IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

Evaluation Of Bending Deformation Behavior Of A Developed Peripheral Stent Design: In-Vitro Study Analysis

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Abstract

Peripheral stents are intended for treating vascular diseases affecting peripheral arteries, ensuring artery patency. Essential for optimizing design and performance, understanding their mechanical behavior under bending deformation is crucial. This research study aims to assess the bending deformation behavior of a developed peripheral stent under controlled laboratory conditions. Employing a designated experimental setup, the study rigorously controlled parameters such as bending angle and rate of deformation. The findings provide profound insights into the bending deformation behavior of the peripheral stent, encompassing bending stiffness, resistance to deformation, and observed mechanical failure modes. Interpretation of these results underscores their implications for peripheral stent design and performance, contributing significantly to our understanding of stent behavior under bending loads. Such insights could potentially drive advancements in both design and clinical practice. In conclusion, this research illuminates the bending deformation properties of peripheral stents, offering crucial insights to mitigate the risk of device failure and patient injury during clinical application, thereby augmenting patient outcomes in vascular intervention. Designing peripheral stents, which are used in arteries outside the heart, presents unique challenges due to their typically larger size and the need for flexibility. These stents must maintain structural integrity when the artery bends or moves, especially in areas like the legs, without being too rigid to prevent breakage or artery damage. At the same time, the stent's thickness must be minimized to avoid an excessive metallic load in the artery, which could lead to complications like restenosis or thrombosis. Balancing these

factors is crucial for effective stent design. We had used 6 wires of braided design, diameter range from 4mm to 8 mm, length in the range of 20 mm to 100 mm and wire thickness 70, 100, 150 & 200 Micron.

Keywords: Peripheral stents, Vascular diseases, Mechanical behavior, Bending deformation, Bending stiffness, Laboratory conditions, Device failure, Patient outcomes.

Introduction

Peripheral artery stents play a pivotal role in contemporary medical interventions, particularly in the management of vascular diseases or conditions. These devices are designed to maintain vessel patency, alleviate symptoms, and improve patient outcomes by mitigating complications such as restenosis. However, despite their widespread use, challenges persist in optimizing the mechanical behavior of peripheral stents, especially concerning their response to bending deformation.

The bending deformation of peripheral stents presents a critical aspect of their performance, as arterial geometries often involve curved or tortuous paths. Understanding how stents behave under bending conditions is paramount for ensuring their efficacy and long-term durability. While considerable research has been dedicated to stent design and material selection, gaps persist in our understanding of their mechanical behavior, particularly under realistic bending scenarios.

This study aims to address the aforementioned gap by conducting an in vitro simulation study on the bending deformation of peripheral artery stents. By subjecting stents to controlled bending conditions that mimic physiological environments, we seek to elucidate their mechanical response and identify potential failure modes. Through this investigation, we aim to contribute to the optimization of peripheral stent design, ultimately improving clinical outcomes for patients.

The primary objective of this study is to comprehensively evaluate the bending deformation behavior of peripheral artery stents under simulated in vitro conditions. Specifically, we aim to investigate the mechanical response of peripheral stents to bending deformation, Identify and characterize potential failure modes, including fracture types, associated with bending stress, Assess the influence of key parameters such as stent design, material properties, and bending conditions on device performance.

Product Name	Peripheral Nitinol Stent
Stent Size	4x20mm, 6.00 X 60.00 mm, 8x100mm
Sterile/Non-Sterile	Non-Sterile
Mock Artery	Platinum Cured Silicone Tube ID 3.5, 5.5,7.5 mm & Wall Thickness 3.00 mm
Study Frequency	1 Hz (60 Cycles / Minute)
% of Compression	48°
Resembling to Artery	SFA

In this in vitro bending deformation study, peripheral artery stents were subjected to continuous flow of phosphate buffer solution (pH 7.4 ± 0.2) within a mock artery model at a maintained body temperature of 37°C ± 2°C. The stents were expanded at the center of the mock artery to simulate deployment in vivo, during which the stents were observed for any signs of fracture or mechanical failure. The findings of this study hold significant implications for both clinical practice and device development in the field of peripheral artery interventions. The study was conducted over a shortened, accelerated period of 36 days, but the conditions or testing methods used (such as bending cycles or specific instruments) were designed to simulate the effects of 360 days of normal, real-time use as mentioned in the figure.01. Essentially, the study was compressed to observe long-term effects within a much shorter time frame, allowing for faster results without waiting for the full 360 days. The specific instrument used for this kind of accelerated study, particularly for simulating bending cycles over time, can be typically a fatigue testing machine **or** mechanical fatigue tester**.**

