

**DESIGN, FINITE ELEMENT MODELLING AND EXPERIMENTAL
INVESTIGATION OF THE NOVEL AUXETIC STENTS FOR
ENHANCED MECHANICAL AND FUNCTIONAL ATTRIBUTES**

KHANISH GUPTA



**DEPARTMENT OF MECHANICAL ENGINEERING
INDIAN INSTITUTE OF TECHNOLOGY DELHI
NEW DELHI-110016, INDIA
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**Design, Finite Element Modelling and Experimental Investigation of the
Novel Auxetic Stents for Enhanced Mechanical and Functional Attributes**

by

KHANISH GUPTA

Department of Mechanical Engineering

Submitted

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Dedicated to

My Parents

and

Grandparents

CERTIFICATE

This is to certify that the thesis entitled “**Design, Finite Element Modelling and Experimental Investigation of the Novel Auxetic Stents for Enhanced Mechanical and Functional Attributes**” being submitted by **Mr. Khanish Gupta** to the **Indian Institute of Technology Delhi** in fulfillment of the award of **Doctor of Philosophy** in Department of Mechanical Engineering is an authentic record of the investigations carried out by him under my guidance and supervision.. The presented work has fulfilled the requirement for the submission of this thesis and has reached the required criterion to the best of my knowledge and belief.

The research reports and the results presented in this thesis have not been submitted in parts or in full previously for the award of any degree or diploma to any other University or Institute.

Prof. Kusum Meena

Assistant Professor

Department of Mechanical Engineering

Indian Institute of Technology Delhi

New Delhi - 110016

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(KHANISH GUPTA)

ABSTRACT

Vascular diseases, particularly atherosclerosis, are among the most prevalent and significant health challenges globally. Atherosclerosis is characterized by the buildup of plaques composed of fat, cholesterol, and other substances along the inner walls of arteries, leading to their narrowing and hardening. This condition often necessitates medical interventions, with stent implantation being a standard procedure for treating various artery diseases. Stents, whether metallic or polymeric, are used to expand the plaqued artery and remain in place to provide structural support until the remodelling process is complete. However, traditional stents have several limitations, including low radial strength, which can lead to late in-stent restenosis, foreshortening, high radial recoil, etc. These issues can compromise the effectiveness of conventional stents and lead to adverse clinical outcomes. In response, researchers have explored various stent designs to address these challenges. Recently, stents with auxetic designs have gained attention due to their unique deformation characteristics. Auxetic materials exhibit a negative Poisson's ratio, meaning they expand laterally when stretched longitudinally. This property can enhance their mechanical properties, such as radial strength, radial recoil, foreshortening, and others, making them promising candidates for overcoming the limitations of conventional stents.

The present study focused on three novel auxetic stent designs: Double Arrowhead (DA), Re-entrant (RE), and S-shaped auxetic designs. The designed stent had an outer diameter of 1.6mm and a wall thickness of 0.11mm. The effect of different design parameters (angle, amplitude, and width) on the mechanical properties (radial strength and radial recoil) of each auxetic stent was studied using finite element analysis (FEA). Parametric analysis was conducted using two statistical tools, i.e., the Taguchi method and ANOVA to optimize the design parameters for each auxetic stent design. The results of the parametric analysis revealed that width was the most influential factor for the DA and S-shaped auxetic stents, while the RE auxetic stent was nearly equally influenced by width and angle. Amplitude had a minimal influence on the mechanical properties of the DA and RE auxetic stents. Similarly, the angle has a minimum influence on the mechanical properties of DA and S auxetic stents. Following the optimization of design parameters, full-length auxetic stents for each design were modelled using the optimized design parameters and then simulated and compared with the commercially available Abbott Xience stent. The FEA simulations showed that the auxetic stents had more than double the radial strength of the Abbott Xience stent. Additionally, the auxetic stents

exhibited significantly reduced radial recoil and completely eliminated the issue of foreshortening, which is a common problem in conventional commercial stents.

