

Finite Element Modelling and Experimental Validation of Endovascular Nitinol Stents: A Pathway to Additive Manufacturing Optimization

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Abstract. Nitinol (NiTi) is renowned for its unique properties, such as superelastic behaviour, which make it particularly suitable for medical devices, including endovascular stents. This study focuses on the modelling, simulation, and experimental testing of self-expanding NiTi stents, with the aim of exploring new strategies for design optimization enabled by additive manufacturing (AM). By combining AM with advanced numerical simulations, complex and customised stent geometries can be developed, overcoming the limitations of conventional manufacturing techniques and enabling improved fabrication processes and performance assessment. An integrated experimental–computational approach is adopted to characterize the mechanical response of a commercial self-expanding NiTi stent used as a case study. In particular, two key mechanical performance metrics are considered: bending compliance and crush resistance. Material parameters are identified by adapting a literature-based constitutive framework through a fitting procedure that combines experimental testing and finite element modelling in Abaqus. The calibrated model is then employed to propose alternative stent designs compatible with additive manufacturing constraints. The results provide valuable insight into the mechanical behavior of self-expanding stents and highlight the potential of additive manufacturing as an effective tool for stent performance optimization.

Keywords: Self-expanding stent, Nitinol, Finite element modelling, additive manufacturing.

1 INTRODUCTION

Endovascular stents are a specific class of stent primarily used to treat vascular pathologies, excluding coronary conditions. This study focuses on the prominent category of endovascular stents: self-expanding (SX) Nitinol (NiTi) stents [1]. SX stents are engineered to expand upon deployment within the vessel autonomously, leveraging the inherent superelastic properties of NiTi. These stents are crimped onto a delivery system housed within a sheath and positioned accordingly. Upon release from the delivery system, the sheath is removed, allowing the stent to expand until it contacts the vessel wall, exerting outward pressure to maintain vessel patency. SX stents are intended for permanent placement, providing long-term support, preventing vessel recoil, and ensuring sustained patency. [2].

Before SX stent insertion, angioplasty or other vessel preparation techniques may be employed for several reasons: to dilate narrowed arteries at the lesion site, facilitate optimal stent positioning and deployment, debulk atherosclerotic plaque to create space for stent placement, and mitigate the risk of complications. This preparatory step is especially critical in

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cases involving calcified lesions or tortuous vessels. Frequently, SX stents necessitate post-dilation balloon angioplasty to achieve full expansion and proper apposition against the arterial wall.

The defining feature of these devices is their material properties, which allow for significant recoverable deformation (up to 5-8%) compared to other metals, an essential characteristic for accommodating physiological movements. [3]. The stent must maintain vessel openness while exerting sufficient force in position, possess adequate stiffness to prevent recoil, and be capable of substantial radial compression for endovascular insertion. Furthermore, it should exhibit flexibility to navigate vessel curvatures and resist fatigue loading. [4]. These mechanical requirements, alongside clinical considerations not addressed in this analysis, render the design of SX stents complex and an excellent candidate for optimization through modern manufacturing techniques. The traditional manufacturing method for these devices is the laser ablation of NiTi tubes of very thin thickness. [5], obtaining a very fine net structure with a large part of the material wasted in the process. The use of additive manufacturing provides an alternative as a net-shape method to save material, and moreover, it opens the possibility to tailor the stent dimension to the patient's needs [6], [7], [8]. This possibility is crucial to increase the efficacy of the device, which must be oversized on the artery diameter to ensure a certain degree of pressure on the vessel wall. Having only off-the-shelf dimensions for the stent diameter, forces the surgeon to operate a trade-off choice between high oversizing (which could lead to inflammation) and low oversizing (which could lead to recoiling of the vessel) [9]. The use of ordered or auxetic disordered metamaterial structures may help in improving the performance of these devices, especially in terms of foreshortening after deployment.

This work aims at evaluating and optimizing the performance of an SX NiTi stent in terms of the main mechanical figures of merit, considering aspects of its performance linked to the physiological behavior and to its manufacturing with additive manufacturing techniques.