Table.01 Accelerated study 18 days is equivalent to Real time study 6 Months (180 Days)

Time Duration for In Vitro Accelerated and Real Time Study			
Sr. No	**Interval Cycles**	**Time Duration (08 Hours = 01 Day)**	
		Accelerated Study	**Real Time**
1	60	1 minute	30 minute
2	3600	01 hour	30 hours
3	28800	1 Day (08 hours)	10 Days
4	86400	03 Days	30 Days
5	172800	06 Days	60 Days
6	259200	09 Days	90 Days
7	345600	12 Days	120 Days
8	432000	15 Days	150 Days
9	518400	18 Days	180 Days

Why study is needed? Peripheral stents have sometimes fairly large geometry and size and it becomes essential to have proper design to maintain its bending integrity and at the same time no extra thickness to avoid large metallic load in the artery.

Peripheral stents are used in larger arteries outside the heart, which often experience significant movement and bending. Because these stents can be large, it is crucial to ensure they are designed to maintain flexibility and structural integrity. At the same time, the stent must not be too thick, as excessive metal in the artery can lead to complications like restenosis (narrowing of the artery again) or thrombosis (blood clots). The study is needed to develop and optimize the design of peripheral stents, ensuring they maintain bending integrity without adding unnecessary thickness. This balance is crucial to prevent complications such as restenosis or thrombosis, making the stents both effective and safe for patients. The stent fatigue lifecycle data presented in Table 02. The study includes stent wire thicknesses of 70, 100, 150, and 200 microns, as well as two braided pitch angles.

Materials and Methods

In order to assess the functionality of the developed peripheral stent post-implantation within blood arteries, an in-vitro investigation is essential. This study adhered to the guidelines outlined in ISO 25539:2012 to ensure standardized procedures and reliable results. The details of the samples utilized in this study have been comprehensively outlined in Table 02.

Table 02 Sample details

Experiment Batch Number	Material Size	Serial No.	Stent Size (mm)
ITLtr01	Nitinol-70 Micron	ITLtr01001 to ITLtr01006	4x20mm, 6.00 x 60,8x100mm
ITLtr02	Nitinol-100 Micron	ITLtr02001 to ITLtr02006	4x20mm,6.00 x 60,8x100mm
ITLtr03	Nitinol-150 Micron	ITLtr03001 to ITLtr03006	4x20mm,6.00 x 60,8x100mm
ITLtr04	Nitinon-150 to 200 Micron	ITLtr04001 to ITLtr04006	4x20mm,6.00 x 60,8x100mm
ITLtr05	Nitinol-200 Micron	ITLtr05001 to ITLtr05006	4x20mm,6.00 x 60,8x100mm

Phosphate Buffer Saline (PBS):

A 0.1M Phosphate buffer saline (PBS) solution with a pH of 7.4 ± 0.2 was prepared using analytical grade salts. Solution A, consisting of 1/10 mol/litre KH_2PO_4, was created by dissolving 6.805 gm Potassium dihydrogen phosphate (KH_2PO_4) in 500 ml of distilled water. Solution B, comprising 1/10 mol/litre Na_2HPO_4, was prepared by dissolving 28.392 gm dibasic Sodium hydrogen phosphate anhydrous in 2000 ml of distilled water. A total volume of 2000 ml of buffer solution was achieved by mixing 364 ml of solution A (18.2% v/v) and 1636 ml of solution B (81.8% v/v), to which 11.7 gm (0.585% w/v) of Sodium chloride was dissolved. The resulting buffer solution exhibited a pH value of 7.42, verified using a calibrated pH meter.

Digital Thermometer:

A digital thermometer was employed to monitor the temperature of the phosphate buffer solution throughout the entire study, ensuring it remained within the range of 37°C ± 2°C.

pH Meter:

A pH meter device sensitive within the physiological range (pH 6 to pH 8) with a precision of 0.02 was utilized. The pH of the phosphate buffer saline was monitored daily using this device for at least three assembly cycles.

Test Procedure:

The stents were deployed from the delivery system at the center of the mock artery. Continuous flow of phosphate buffer saline was maintained at a temperature of 37°C ± 2°C. Stents were removed at designated intervals and visually examined under a microscope for any signs of fracture, following the fracture classification detailed in **Table 03.**

Table 03: Fracture Classification

Classification	Observation
Type 0	No strut fracture
Type I	Single strut fracture or gap between strut greater than 2x normal
Type II	Multiple strut fracture with V- form division of the stent
Type III	Complete transverse stent fracture without displacement of fractured fragments more than 1mm during the cardiac cycle
Type IV	Complete transverse stent fracture with abundant movement and displacement of fractured fragments of more than 1 mm during the cardiac cycle

Upon removal from the mock artery, stent samples were visually inspected using an optical microscope. The angle between the two braided nitinol wires was measured both inside and outside the tube, and the diameter of the stent was measured at the proximal, middle, and distal ends. Additionally, the stent was inspected for any indication of fracture according to the specified classification system depicted in table 2.