The designed auxetic stents were then manufactured using the femtosecond laser cutting technique, and electrochemical polishing was performed to enhance their surface quality. The final electropolished stents had a strut width of 80 μm (0.08 mm), comparable to commercially available stents. Subsequently, in-vitro testing was conducted to evaluate the mechanical properties of the fabricated auxetic stents, including radial strength, recoil properties, foreshortening, Poisson's ratio, crushing strength, bending strength, Maximum Circular Unsupported Surface area (MCUSA), open cell area, and artery coverage ratio. The results revealed significant improvements in the radial strength of the auxetic stents compared to the commercial Abbott Xience stent, with increases of 81%, 155.55%, and 112.69% for the DA, RE, and S-shaped stents, respectively. Additionally, the radial recoil was substantially reduced, and the issue of foreshortening, present in the commercial stent, was completely eliminated. The Re-entrant and S-shaped auxetic stents showed similar maximum circular unsupported surface area values to the commercial stent. While variations in the open cell area were observed across different fabricated stent designs, with an increasing trend from the DA stent to the RE, S, and AB stents, which exhibit progressively larger open cell areas. The analysis of artery coverage showed relatively minor variations across different fabricated stent designs. The commercial AB Xience stent exhibited the least artery coverage, followed by the RE stent, slightly higher coverage by the S stent, and the maximum coverage by the DA stent. The results confirmed the superior mechanical properties of the auxetic stents compared to the commercial Abbott Xience stent. These enhancements in radial strength, recoil reduction, and elimination of foreshortening underscore the potential of auxetic stents as advanced alternatives for vascular interventions, offering improved performance and reduced complications.

The FEA models can be developed to evaluate future stent designs, streamline development processes, and reduce costs. The manufacturing of such futuristic stents represents a promising advancement in plaqued artery treatment, with the potential to enhance patient outcomes and reduce the risk of restenosis and thrombosis. As research continues to evolve, the integration of auxetic design into stent design is likely to play a critical role in shaping the future of vascular interventions.

सार

संवहनी रोग, विशेष रूप से एथेरोस्क्लेरोसिस, वैश्विक स्तर पर सबसे प्रचलित और महत्वपूर्ण स्वास्थ्य चुनौतियों में से एक हैं। एथेरोस्क्लेरोसिस की विशेषता धमनियों की आंतरिक दीवारों के साथ वसा, कोलेस्ट्रॉल और अन्य पदार्थों से बने प्लाक के निर्माण से होती है, जिससे वे संकीर्ण और सख्त हो जाते हैं। इस स्थिति में अक्सर चिकित्सा हस्तक्षेप की आवश्यकता होती है, जिसमें स्टेंट प्रत्यारोपण विभिन्न धमनी रोगों के इलाज के लिए एक मानक प्रक्रिया है। स्टेंट, चाहे धातु हो या बहुलक, प्लाक वाली धमनी को फैलाने के लिए उपयोग किए जाते हैं और रीमॉडलिंग प्रक्रिया पूरी होने तक संरचनात्मक सहायता प्रदान करने के लिए जगह पर रहते हैं। हालाँकि, पारंपरिक स्टेंट की कई सीमाएँ हैं, जिनमें कम रेडियल ताकत शामिल है, जो देर से इन-स्टेंट रेस्टेनोसिस, फोरशॉर्टनिंग, उच्च रेडियल रिकॉइल आदि का कारण बन सकती है। ये मुद्दे पारंपरिक स्टेंट की प्रभावशीलता से समझौता कर सकते हैं और प्रतिकूल नैदानिक परिणामों को जन्म दे सकते हैं। जवाब में, शोधकर्ताओं ने इन चुनौतियों का समाधान करने के लिए विभिन्न स्टेंट डिज़ाइनों की खोज की है। हाल ही में, ऑक्सेटिक डिज़ाइन वाले स्टेंट ने अपनी अनूठी विरूपण विशेषताओं के कारण ध्यान आकर्षित किया है। ऑक्सेटिक पदार्थ नकारात्मक पॉइसन अनुपात प्रदर्शित करते हैं, जिसका अर्थ है कि जब उन्हें अनुदैर्ध्य रूप से खींचा जाता है तो वे पार्श्व रूप से फैलते हैं। यह गुण उनके यांत्रिक गुणों को बढ़ा सकता है, जैसे कि रेडियल ताकत, रेडियल रिकॉइल, फोरशॉर्टनिंग और अन्य, जो उन्हें पारंपरिक स्टेंट की सीमाओं पर काबू पाने के लिए आशाजनक उम्मीदवार बनाता है।

