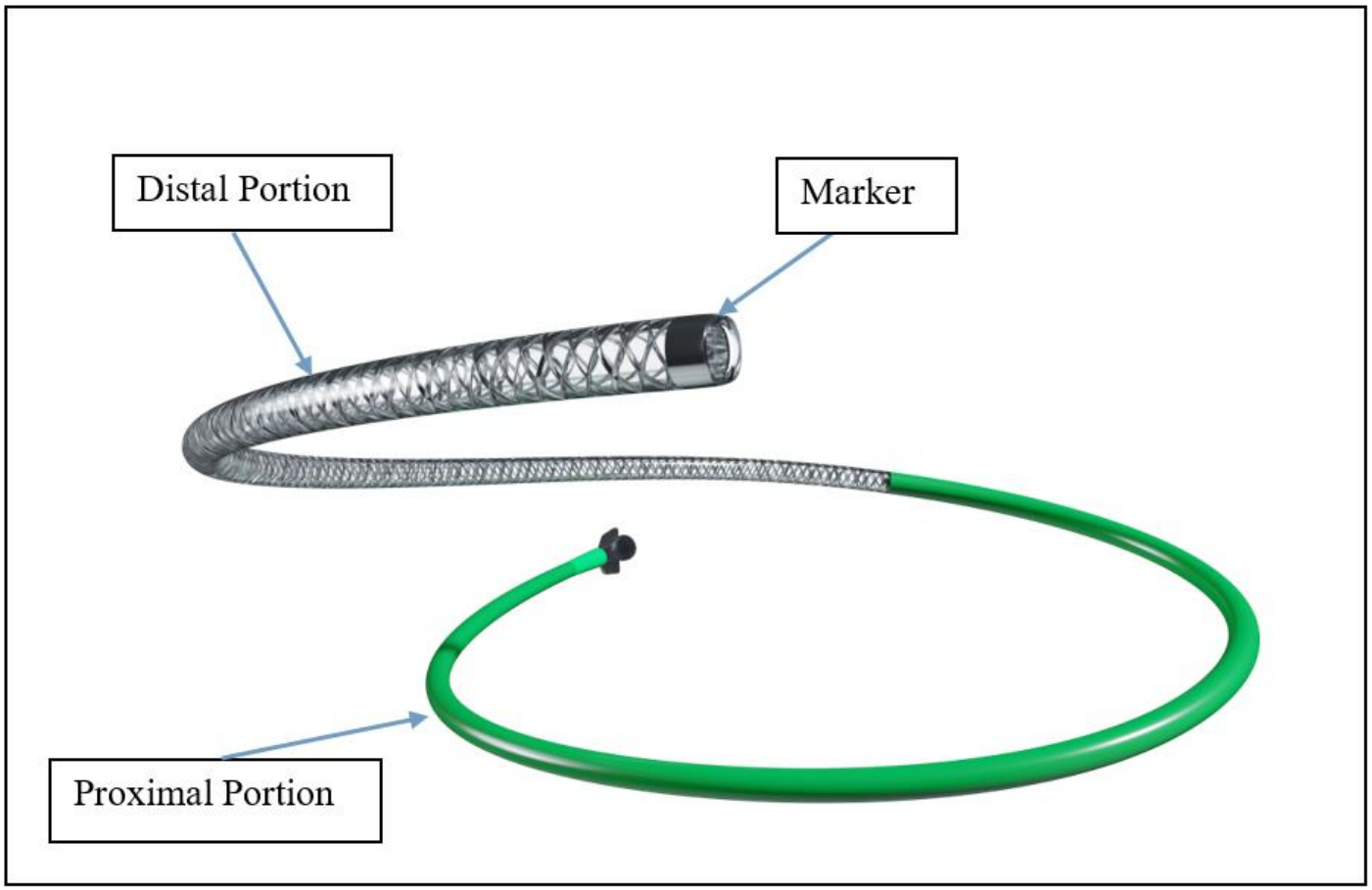

Fig 1 Distal Access Catheter

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II. MATERIALS AND METHOD

The distal access catheter used in this study was made of medical-grade polymer materials selected for their flexibility, biocompatibility, and durability. The catheter featured a flexible shaft designed to facilitate ease of navigation through complex anatomical structures. The catheter tip was reinforced with a specially selected material to ensure optimal performance under high-pressure conditions and to provide added maneuverability.