2 MATERIALS AND METHODS

The mechanical specifications important for an SX stent heavily depend on its deployment inside the vessel and on the superelastic curve of the material. A good explanation of the deployment is described in [10], **Figure 1** shows a schematic to clarify this point by showing normalized radial forces (N/mm) on the stent and on the vessel, with respect to their diameters (mm), in three phases of stent deployment. The blue line depicts the initial crimping of the stent, from a completely uncrimped stent (initial stent diameter, D_{si} , no radial force on it (point **A**), to a crimped state (minimum diameter D_{sc} , point **B**). This force, which reaches its maximum in point B, is the radial resistive force (**RRF**). Upon release from the sheath, the stent expands until it encounters the inner wall of the vessel at point **C**. From this point the force on the vessel increases until the stent and the vessel find a first equilibrium diameter, D_e (point **D**). Further expansion is then possible through balloon angioplasty, extending the stent to point **E**, which in turn causes the vessel to expand to the same diameter (point **E'**). Following balloon deflation, compressive force from the vessel is exerted on the stent, causing it to recoil to the diameter D'_e at point **F** due to typical stress strain curve of NiTi. This point provides the final equilibrium in the force displacement diagrams and gives one of the crucial parameters of the stent, the so-called chronic outward force (**COF**). Other important mechanical parameters of the stent are the crush resistance (**CR**) and the bending compliance (**BC**). The first is linked to its ability to sustain load when compressed radially and while the second is fundamental since having a compliant stent makes it easier to deploy and capable of sustaining larger physiological movement.

This four main mechanical figures of merits of a SX NiTi stent are in partial conflict, as already reported in [11], especially increasing the compliance lowers the RRF and the CR so the optimal structure which can be pursued in this investigation finds a trade-off between these four parameters, which are investigated through numerical finite element analyses and once a solution is found the capability of AM can be exploited to prototype the structure.

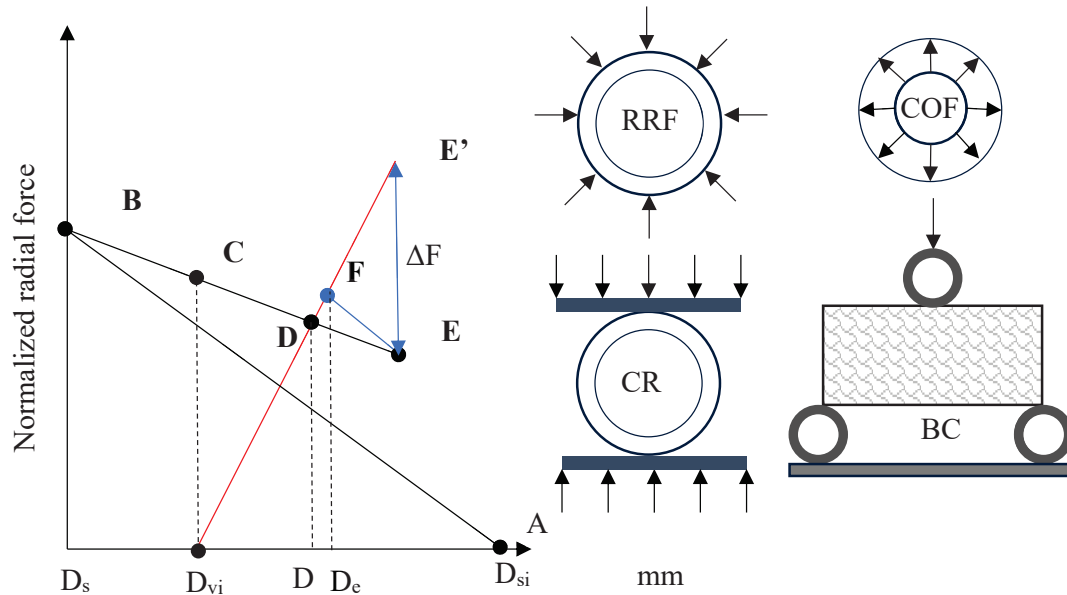


Figure 1: Stent deployment mechanics on the left and schematic representation of COF, RRF, CR and BC on the right

To estimate the behavior of a realistic solution for the stent parametric analysis, a commercial stent was analyzed in detail. The Scitech SOLARIS is a flexible self-expanding endograft, comprised of a thin PTFE membrane encapsulating a Nitinol stent structure, used in the peripheral district [12]. The device has been engineered to provide a higher multidirectional resistance force, high compliance, balanced radial force and low shortening rate. Due to some problems linked to the unexpected rupture of this device when deployed in the popliteal district [13] we envision the need for a structured analysis and optimization of this product, even though the methodology is general and can be applied to each commercial stent. First, a detailed analysis of Solaris stent is carried out by using both microscopy and mechanical tests; then a digital twin is created through the CAD Solidworks, and a series of Finite Elements simulations are carried out to mimic the real structure behavior. The material model, which is a Souza-Auricchio superelastic model already present in the software, is fitted on the experimental curves, and a parametric numerical analysis is carried out to optimize the system, envisioning possible application of AM technology as a printing methodology.

