Aortic, Coronary and Structural Heart Class III Medical Device, Implant Failures, Causes and Challenges

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Abstract

Aortic, Coronary and Structural Heart Class III medical devices or implants, support and sustain human lifeare usually permanent implanted devices, have emerged as crucial medical devices in the treatment of a wide range of diseases.Class III medical device and implant failures significantly impact patient outcomes, therapy delivery, and the sustainability of medical devices. Understanding the causes of these failures, including fatigue fractures, anatomical pressures, and wear between implant components, is critical to developing more durable devices and establishing effective testing methods for safe product delivery, performance, and sustainability. This paper explores the maincauses of Class III medical device and implant failure, examining existing problems and limitations. By understanding these issues in detail, It helps mitigate risks in the medical device development process. This paper provides detailed understanding of problems, implants failure for improving reliability and enhancing medical device performance confidence.

Keywords: Aortic, Coronary and Structural Heart Class III medical devices, Implants, Mechanical Failures, Fatigue failures, Implant failure causes, High anatomical pressure, Abrasive wear, Structural failure

Introduction

Aortic, Coronary and Structural Heart Class III medical devices or implants, which are usually permanent implanted devices, have emerged as crucial instruments in the treatment of a wide range of medical diseases. Implant settings might range from quiet to extremely active. implants that may be subjected to high levels of cyclic mechanical stress and have irregular material characteristics. These medical devices are expected to last for many decades because most patients who have them put are children or young adults. Even though they are relatively uncommon, fractures of Class III medical devices and other implantable cardiac devices are likely to become more significant factors in both clinical patient management and the assessment of new technologies as their use in this population increases.

The study of implant failures, particularly in Aortic, Coronary and Structural Heart Class III medical devices, is essential due to the serious clinical complications that can arise when these devices malfunction. Implant failures can lead to conditions such as occlusion, stenosis, migration, pin fractures, and excessive bleeding, all of which pose significant risks to patient health and therapeutic outcomes. These issues are often exacerbated by the complex biomechanical environment within the human body, which subjects implants to a variety of mechanical stresses, including compression, stretching, bending, and twisting forces. Understanding the mechanisms of these failures is crucial for developing more durable devices and enhancing their safety and reliability.

Aortic, Coronary and Structural Heart Class III medical devices, including stents and aortic grafts, are particularly vulnerable to mechanical fatigue and fractures due to their placement in dynamic anatomical regions. For instance, aortic stent graft fractures can result in loss of seal, leakage into the aneurysm sac, stent migration, or embolization of stent fragments, necessitating revision surgeries. Although fractures have been clinically observed in devices like the InCraft and EndurantEvo stents, these fractures do not always correlate directly with adverse outcomes and are often considered as part of a broader benefit-risk assessment.

Potential sequelae of stent fractures vary depending on the type of device and anatomical location. For example, fractures in stents placed in the superficial femoral artery (SFA) have been associated with restenosis in certain cases, particularly for Type III and IV fractures (Scheinert, 2005; Allie, 2006). These failures may lead to repeat procedures, migration, vessel perforation, and embolization of struts or fragments to downstream tissues, including the toes in SFA cases, the heart and lungs in venous stents, and neurovascular regions in carotid stents. However, the correlation between stent fractures and restenosis or other complications is not always straightforward. For example, the LifeStent RESILIENT study observed no clear association between patency and stent fractures (SSED, 2009), while Weinberg et al. (2018) reported no link between carotid stent fractures and restenosis. These inconsistencies highlight the need for a more comprehensive understanding of the mechanisms and clinical implications of stent fractures.

Main Body:

Aortic, Coronary and Structural Heart implant Failures,Causes and Challenges:

Fundamentally, material failure in implants results from an imbalance between the applied stress and the inherent strength of the material, which can be due to external forces like compression, stretching, bending, and twisting. These forces act on critical components, including pipes, stents, and even biological structures like the aortic wall and coronary plaques, making a thorough understanding of these mechanisms essential for the development of robust Class III medical devices.