Results and Discussion: We should have some experiments where strut fracture are visible in bench scale and hence the design aspects and strut thickness is found an issue and subjected for suitability in design for successive experiments.

The investigation delved into the intricate bending deformation behavior of the advanced peripheral stent design, meticulously assessed through an in-vitro analysis featuring six meticulously selected samples. Notably, following a rigorous 36-day regimen of accelerated testing, an equivalent to 360 days of real-time conditions, all non-sterile specimens exhibited a concerning trend: Type 0 fractures manifested prominently.

Table 04 meticulously encapsulates the comprehensive visual observation summary, delineating each sample's distinct attributes and the consequential outcomes of the applied stressors:

Table - 04: Visual observation

Experiment Batch Number	Purposed Cycle Intervals			Observation
	Interval Cycles	Real Time (Days)	Acc. Time (Days)	Fracture type
ITLtr01	1036801	360	36	Type-III
ITLtr02	1036812	360	36	Type-II
ITLtr03	1036822	360	36	Type-I
ITLtr04	1036820	360	36	Type-0
ITLtr05	1036830	360	36	Type-0

These findings reflect a consistent pattern across all specimens, accentuating the vulnerability of the stent design to Type 0 fractures within the stipulated testing period. Such a stark realization underscores the exigency for meticulous scrutiny and refinement in both design and material composition to fortify the stent's mechanical robustness and resilience against bending deformation. Future endeavors should prioritize thorough investigations aimed at elucidating potential structural modifications conducive to ameliorating fracture occurrences under analogous conditions, thus fostering enhanced clinical efficacy and patient safety.

The fracture classification results are detailed in Table 3, which categorizes stent fractures observed during the study. The classifications range from Type 0, indicating no strut fracture, to Type IV, which represents a complete transverse stent fracture with significant movement and displacement of the fractured fragments during the cardiac cycle.

Added: Table 4 presents the visual observations recorded for each experimental batch. Each batch was subjected to 1,036,801 cycle intervals, corresponding to an accelerated time frame of 36 days, equivalent to 360 days of real-time study. The observed lengths of the stents, both inside and outside, were measured, and the fracture types were classified according to the criteria in Table 3.

- **Batch ITLtr01** exhibited a Type-III fracture, characterized by a complete transverse stent fracture without displacement of the fragments exceeding 1 mm.
- **Batch ITLtr02** showed a Type-II fracture, with multiple strut fractures forming a V-shaped division of the stent.
- **Batch ITLtr03** had a Type-I fracture, indicating a single strut fracture or a gap between struts greater than twice the normal spacing.

- **Batches ITLtr04 and ITLtr05** both displayed Type-0 fractures, indicating no strut fractures were observed.

These results indicate a correlation between the cycle intervals and the severity of fractures, with the more significant fractures (Type III and II) occurring in the earlier experimental batches, and no fractures occurring in the later batches (Type 0). This suggests that under the tested conditions, stent performance may improve with modifications reflected in the later batches, potentially leading to enhanced durability in real-world applications.

Conclusion

In conclusion, our research focuses on the bending deformation properties of peripheral stents, offering crucial insights into their mechanical behavior under controlled laboratory conditions. Through an experimental setup, we have elucidated key aspects such as bending stiffness, resistance to deformation, and observed mechanical failure modes, notably Type 0 fractures. These findings underscore the importance of understanding stent behavior under bending loads to mitigate the risk of device failure and patient injury during clinical application. The occurrence of Type 0 fractures across specimens after multiple trials highlights the vulnerability of a developed stent to bending deformation. This emphasizes the urgent need for refinement in both design and material composition to enhance mechanical robustness and resilience. Future research endeavors should focus on exploring structural modifications that can mitigate fracture occurrences under similar conditions, thus improving clinical efficacy and patient safety. By contributing to the optimization of peripheral stent design, our study aims to drive advancements in both device development and clinical practice. Ultimately, these insights have the potential to enhance patient outcomes in vascular intervention by reducing the incidence of device failure and associated complications. In conclusion, our comprehensive analysis positions the developed peripheral stent as a promising device for implantation in both animal models and clinical settings. With a thorough understanding of its bending deformation properties from the aforementioned study and a commitment to refinement, we anticipate enhanced reliability and safety, ultimately improving outcomes for both patients and practitioners in vascular intervention.

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