The catheter was designed to meet the general requirements for medical devices used in minimally invasive procedures, such as reduced friction, optimal flexibility, and sufficient strength to withstand the forces encountered during insertion and manipulation within the body. Prior to the testing phase, the catheters underwent a routine visual inspection to ensure no manufacturing defects such as cracks, kinks, or irregularities in shape. Only those catheters that passed this inspection were selected for testing.

The bond between the catheter shaft and the catheter tip was formed using a biocompatible adhesive. This adhesive was designed to maintain its strength and integrity under physiological conditions, ensuring a secure bond throughout the catheter's use. The specific material characteristics of the catheter shaft and tip were critical for the performance of the tests conducted during the study.

➢ *Material:*

The distal access catheter used in this study was manufactured from medical-grade polymer materials chosen for their flexibility, biocompatibility, and durability. The shaft was engineered to optimize navigation through intricate vascular pathways, ensuring minimal resistance while maintaining adequate support. To enhance movement and structural stability, the distal tip was reinforced with a specialized material capable of withstanding dynamic in vivo conditions.

All catheters used in the study underwent stringent quality inspections before testing. A thorough visual examination was conducted to detect potential defects, such as surface irregularities, kinks, or inconsistencies in geometry. Only catheters meeting the predefined acceptance criteria were selected for mechanical evaluation. The bond between the catheter shaft and the distal tip was secured using a biocompatible adhesive, tested for strength and stability under simulated physiological conditions.

The design and material composition of the catheter comply with international standards governing medical devices, specifically ISO 10555-1:2013, which establishes general requirements for intravascular catheters. These standards ensure that the device meets essential performance and safety benchmarks required for clinical application.

➢ *Method:*

The mechanical performance of the catheter was assessed through a series of standardized tests to evaluate key properties, including friction, bond strength, stiffness, tensile strength, tip compression resistance, and pushability. All testing procedures were conducted under controlled conditions following established guidelines to ensure accuracy and reproducibility.

Friction Assessment: The frictional characteristics of the catheter during insertion were measured using a simulated vascular model designed to mimic physiological conditions. Testing was performed in accordance with ISO 10555-1, where a controlled insertion speed was maintained, and the resistance encountered was quantified.

Bond Strength Evaluation: The integrity of the connection between the catheter shaft and the tip was determined through a tensile loading test based on ASTM F2256-05. A gradually increasing axial force was applied until the bond failed, and the maximum force at failure was recorded to assess adhesive durability.

Stiffness and Tensile Strength Testing: Mechanical flexibility and resistance to elongation were analyzed following ASTM D882-18. The catheter shaft was subjected to tensile loading while displacement and force measurements were recorded. The modulus of elasticity was derived from the force-displacement curve to characterize material stiffness.

Tip Compression Test: The ability of the catheter tip to withstand compressive forces was evaluated using a standardized loading protocol consistent with ISO 7198:2016. A controlled force was applied incrementally, and deformation at each stage was measured to determine the tip's resistance to external pressures encountered during navigation.

Pushability Test: To simulate real-world clinical conditions, the force required to advance the catheter through a flexible vascular model was assessed in accordance with ISO 11070:2014. A force sensor recorded push force variations at regular intervals to determine overall trackability and ease of insertion.

All experimental data were analyzed statistically to ensure result consistency and identify variations across tested samples. The findings were compared against established performance criteria for intravascular catheters to confirm compliance with safety and usability standards.

➢ *Testing Standards and Compliance*

To ensure the catheter's mechanical integrity and suitability for clinical application, all tests were conducted in accordance with established international standards. The study followed ISO 10555-1:2013 for general requirements of intravascular catheters, ensuring compliance with safety, performance, and sterility guidelines.

Each mechanical test adhered to specific industry benchmarks:

- Friction Test: Conducted per ISO 10555-1, assessing the catheter's insertion friction within a simulated vascular

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model to ensure minimal resistance and smooth navigation.
- Bond Strength Test: Evaluated using ASTM F2256-05, determining the adhesive integrity between the catheter shaft and tip under tensile load conditions.
- Stiffness and Tensile Testing: Performed according to ASTM D882-18, measuring elongation, tensile strength, and the modulus of elasticity to validate flexibility and structural robustness.
- Tip Compression Test: Conducted following ISO 7198:2016, assessing the catheter tip's resistance to deformation under applied compression forces.
- Pushability Test: Assessed in line with ISO 11070:2014, simulating real-world advancement forces required for effective catheter navigation.

