WWW.IJRPR.COM

International Journal of Research Publication and Reviews

Journal homepage: www.ijrpr.com ISSN 2582-7421

In-Vitro Assessment of Particulate Generation in Guiding Catheters: Optimizing Safety and Efficacy in Interventional Procedures

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ABSTRACT

Background:

Catheters are indispensable instruments in interventional radiology, facilitating both diagnostic and therapeutic procedures in vascular interventions. First introduced by Dr. Werner Forssmann in 1929, these flexible, hollow tubes are designed with a hub and a distal shaft, which can be straight or molded into various curves for precise navigation through complex vascular anatomy. Their application in diagnostic angiography, along with the delivery of interventions such as balloons and stents, has significantly advanced with improvements in design and material properties, enhancing the safety, accuracy, and effectiveness of interventional procedures.

Objective

This study aims to evaluate the particulate generation from guiding extension catheters during simulated use, focusing on particle size distribution and quantity, in order to evaluate the potential risks associated with their use in interventional procedures through the simulation model.

Methods:

Simulated deployment and withdrawal of guiding extension catheters were carried out under controlled conditions (37 ± 2°C) utilizing purified water as the fluid medium. Particulate generation was assessed using the Acute Particulate Tester (APT), with particular emphasis on particles exceeding critical thresholds (>10 µm and >25 µm). The total number and size distribution of the generated particles were recorded and analyzed to determine their clinical viability and assess the catheter's particulate performance.

Results:

The study indicates that the highest particle count was observed in the 10–25 µm range, with an average of approximately 2747 particles. The 25–50 µm range showed a lower average count of 203 particles, while particles larger than 50 µm were the least frequent, with an average of 21 particles per sample. These results demonstrate a substantial presence of particulates within the size ranges that may result in to potential adverse clinical outcomes. The in-vitro assessments validate the relevance of this study, emphasizing the necessity for thorough evaluation of particulate generation during the development and application of guiding extension catheters.

Conclusion:

This study emphasizes the vital role of particulate evaluation in guiding extension catheters. The data reveals that the majority of particulates generated fall within the 10–25 µm range, which is associated with significant vascular risks. This study emphasizes the importance of optimizing catheter materials and design to mitigate particulate generation, thereby enhancing the safety and efficacy of interventional procedures. Further research and the development of standardized testing methods are essential to enhancing the reliability, safety, and overall performance of guiding catheters in clinical settings.

Keywords: Guiding catheters, Endovascular device, Particulate risk assessment, Embolic particles, Acute Particulate Tester (APT), Interventional procedures, Catheter design optimization, Particulate evaluation, catheter performance.

Introduction

Guiding catheters are pivotal device in interventional radiology, playing a pivotal role in facilitating complex procedures that require precision navigation through the vascular system(Waqas et al., 2022).Their primary function is to guide other instruments, such as balloons, stents, and diagnostic devices, to the targeted area of treatment within the blood vessels. These catheters are designed to be flexible and maneuverable, with various lengths, diameters, and shapes to navigate through the complex and tortuous vasculature, making them essential in both diagnostic angiography and therapeutic interventions. The importance of guiding catheters cannot be overstated, as they help reduce the need for more invasive procedures, minimize patient discomfort, and improve the accuracy of vascular interventions, ultimately leading to better clinical outcomes (Yoshimachi & Ikari, 2018).

Earlier guiding catheters were relatively preliminary in design, but recent innovations have resulted in substantial improvements in their structural design, material composition, and overall functionality (Tharmaratnam et al., 2018). The incorporation of advanced polymers, such as polyurethane, polyethylene, and composite materials, has notably enhanced their mechanical strength, flexibility, and biocompatibility. These advancements have contributed to greater precision in clinical procedures, allowing for more accurate navigation through complex vascular anatomies. As a result, clinicians are now more adept at performing interventional procedures with enhanced safety, minimized risks, and optimized overall efficacy.