In some cases, structural failures in stents may lead to more severe outcomes. Closed-cell stent designs, particularly those with gold coatings, have shown tendencies toward kinking, fracturing, and even separation, which can necessitate surgical revascularization for affected patients (N Engl J Med, 2002). Such failures underscore the importance of balancing material strength and device design to withstand the external forces they encounter in vivo.Following are examples of implant failures:

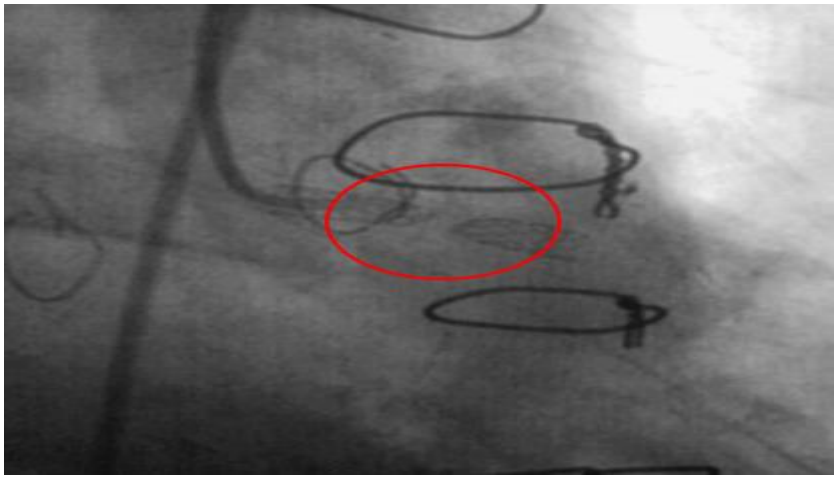


Figure 1: Implant mechanical failure, Kink and breakage of implant.

Source: N Engl J Med, Vol. 347, No. 8, August 22, 2002, www.nejm.org p.581

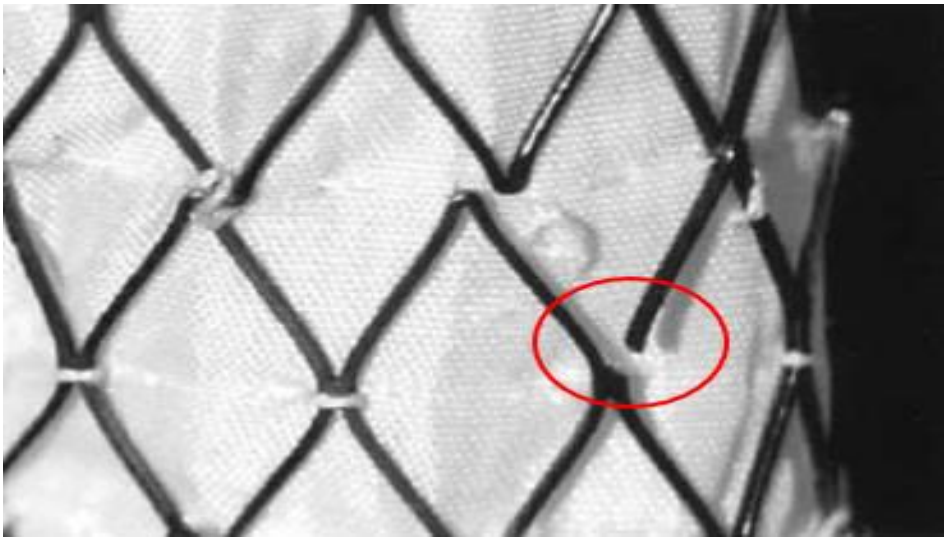


Figure 2: Implant mechanical failure, broken strut.

Source: *C.K. Zarins, MD, Explant analysis of AneuRxstent grafts: Relationship between structural findings and clinical outcome, 2004, JVS*