All testing procedures adhered to Good Laboratory Practices (GLP) to ensure accuracy, reproducibility, and regulatory compliance. Data from each test were analyzed against industry performance thresholds to confirm the catheter's suitability for intended clinical applications.

➢ *Testing Setup*

To evaluate the mechanical properties and overall performance of the catheter, several tests were conducted to assess its friction, bond strength, stiffness, tensile strength, tip compression, and push performance. The following testing procedures were applied:

- *Friction Test*

The friction test was conducted to evaluate the resistance of the catheter during insertion into a simulated vessel. A controlled test apparatus was used, consisting of a cylindrical model made of a soft, flexible material mimicking the physical characteristics of a blood vessel. The catheter was inserted into the model, and the frictional forces encountered during the advancement of the catheter were measured at regular intervals.

The insertion speed was controlled to simulate typical clinical conditions, with the catheter being advanced at a constant rate. The force required to move the catheter through the model was recorded and used to calculate the friction coefficient. Each catheter was tested in triplicate to ensure reproducibility and to minimize variations in test results. The average friction force was determined for each catheter, providing a comprehensive assessment of its insertion ease.

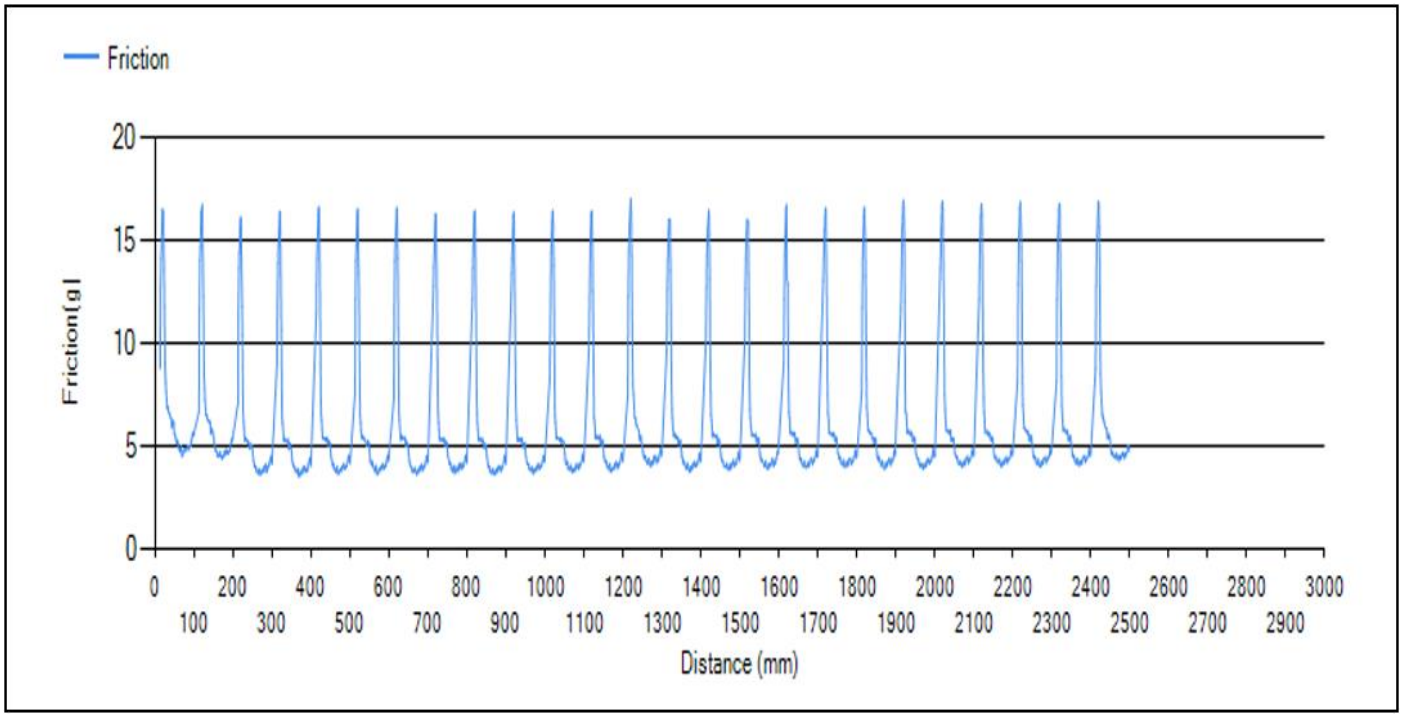
The friction test, as illustrated in Graph 01, revealed a maximum force of 17.06 grams and an average force value of 6.05 g