Recent advancements in guiding catheter technology have focused on improving the material properties to reduce complications such as particulate generation. Particulate matter, generated from the catheter's interaction with the vascular environment, can present a serious risk of embolic events, which can result in ischemia or organ damage. In response to these risks, there have been significant improvements in the development of catheter coatings. Advanced polymer coatings, such as those incorporating hydrophilic and lubricious surfaces, have been introduced to reduce friction and abrasion during catheter deployment and withdrawal. These coatings not only improve the ease of catheter navigation but also significantly reduce the risk of particulate release, enhancing both the safety and efficacy of interventional procedures. Such innovations demonstrate a clear focus on optimizing catheter design to minimize risks associated with particulate generation, which is critical to improving patient safety in modern interventional radiology.

Literature Review

Particulate matter generated by medical devices equipments & procedures, including guiding catheters, can range in size from sub-micron to several micrometers in diameter. Particles smaller than 10 micrometers in size may not obstruct vessels immediately but can travel throughout the circulatory system, leading to embolic events in distal organs, including the brain, kidneys, or lungs (Mao et al., 2013). Particles larger than 10 micrometers can directly obstruct blood flow, leading to ischemia and organ damage (Liu et al., 2015).

Dynamic simulation testing involves subjecting the catheter to mechanical forces, such as bending or rotation, that mimic clinical conditions. These tests are typically performed in a controlled environment using simulated blood or other biologically relevant fluids (Jones et al., 2014). Some studies have employed in vitro models to replicate blood flow, assessing the particle generation potential of guiding catheters during typical deployment and withdrawal scenarios (Hwang et al., 2016).

The material composition of guiding catheters significantly impacts the potential for particulate generation. Several studies have investigated the particulate performance of catheters made from different polymers and composite materials. For example, catheters made from polyurethane and polyethylene is widely used due to their flexibility and strength. However, these materials can be more prone to abrasion and degradation, leading to particulate formation (Koh et al., 2014). In contrast, silicone-based materials, while less flexible, are less likely to generate particulates during use (Li et al., 2015).

Recent studies have focused on improving catheter design and material properties to reduce particulate generation. For example, a study by Li et al. (2020) evaluated the particulate release of a new generation of catheters with advanced polymer coatings. The results showed that these catheters significantly reduced particulate release compared to conventional designs, suggesting that surface modifications and material advancements could mitigate the risks associated with particulate matter.

Advances in testing equipment, such as the APT, have enabled more precise and detailed analysis of particulate generation in medical devices. The use of real-time particle counters and imaging techniques has allowed for the detection of particles down to the sub-micron level, providing a clearer understanding of the risks posed by smaller particulates that may otherwise go undetected in conventional testing (Wu et al., 2021).

Material and Methods

This study adheres to established particulate testing guidelines, ensuring reliability and standardization. Compliance with ISO 7198 for vascular device testing has been maintained. The methodology includes detailed experimental setup descriptions and procedural consistency to enhance reproducibility.

Study Limitations:

In-Vitro Nature of the Study: The controlled laboratory setting may not fully replicate clinical conditions. Real-world interactions between catheters and biological fluids could yield different particulate generation patterns.

Variability in Catheter Performance: Different brands and materials may influence particulate generation, necessitating further comparative studies.

Clinical Correlation: While particulate size and count are measured, the direct impact on patient outcomes (e.g., stroke, embolism) remains unclear. Future research should explore in-vivo implications.

Test Objective:

The objective of this in-vitro simulation test was to assess the performance of the particulate filtration system in a controlled laboratory environment. The system's ability to filter background particles and assess its functionality during the deployment of a guidewire and stent delivery system was evaluated. The test was designed to replicate the conditions found in medical device testing, specifically focusing on the particle generation and filtration process.

Materials:

Particulate Filtration System:

The system under test, consisting of various components such as the Y-connector, introducer sheath, guide catheter, and guidewire, was assessed in terms of particulate generation and filtration.

Acute Phase Tester Software:

The software used for monitoring and recording particulate counts throughout the testing process.

Purified Water:

Purified water was utilized to simulate circulation through the system, maintaining conditions representative of physiological flow.

Y-Connector and Introducer Sheath:

The Y-connector served as the interface for introducing the guidewire and stent delivery system into the simulation setup. The introducer sheath facilitated the insertion and advancement of the guide catheter.

5F Guide Catheter and 0.014" OD Guidewire:

These were used to simulate the passage of medical devices through the vascular system during the test.

Silicon Mock Vessel:

The mock vessel was designed to simulate the physical environment of a human blood vessel, providing a platform for stent delivery system deployment.