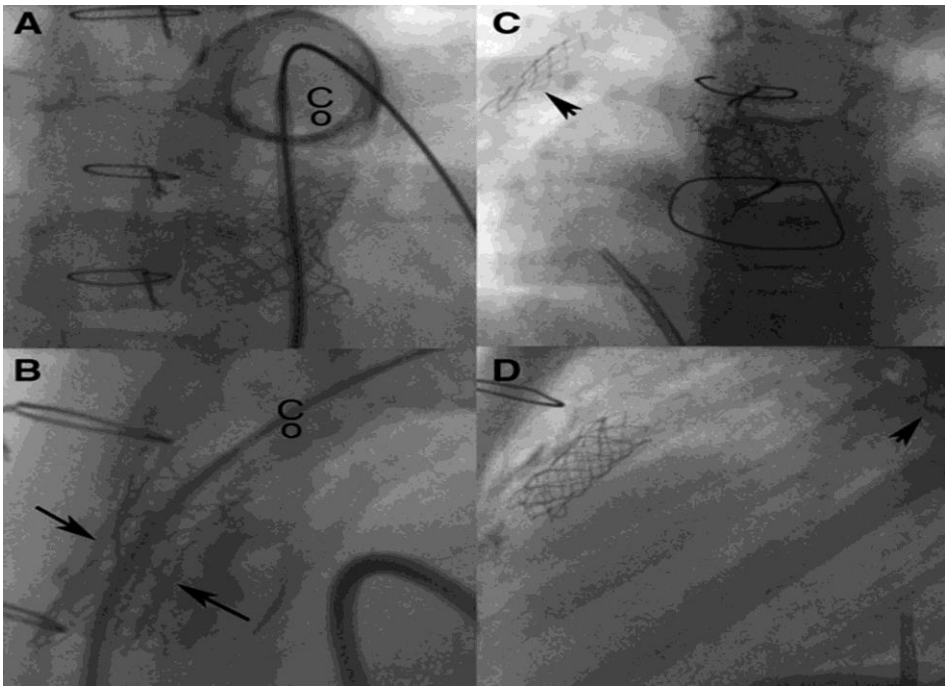


Figure 3.Examples of 2 different complete, longitudinal fractures of Palmaz stents in right ventricular outflow tract conduits. In A and B, anteroposterior and lateral views in the same patient, the heavily calcified homograft conduit (Co) is directly apposed to the anterior chest wall, and the fractured stent is compressed in an anteroposterior orientation (arrows). In C and D, anteroposterior and lateral views in a different patient, the stent is partially apposed to the anterior chest wall, and a large fragment of the stent has embolized to the right lung (arrowheads)

Source: Doff B. McElhinney. Circulation: Cardiovascular Interventions. Fracture of Cardiovascular Stents in Patients With Congenital Heart Disease, Volume: 6, Issue: 5, Pages: 575-585, DOI: (10.1161/CIRCINTERVENTIONS.113.000148)

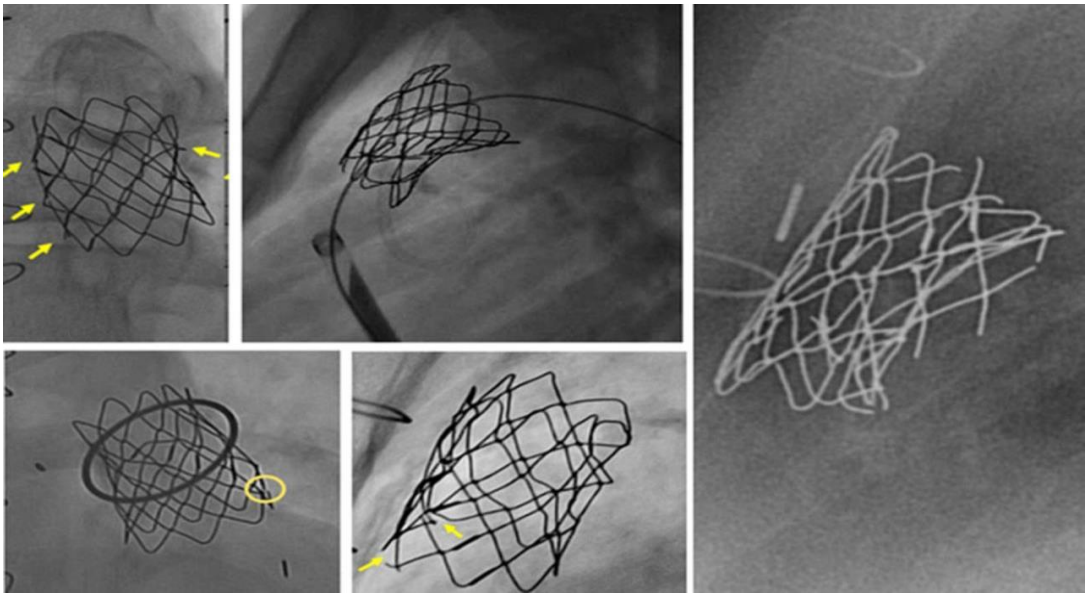
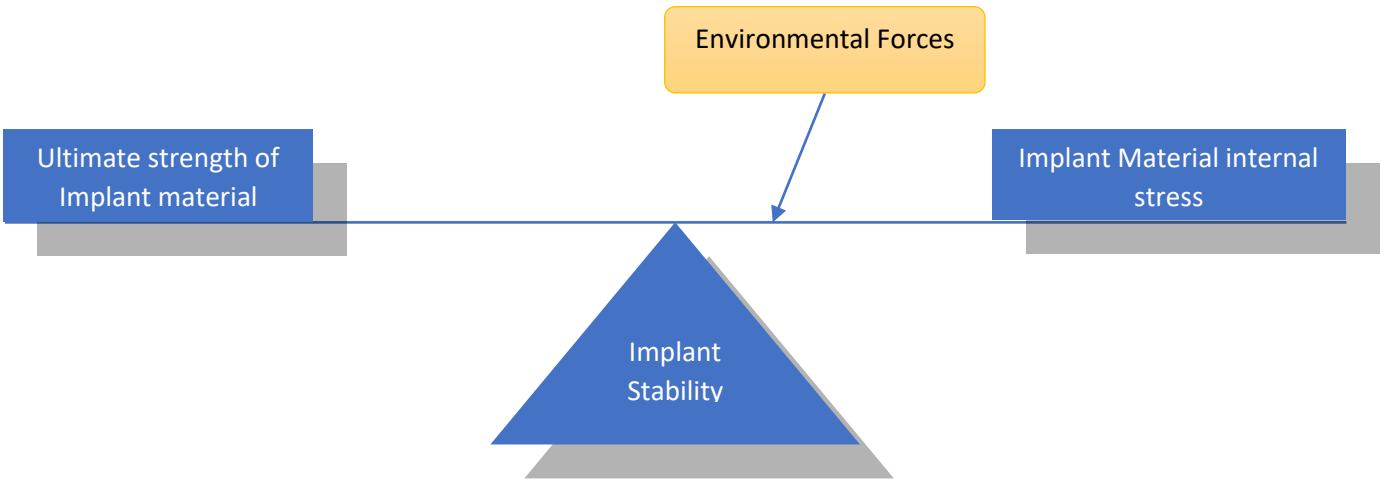