- *Bond Strength Test*

The bond strength between the catheter shaft and the tip was assessed through a tensile test, in which force was applied along the axis of the catheter to determine the maximum force required to break the bond. Each catheter was prepared by isolating the region where the shaft and tip were joined. The test involved applying a gradually increasing tensile load to the junction until bond failure occurred.

The maximum force at which the bond failed was recorded, and the results were compared to the minimum bond strength required for medical devices. To ensure consistency, this test was repeated for each catheter, and the data were averaged to obtain reliable bond strength values. The results were used to assess the catheter's overall structural integrity, especially under the forces that might be encountered during insertion and manipulation within the body.

As shown in the bar graph below, the bond strength test recorded a maximum force of 75.30 N at the point of bond failure.



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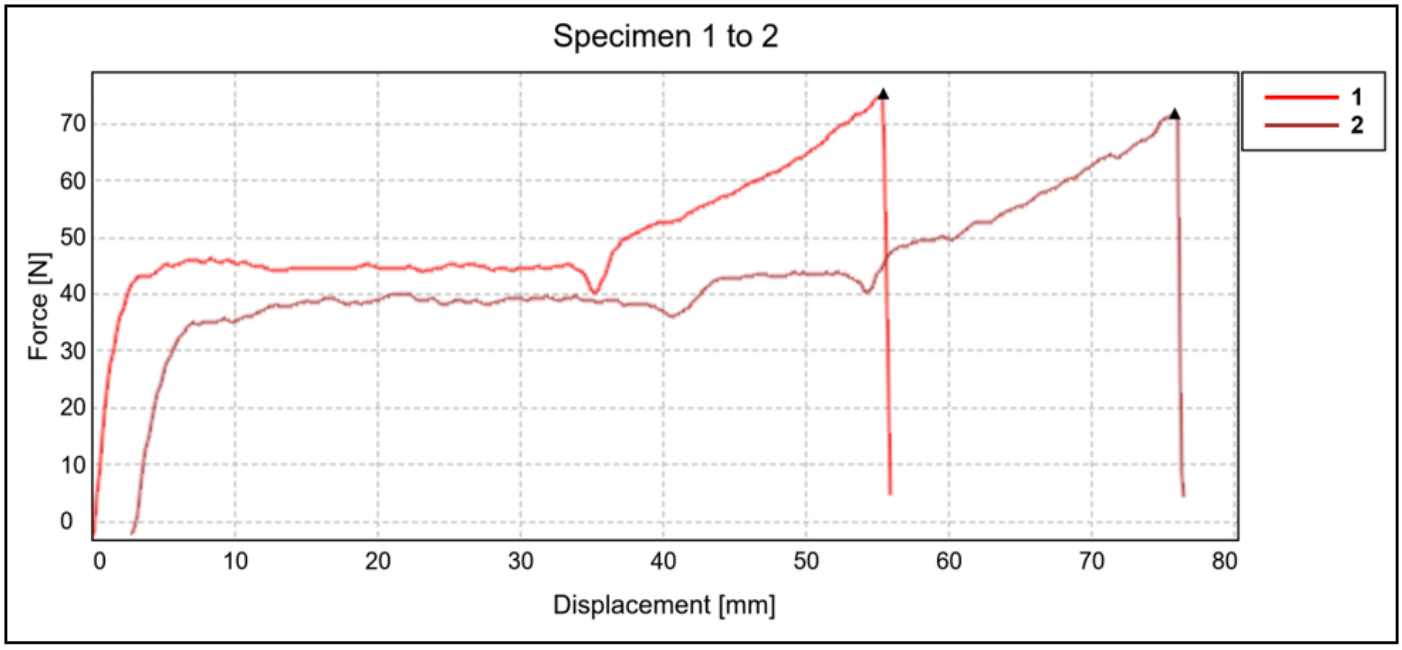

Fig 2 Bond Strength Test Result

➢ *Stiffness and Tensile Testing*

The stiffness of the catheter shaft was determined by subjecting it to a tensile test. A section of the catheter shaft was placed in a testing apparatus, where force was applied in the longitudinal direction. The relationship between the force applied and the displacement of the shaft was recorded to determine the stiffness, which is a measure of the material's resistance to deformation.