वर्तमान अध्ययन तीन नए ऑक्सेटिक स्टेंट डिज़ाइनों पर केंद्रित है: डबल एरोहेड (डीए), री-एंट्रेंट (आरई), और एस-आकार के ऑक्सेटिक डिज़ाइन। डिज़ाइन किए गए स्टेंट का बाहरी व्यास 1.6 मिमी और दीवार की मोटाई 0.11 मिमी थी। प्रत्येक ऑक्सेटिक स्टेंट के यांत्रिक गुणों (रेडियल ताकत और रेडियल रिकॉइल) पर विभिन्न डिज़ाइन मापदंडों (कोण, आयाम और चौड़ाई) के प्रभाव का अध्ययन परिमित तत्व विश्लेषण (FEA) का उपयोग करके किया गया था। प्रत्येक ऑक्सेटिक स्टेंट डिज़ाइन के लिए डिज़ाइन मापदंडों को अनुकूलित करने के लिए दो सांख्यिकीय उपकरणों, यानी, तागुची विधि और एनोवा का उपयोग करके पैरामीट्रिक विश्लेषण किया गया था। पैरामीट्रिक विश्लेषण के परिणामों से पता चला कि डीए और एस-आकार के ऑक्सेटिक स्टेंट के लिए चौड़ाई सबसे प्रभावशाली कारक थी, जबकि आरई ऑक्सेटिक स्टेंट चौड़ाई और कोण से लगभग समान रूप से प्रभावित था। आयाम का डीए और आरई ऑक्सेटिक स्टेंट के यांत्रिक गुणों पर न्यूनतम प्रभाव था। इसी तरह, कोण का डीए और एस ऑक्सेटिक स्टेंट के यांत्रिक गुणों पर न्यूनतम प्रभाव पड़ता है। डिज़ाइन मापदंडों के अनुकूलन के बाद, प्रत्येक डिज़ाइन के लिए पूर्ण-लंबाई वाले ऑक्सेटिक स्टेंट को अनुकूलित डिज़ाइन मापदंडों का उपयोग करके मॉडल किया गया और फिर व्यावसायिक रूप से उपलब्ध एबॉट ज़िएंस स्टेंट के साथ सिम्युलेट और तुलना की गई। FEA सिमुलेशन ने दिखाया कि ऑक्सेटिक स्टेंट में एबॉट ज़िएंस स्टेंट की तुलना में

दोगुनी से अधिक रेडियल ताकत थी। इसके अतिरिक्त, ऑक्सेटिक स्टेंट ने रेडियल रिकॉइल को काफी कम कर दिया और फ़ॉरशॉर्टनिंग की समस्या को पूरी तरह से समाप्त कर दिया, जो पारंपरिक वाणिज्यिक स्टेंट में एक आम समस्या है।

इसके बाद डिज़ाइन किए गए ऑक्सेटिक स्टेंट को फेमटोसेकंड लेजर कटिंग तकनीक का उपयोग करके निर्मित किया गया, और उनकी सतह की गुणवत्ता को बढ़ाने के लिए इलेक्ट्रोकेमिकल पॉलिशिंग की गई। अंतिम इलेक्ट्रोपॉलिश किए गए स्टेंट की स्ट्रूट चौड़ाई $80\ \mu\text{m}$ (0.08 मिमी) थी, जो व्यावसायिक रूप से उपलब्ध स्टेंट के बराबर थी। इसके बाद, निर्मित ऑक्सेटिक स्टेंट के यांत्रिक गुणों का मूल्यांकन करने के लिए इन-विट्रो परीक्षण किया गया, जिसमें रेडियल ताकत, रिकॉइल गुण, फोरशॉर्टनिंग, पॉइसन अनुपात, क्रशिंग ताकत, झुकने की ताकत, अधिकतम परिपत्र असमर्थित सतह क्षेत्र (MCUSA), खुला सेल क्षेत्र और धमनी कवरेज अनुपात शामिल हैं। परिणामों ने वाणिज्यिक एबॉट ज़िएंस स्टेंट की तुलना में ऑक्सेटिक स्टेंट की रेडियल ताकत में महत्वपूर्ण सुधार दिखाया, जिसमें क्रमशः डीए, आरई और एस-आकार के स्टेंट के लिए 81%, 155.55% और 112.69% की वृद्धि हुई। इसके अतिरिक्त, रेडियल रिकॉइल में काफी कमी आई और वाणिज्यिक स्टेंट में मौजूद फोरशॉर्टनिंग की समस्या पूरी तरह से समाप्त हो गई। री-एंट्रेंट और एस-आकार के ऑक्सेटिक स्टेंट ने वाणिज्यिक स्टेंट के समान अधिकतम गोलाकार असमर्थित सतह क्षेत्र मान दिखाए। जबकि विभिन्न फैब्रिकेटेड स्टेंट डिज़ाइनों में ओपन सेल क्षेत्र में भिन्नता देखी गई, जिसमें डीए स्टेंट से लेकर आरई, एस और एबी स्टेंट तक की प्रवृत्ति में वृद्धि देखी गई, जो उत्तरोत्तर बड़े ओपन सेल क्षेत्र प्रदर्शित करते हैं। धमनी कवरेज के विश्लेषण ने विभिन्न फैब्रिकेटेड स्टेंट डिज़ाइनों में अपेक्षाकृत मामूली भिन्नताएँ दिखाईं। वाणिज्यिक एबॉट ज़िएंस स्टेंट ने सबसे कम धमनी कवरेज प्रदर्शित किया, उसके बाद आरई स्टेंट, एस स्टेंट द्वारा थोड़ा अधिक कवरेज, तथा डीए स्टेंट द्वारा अधिकतम कवरेज प्रदर्शित किया। परिणामों ने वाणिज्यिक एबॉट ज़िएंस स्टेंट की तुलना में ऑक्सेटिक स्टेंट के बेहतर यांत्रिक गुणों की पुष्टि की। रेडियल ताकत, रिकॉइल कमी, तथा फोरशॉर्टनिंग के उन्मूलन में ये वृद्धि संवहनी हस्तक्षेपों के लिए उन्नत विकल्प के रूप में ऑक्सेटिक स्टेंट की क्षमता को रेखांकित करती है, जो बेहतर प्रदर्शन और कम जटिलताएं प्रदान करती है।