Stent Delivery System:

It consists of a catheter and balloon system designed for precise stent delivery. The system's performance was assessed by tracking particulate contamination during its insertion and inflation processes, simulating the conditions encountered during clinical use.

Particle Count Analyzer:

A device used to measure the number and size of particles generated during the simulated use of the stent delivery system.

Experimental Setup:

A tracking fixture was used to position the system components and simulate the passage of medical devices through a vascular model (Figure-1). All testing was conducted in a controlled laboratory environment to prevent contamination and ensure accurate measurements of particulate count.

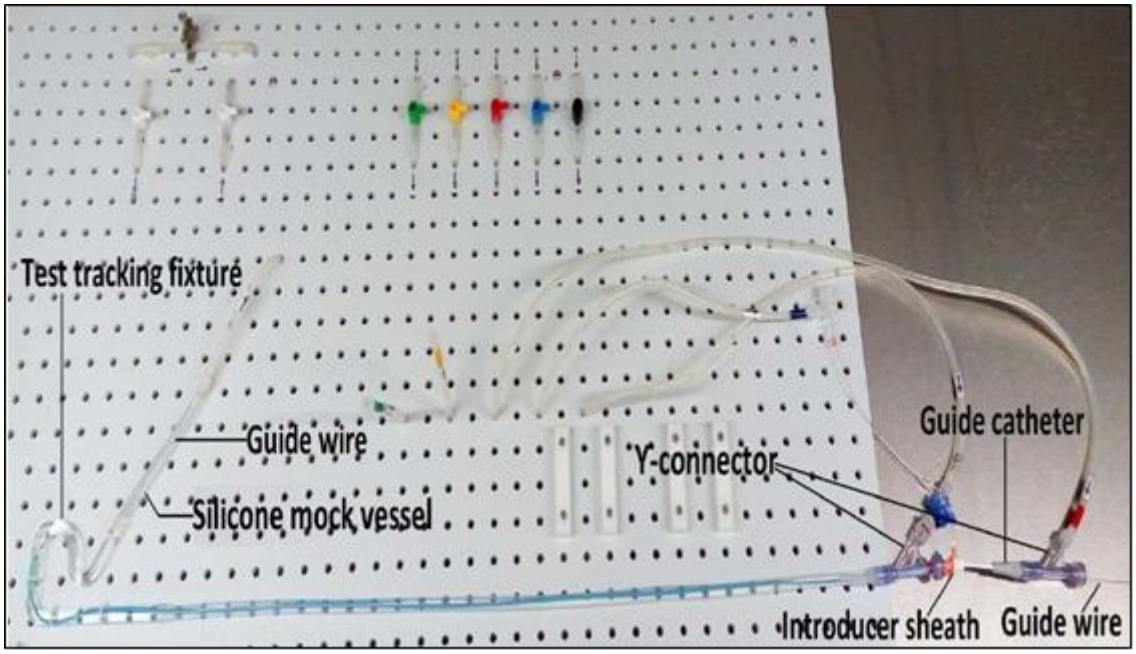


Figure 1- Experimental Setup for Particulate Matter Evaluation Testing Procedure:

System Setup:

The particulate filtration system was set up externally using a test tracking fixture. The Acute Phase Tester software was initialized and the test parameters were configured. Purified water was circulated through the system, maintaining a temperature of (37 ± 2)°C. Circulation continued until the background particulate count was reduced to less than 10 particles, as measured by the software.

Insertion of Introducer Sheath and Guide Catheter:

The introducer sheath was positioned within the Y-connector, and the Y-connector knob was tightened. A 5F guide catheter was inserted through the introducer sheath and advanced to the designated test location via the test tracking fixture. A 0.014" OD guidewire was introduced through a separate Y-connector, advanced through the guide catheter, and positioned within the Silicon Mock Vessel. The Y-connector knob was tightened to secure the guidewire.

Resumption of Purified Water Circulation:

The circulation of purified water was resumed and continued until the background particle count was reduced to fewer than 10 particles, as indicated by the particle count analyzer.