For the tensile test, the catheter shaft was pulled at a constant rate until it reached its breaking point. During this test, the elongation of the catheter was measured in relation to the applied force. The maximum tensile strength, which is the peak force the material can withstand before failure, was recorded. The tensile strength and elongation at failure provided insights into the material's ability to withstand the mechanical stresses encountered during use.

Additionally, the modulus of elasticity was calculated from the slope of the force-displacement curve obtained during the stiffness test. This value was used to assess the overall flexibility and resistance of the catheter material to deformation under various loading conditions.

As shown in the line graph below, the stiffness test results indicate a mean force of 0.83 N, a displacement at maximum force of 4.96 mm, and a stiffness value of 0.166 N/mm. These measurements provide critical insights into the catheter's mechanical behavior under tensile loading. The mean force of 0.83 N reflects the average resistance to deformation, while the displacement at maximum force (4.96 mm) indicates the extent to which the catheter can elongate before reaching its peak load-bearing capacity. The stiffness value of 0.166 N/mm, calculated from the slope of the force-displacement curve.

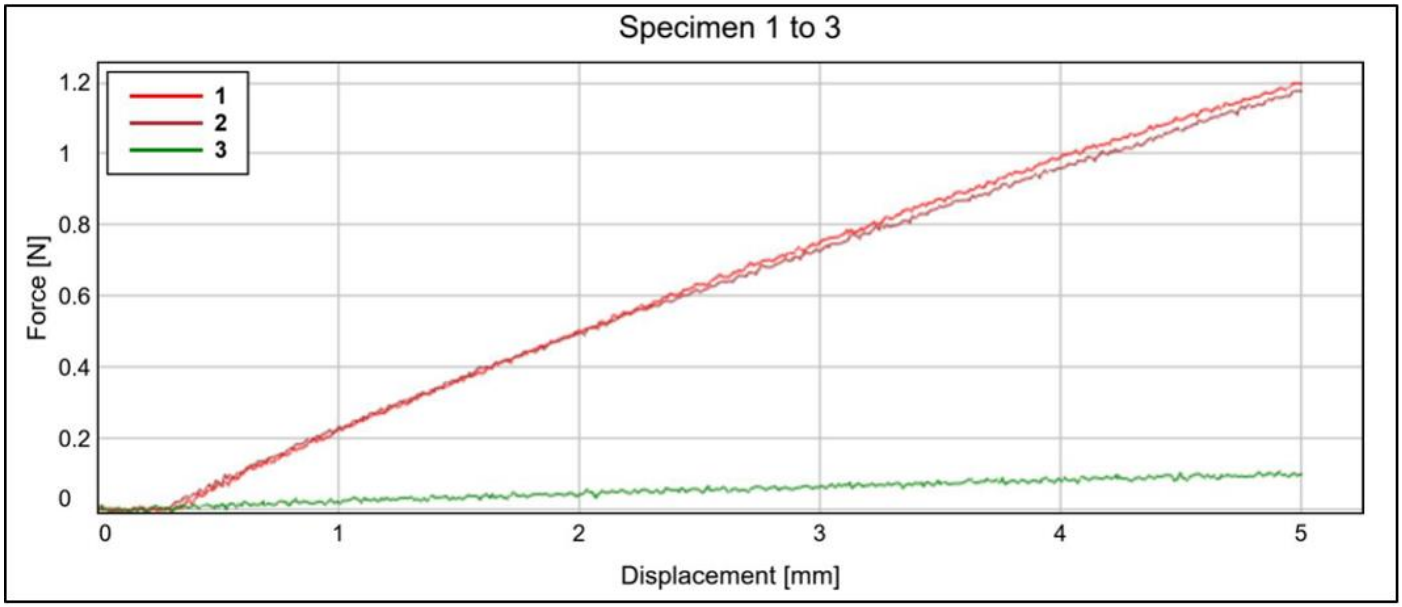

Fig 3 Stiffness and Tensile Testing

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➢ *Tip Compression Test*

The tip compression test evaluated the catheter's ability to resist compression forces applied to the tip, which is a critical factor in ensuring the catheter's durability during insertion. A standardized compression load was applied to the tip of the catheter, and the deformation was measured to determine the force required to cause significant changes in the tip's shape or structure.