भविष्य के स्टेंट डिज़ाइनों का मूल्यांकन करने, विकास प्रक्रियाओं को सुव्यवस्थित करने और लागत कम करने के लिए FEA मॉडल विकसित किए जा सकते हैं। ऐसे भविष्य के स्टेंट का निर्माण प्लेक्ड धमनी उपचार में एक आशाजनक प्रगति का प्रतिनिधित्व करता है, जिसमें रोगी के परिणामों को बढ़ाने और रेस्टेनोसिस और थ्रोम्बोसिस के जोखिम को कम करने की क्षमता है। जैसा कि अनुसंधान विकसित हो रहा है, स्टेंट डिज़ाइन में ऑक्सेटिक डिज़ाइन का एकीकरण संवहनी हस्तक्षेपों के भविष्य को आकार देने में महत्वपूर्ण भूमिका निभाने की संभावना है।

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LIST OF ABBREVIATION

DA	Double Arrowhead
RE	Re-entrant
FEA	Finite element analysis
FEM	Finite element methods
MCUSA	Maximum Circular Unsupported Surface Area
CAD	Coronary Artery Disease
CABG	Coronary artery bypass grafting
CVD	Cardiovascular diseases
WHO	World Health Organization
PAD	Peripheral Artery Disease
PTCA	Percutaneous transluminal coronary angioplasty
BMS	Bare metal stents
FDA	Food and Drug Administration
MRI	Magnetic resonance imaging
PCI	Percutaneous coronary intervention
DES	Drug-eluting stents
BRS	Bioresorbable stents
PLLA	Poly-L-lactic acid
PCL	Poly- ϵ -caprolactone
PLGA	Poly(lactide-co-glycolic acid)
FE	Finite Element
ISO	International Standards Organization
ASTM	American Society for Testing and Materials
SLM	Selective Laser Melting
PCM	Photochemical machining
UV	Ultraviolet
SS	Stainless steel
CoCr	Cobalt-chromium
ISA	Incomplete strut apposition
SAR	Stent-to-artery ratio
RCP	Radial collapse pressure
CSA	Cross-sectional area
CFD	Computational fluid dynamics

Mg	Magnesium
RSM	Response surface methodology
NPR	Negative Poisson's ratio
DOE	Design of experiments
RVE	Representative volume element
RMCA	Re-entrant meta-trichiral auxetic
RCA	Re-entrant chiral auxetic
RAS	Re-entrant-Arrow-Snake
TPU	Thermoplastic polyurethane
CRE	Chiral-re-entrant hybrid
NiTi	Nickel titanium
L-PBF	Laser Powder Bed Fusion
HAZ	Heat-affected zones
ECP	Electrochemical polishing
SEMSs	Self-expandable metallic stents
DMBO	Distal malignant biliary obstruction
FDM	Fused deposition modelling
SEM	Scanning Electron Microscopy
CR	Crimping recoil
ER	Expansion recoil
PEEQ	Equivalent plastic strain
ANOVA	Analysis of variance
S/N	Signal-to-Noise
AB	Abbott Xience
EPMA	Electron Probe Microanalysis
DC	Direct Current
DI	Deionized
MRR	Material Removal Rate
AFM	Atomic Force Microscopy