Figure 4. Examples of Implants mechanical failures

Source: Doff B. McElhinney. Circulation: Cardiovascular Interventions. Fracture of Cardiovascular Stents in Patients With Congenital Heart Disease, Volume: 6, Issue: 5, Pages: 575-585, DOI: (10.1161/CIRCINTERVENTIONS.113.000148)

This paper investigates the detailed causes of implant failures in Class III medical devices and explores problems and challenges to enhance testing methodologies aimed at improving implant durability and reliability. By examining both the fundamental mechanisms of material failure and specific clinical outcomes associated with device fractures, this study aims to provide insights that will guide the development of safer and more effective implantable medical devices.



Basic mechanisms of material Class III medical device failure

Causes of Implant Failures

Understanding the various causes of Aortic, Coronary and Structural Heart implant failures is essential for developing sustainable solutions. Key factors include:

- **High Anatomic Pressure and Tortuous Flow Path**: Implants are often subjected to intense anatomical pressures and complex blood flow paths, which may sometimes exceed the material's fatigue limits.

- **Relative Motion and Abrasive Wear**: Movement between components and adjacent tissues can lead to abrasive wear, reducing the implant's functional lifespan.
- **Improper Design and Material Selection**: Poor geometry, unsuitable materials, and inadequate design lead to component fatigue and structural failures under variable loading conditions.

Failure Modes and Clinical Impact

Aortic, Coronary and Structural Heart Implant failures can manifest in various forms, such as longitudinal and transverse strains, metal fatigue, and material degradation. These failures compromise the implant's functionality, posing health risks to patients. Clinically significant fractures may be exacerbated by factors such as muscle contractions, breathing-induced diaphragm movements, and changes in pressure during the cardiac cycle.

The need for geometric characterization is essential in endovascular device design to determine device dimensions, design fatigue tests, and understand how cardiovascular disease pathogenesis is influenced by vessel geometry changes. Unwanted stiffness from stent bridges can lead to fatigue in axial strain, bending, and twist, causing tissue irritation.

Testing Challenges and Limitations

Current testing methods often fail to replicate the complex clinical environment, leading to high variability in data and low predictive power. Key challenges include:

- **Unrealistic Loading Conditions**: Tests that do not simulate clinical loads can yield misleading data regarding device reliability.
- **Statistical Bias**: Selective statistical modeling post-data collection can introduce biases, undermining reliability estimates.
- **Finite Element Analysis (FEA) Limitations**: Many FEA models lack validation and often operate at a macroscopic level, failing to capture nuances in load-displacement behavior and component-level stress distribution.

Conclusion:

Understanding the mechanical failures and associated problems in Aortic, Coronary and Structural Heart Class III medical devices, such as implants, is critical for ensuring patient safety and enhancing device reliability. These failures, often due to fatigue fractures, anatomical pressures, and wear between components, can lead to severe complications, including migration, occlusion, and even life-threatening events. By thoroughly examining the underlying causes of these issues, the medical device industry can develop strategies to mitigate them throughout the various phases of product development, ultimately contributing to safer and more effective medical devices for patients.

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