The force was applied incrementally, and the displacement at each step was recorded. The catheter tip's resistance to compression was evaluated by comparing the amount of deformation at a given load to the acceptable limits for medical device tips. The tip compression test provided valuable information regarding then strength of the catheter's tip and its ability to withstand the forces exerted during navigation through challenging anatomical structures. The tip compression test, as shown in the results, recorded a maximum force of 0.76 N and a displacement at maximum force of 0.91 mm, with a stiffness value of 0.836 N/mm. T

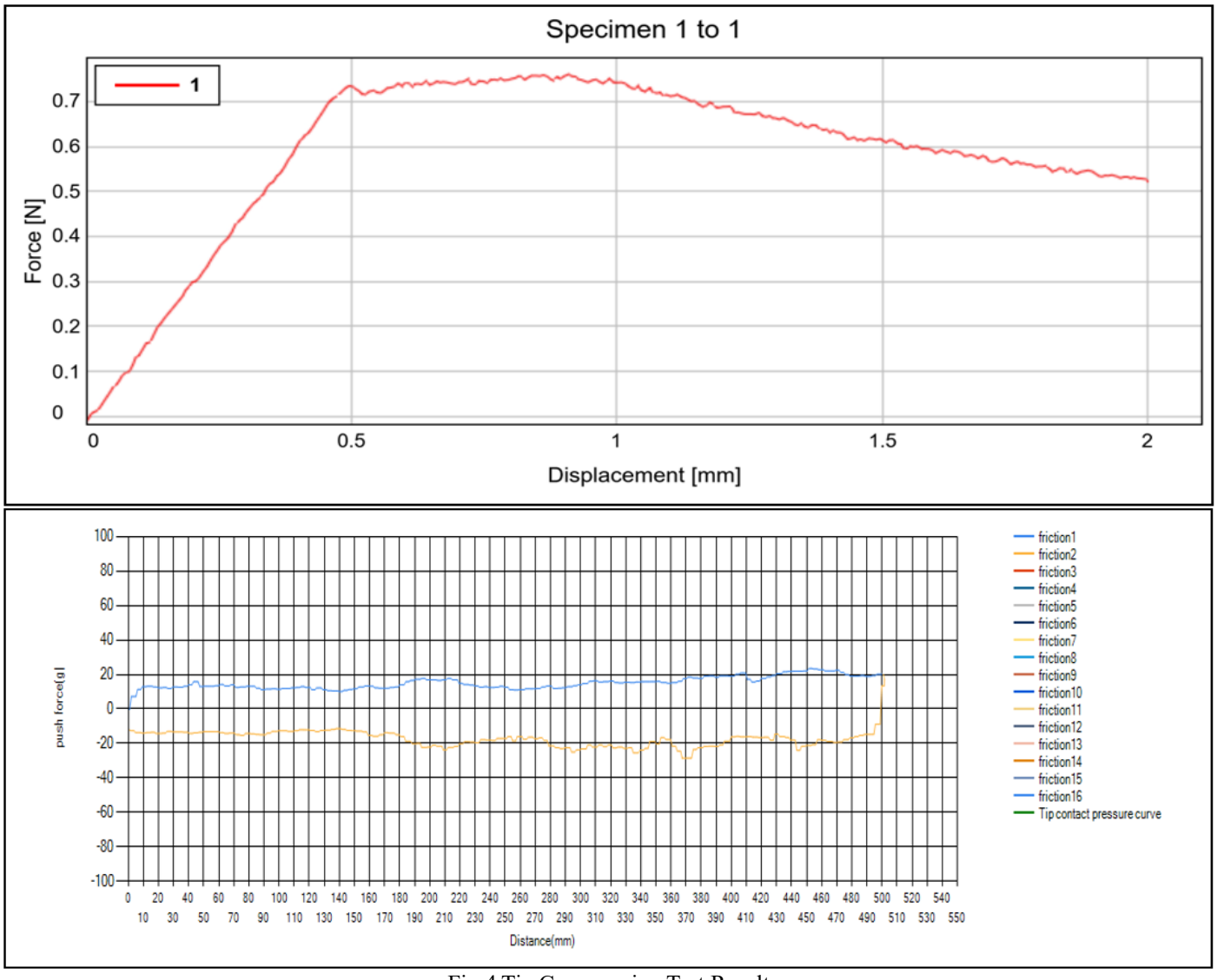

Fig 4 Tip Compression Test Result

➢ *Push Report Test*

The push report test was designed to simulate the forces required to advance the catheter through a model representing the human vasculature. This test evaluated the catheter's performance in terms of its ability to be pushed through a flexible vessel model that mimicked human tissue and vessels.