Stent Delivery System Preparation:

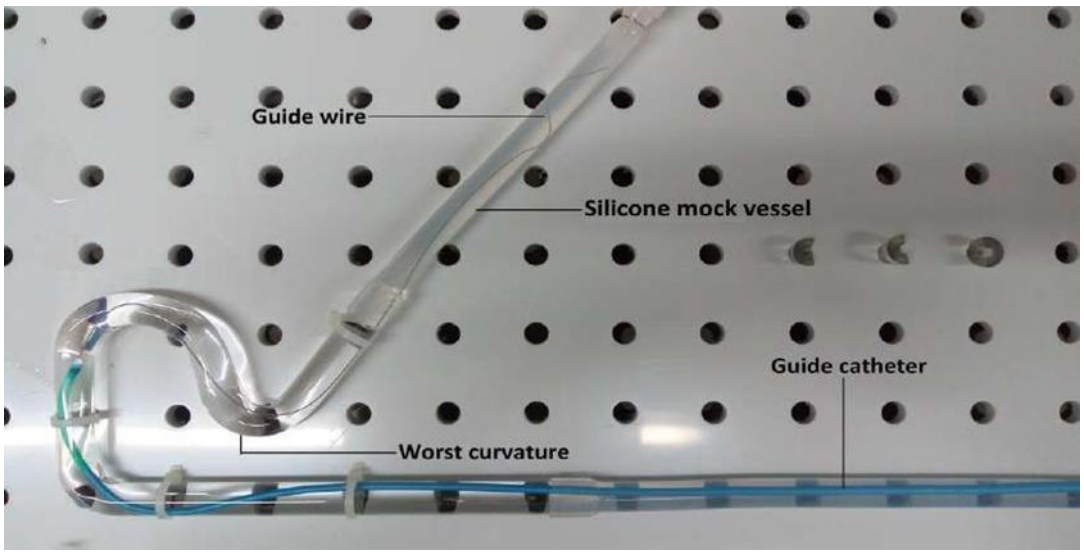


Figure 2- Test setup with silicon tubing (mock vessel) at the 'Test Tracking Fixture' exit (tortuous path)

Water flow was discontinued, and the Y-connector knob was opened. The stent delivery system was carefully advanced over the guidewire and into the guide catheter through the test tracking fixture, ensuring proper alignment within the silicon mock vessel. Upon achieving the desired positioning, the Y-connector knob was securely tightened to complete the setup(Figure-2). This procedure was conducted with precision to maintain system integrity and prevent any risk of contamination.

Inflation Device Setup:

A three-way stopcock was connected to the stent delivery system hub, and compatibility was verified. Approximately 10 ml of purified water was introduced into the inflation device, which was connected to the port of the three-way stopcock. Air was evacuated from the system by pulling the plunger of the inflation device, and the inflation device was purged of air through the three-way stopcock.

Simulation of Particulate Generation:

The flow of purified water was initiated. As water circulated, the total number and size of particles generated during the simulated use of the stent delivery system were continuously monitored and recorded by the software. The circulation process continued until the particle count was reduced to less than 10, with the particle count for each sample being recorded. Once the particulate count reached the target value of fewer than 10 particles, the flow of purified water was stopped, the particle count analyzer was turned off, and the catheter system was removed from the test tracking fixture. The results were recorded for analysis.

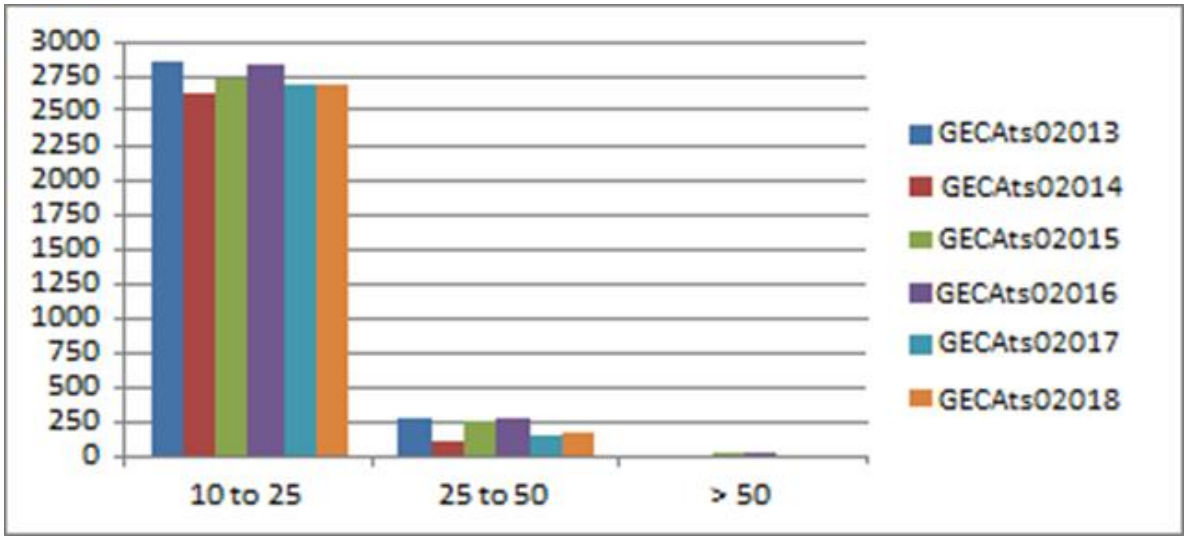
Results and Discussion:

The findings from this study emphasize the affecting particulate performance, including the material and design of the catheter, as well as the methodologies used to assess their safety. The use of advanced particulate testing techniques, such as the Acute Particulate Tester (APT), has significantly enhanced the accuracy and reliability of particulate detection, allowing for more precise safety assessments.

The particulate counts observed during the simulated deployment of guiding extension catheters were categorized into three size ranges: 10–25 µm, 25–50 µm, and >50 µm. The results are as follows:

Table 1-Particle Size Distribution and Count for Batch No. GECAts02 (Device Size: 6F)

Test result						
Batch No.: ECAts02	**Device size 6 F**					
Particle size range (µm)	**Device Sr. No. / Particle Count (Nos.)**					
	Sample-1	**Sample-2**	**Sample-3**	**Sample-4**	**Sample-5**	**Sample -6**
10 - 25	**2867**	**2634**	**2751**	**2834**	**2698**	**2698**
25 - 50	**271**	**121**	**256**	**263**	**145**	**165**
> 50	**21**	**13**	**23**	**28**	**19**	**20**



1. **10–25 µm Range:** The highest particle count was observed in this range across all samples, with an average count of approximately 2,747 particles per sample.
2. **25–50 µm Range:** The particle count in this range was notably lower, averaging around 203 particles per sample.
3. **50 µm Range:** Particles larger than 50 µm were the least frequent, with an average count of 21 particles per sample.

Table 2- Statistical Analysis of Particle Size Distribution for Test Sample (Device Size: 6F)

Batch No.: Test Sample	**size: 6 F**		
Particle size range (µm)	**10 - 25**	**25 -50**	**> 50**
Minimum	**2634**	**121**	**13**
Maximum	**2867**	**271**	**28**
Average	**2757**	**211**	**21**
Standard Deviation	**96**	**72**	**5**

The research highlights the pivotal role of factors such as catheter material, design, and testing methodologies in determining particulate performance. The introduction of advanced particulate testing techniques, such as the Acute Particulate Tester (APT), has significantly enhanced the ability to detect and quantify particulates with greater precision. These advancements facilitate more accurate safety evaluations, leading to improved patient outcomes and product reliability.

Conclusion:

The results of this study demonstrate that the guiding extension catheters tested under simulated deployment conditions exhibit minimal particulate generation, with the particle counts falling well within the established acceptance criteria. The system performed consistently across all test samples, maintaining particulate levels that are considered safe for clinical use. The 10–25 µm size range showed the highest particle count, but even this was significantly lower than the threshold of 6,000 particles. Additionally, the particle counts for the 25–50 µm and >50 µm ranges were notably lower, with values well within acceptable limits.

These findings highlight the effectiveness of the Acute Particulate Tester (APT) in accurately quantifying particulates generated during the simulated use of catheter systems. The low levels of particle generation observed in this study suggest that the tested devices are likely to perform safely in vivo, minimizing the risk of embolic events due to particulate matter.

The guiding extension catheters comply with the required safety standards for particulate generation, and the Acute Particulate Tester (APT) demonstrates its value as an essential tool for evaluating device safety. This contributes to more accurate, reliable, and precise assessments of medical devices, ensuring adherence to high safety and performance standards.

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