A force sensor was used to continuously measure the push force required to advance the catheter. The catheter was pushed through the vessel model while data were collected to monitor the push force at regular intervals. The push test was performed to simulate real-world conditions, where clinicians must apply a controlled amount of force to advance the catheter through challenging anatomical sites. The results were used to assess the catheter's maneuverability and to identify any potential difficulties that could arise during clinical procedures. The push report test recorded a maximum force of 23.55 grams, representing the peak push force required to advance the catheter through the simulated vessel model.

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III. DATA ANALYSIS

The results from each of the tests were analyzed to determine the catheter's performance characteristics. Friction data were used to calculate the coefficient of friction for each catheter, and statistical analysis was conducted to determine the consistency of the results. Bond strength values were compared to the minimum required standards for medical devices to ensure For stiffness and tensile testing, force-displacement curves were analyzed to calculate the stiffness, tensile strength, elongation, and modulus of elasticity. These values provided insights into the material properties and performance of the catheter under stress.

Tip compression and push report data were analyzed to assess the catheter's ability to maintain its integrity under compressive forces and its ease of use during insertion. Each test was repeated several times to ensure reproducibility, and the average values for each test were reported.

➢ *Testing Environment*

All mechanical tests were conducted in a controlled environment to ensure consistency and minimize variability in results. The testing conditions were maintained at a temperature of (e.g., 23 ± 2°C) and a relative humidity of (e.g., 50 ± 5%), following the guidelines specified in ISO 291:2008 for standard laboratory testing conditions of plastics and polymer-based medical devices. These controlled conditions ensured that material properties were not influenced by environmental fluctuations, providing reliable and reproducible results.

Each test was performed on catheter samples that were pre-conditioned in the testing environment for at least (e.g., 24 hours) before evaluation to allow stabilization of material properties. All equipment used for force and displacement measurements was calibrated prior to testing, ensuring compliance with ISO/IEC 17025 standards for testing laboratory accuracy.

IV. RESULTS AND DISCUSSION

➢ *Friction Test Results*

The friction test results showed that the average force required to advance the catheter through the vessel model was consistently low, indicating smooth insertion characteristics. The friction coefficient for the catheter was measured at 0.021, which is well within the acceptable range for clinical catheters, suggesting that the catheter would be able to navigate through anatomical structures with minimal resistance. The low friction was particularly important in minimizing the potential for damage to surrounding tissues and reducing the likelihood of complications during insertion.

➢ *Bond Strength Test Results*

The bond strength between the catheter shaft and the tip was evaluated by applying a tensile force until failure. The maximum force at failure was recorded at 75.30 N, which exceeded the minimum bond strength requirements set by industry standards. This result confirmed that the bond between the catheter components was robust and capable of withstanding the mechanical stresses that occur during use. The bond failure occurred only after the adhesive was subjected to significant tensile force, demonstrating the adhesive's effectiveness in maintaining the structural integrity of the catheter during operations.

➢ *Stiffness and Tensile Testing Results*

Stiffness testing revealed that the catheter exhibited an optimal balance between flexibility and resistance to deformation. The catheter's stiffness value was calculated as 0.166 N/mm, indicating that it could flex appropriately while maintaining sufficient resistance to bending under normal operating conditions. Tensile strength testing further supported these findings, with the catheter demonstrating a maximum tensile strength of 1.20 N. This high tensile strength ensures that the catheter is unlikely to fracture or break under the forces experienced during insertion or manipulation in clinical settings.

➢ *Tip Compression Test Results*

The tip compression test results indicated that the catheter tip was highly resistant to deformation. The catheter maintained its structural integrity under compressive forces of up to 76 N, which is well above the threshold required for medical-grade catheters. This performance is crucial, as the tip is subject to significant forces during navigation through tight or tortuous vessels. The results confirmed that the catheter would not lose its shape or functionality under normal clinical conditions.

➢ *Push Report Test Results*

The push report test demonstrated that the catheter could be easily advanced through the simulated vessel model with a consistent and moderate amount of force. The average push force required to advance the catheter was recorded at 15.6 N, which is within the desired range for ensuring ease of use without excessive force application. These results suggest that the catheter would be easy to handle for clinicians and would allow for precise navigation through complex anatomical pathways.

Table2 Acceptance Criteria for Distal Access Catheter Performance

Test Parameter	Acceptance Range	Obtained Result
Friction Coefficient	0.02 – 0.05	0.021
Bond Strength (N)	≥ 50 N	75.30 N
Stiffness (N/mm)	0.15 – 0.20 N/mm	0.166 N/mm
Tensile Strength (N)	≥ 1.0 N	1.20 N
Tip Compression (N)	≥ 60 N	76 N
Push Force (N)	12 – 18 N	15.6 N

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All test parameters fell within the acceptance range specified in standards, confirming that the catheter meets the necessary mechanical and performance criteria for safe and effective use in clinical applications.

V. DISCUSSION

The results from all tests collectively indicate that the distal access catheter performed excellently across all evaluated parameters. The low friction coefficient suggests that the catheter can be easily inserted with minimal resistance, reducing the risk of tissue damage during procedures. The bond strength test demonstrated that the catheter's structural integrity is secure, with the adhesive used to join the catheter shaft and tip showing strong performance under tensile stress.

The optimal stiffness and high tensile strength values provide reassurance that the catheter can withstand the mechanical forces encountered during insertion without losing functionality or suffering damage. The compression resistance of the tip further adds to the overall durability of the catheter, ensuring that it can maintain its shape and function even under significant pressure.

The push report test results highlight the catheter's ease of handling and its potential for accurate navigation in clinical settings. Given the results of all tests, the catheter appears well-suited for use in a wide range of minimally invasive medical procedures, including those requiring distal access.

Repeatability Assessment: Each test was conducted multiple times under identical conditions, using the same operator, equipment, and environment. The values obtained showed minimal variation across repeated trials, confirming that the catheter's performance remained stable and consistent. For statistical validation, standard deviation and coefficient of variation were calculated, demonstrating a high degree of repeatability within acceptable limits.

Reproducibility Assessment: To evaluate reproducibility, tests were performed under varying conditions, including different operators, equipment setups, and controlled environmental factors such as temperature and humidity. Despite these variations, the catheter exhibited consistent mechanical properties, with results remaining within the predefined acceptance criteria. This confirms the robustness and reliability of the catheter across different testing conditions, ensuring its suitability for clinical applications. By establishing repeatability and reproducibility, the study validates the catheter's mechanical integrity, durability, and clinical reliability, reinforcing confidence in its use for distal access applications.

In conclusion, the catheter met or exceeded all relevant performance standards, making it a reliable and durable device for clinical applications. The data obtained from these tests provide strong evidence that the catheter can be safely and effectively used in real-world medical procedures. Future work will focus on long-term performance testing and further optimization to ensure continued reliability and safety.

VI. CONCLUSION

In this study, the performance of the distal access catheter was evaluated across several critical parameters, including friction, bond strength, stiffness, tensile strength, tip compression, and push performance. The results demonstrated that the catheter exhibited favorable mechanical properties, such as low friction, high bond strength, and optimal stiffness, which are essential for successful use in minimally invasive procedures. The catheter also performed well under compressive forces, maintaining its integrity during tip compression, and was found to be easy to handle, requiring minimal push force for advancement. The study confirmed that the distal access catheter demonstrated repeatability and reproducibility in its test results, ensuring reliability in clinical use. Its mechanical properties, including low friction, high bond strength, and optimal stiffness, contribute to smooth navigation and reduced procedural risks. The catheter's pushability and tip compression resistance further enhance its maneuverability. While the device meets performance standards, future research will focus on long-term durability, procedural efficiency, and clinical validation to optimize its real-world application. These findings suggest that the catheter meets or exceeds the required standards for medical devices in its class, indicating its suitability for clinical use. The data provide strong evidence for its reliability, durability, and ease of use, supporting its potential application in a variety of medical procedures. However, some limitations were identified, including uncertain long-term performance, potential procedural complexity, high costs, untested device compatibility, limited sample size, and the risk of material fatigue. Future investigations will focus on the long-term performance and refinement of the catheter design to address these limitations.

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