3.1 Experimental tests of the stent

The shape of the stent, which has a nominal diameter of 8 mm and a nominal length of 40 mm, is modeled using Solidworks. The model implemented in the CAD is fully parametric and, through a set of equations, allows fast and coherent change of the structure. The stent has a

modular structure, and the representative unit is depicted in Figure 2a. The dimensions of the stent were measured experimentally using an optical microscope for the smallest details, as reported in Figure 2b-c.

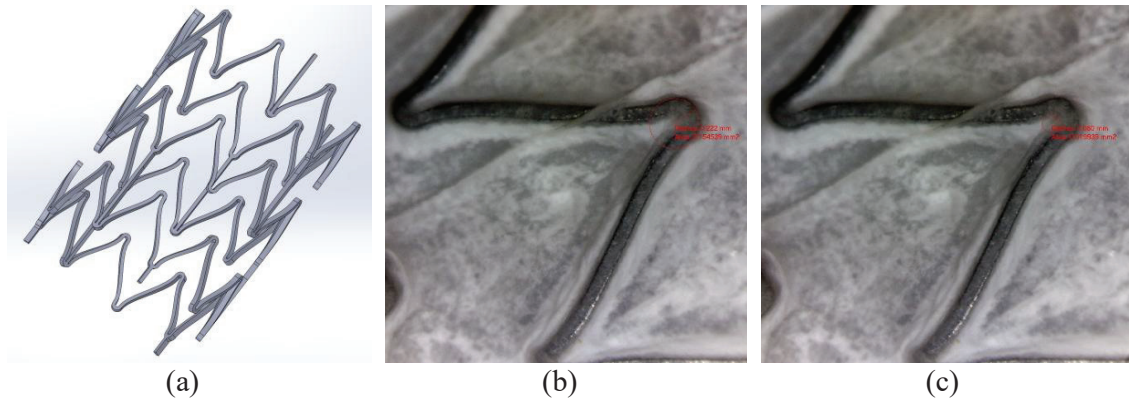


Figure 2: CAD model of the representative unit cell of the stent (a) and details of the external (b) and internal curvature radii (c).

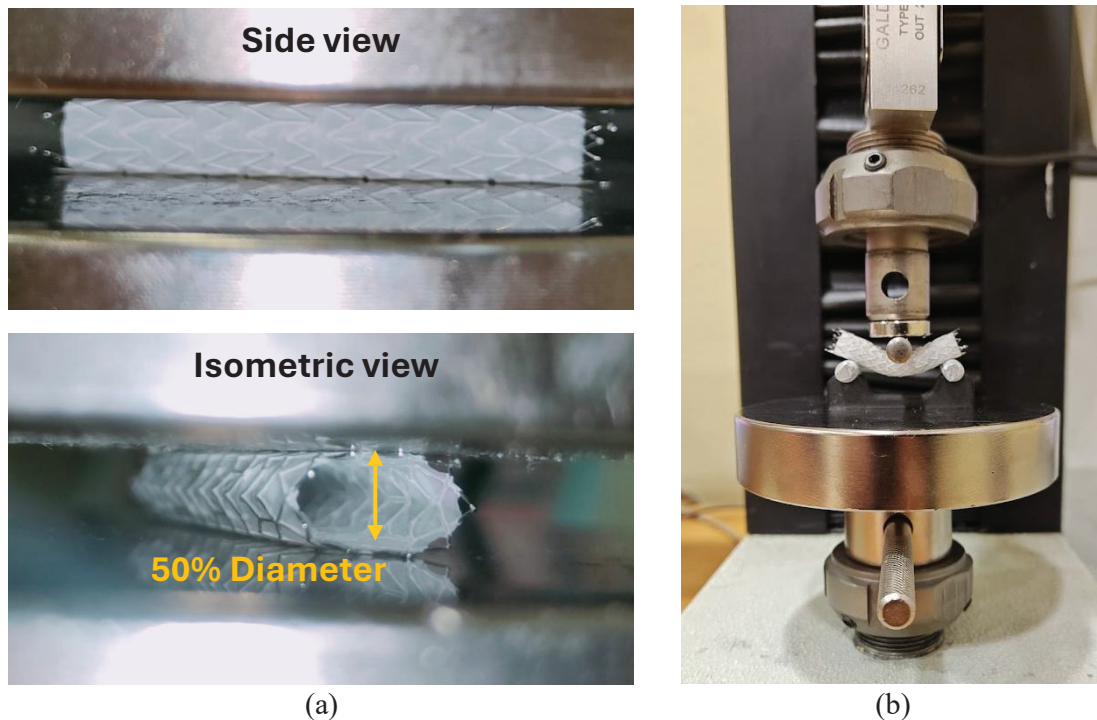


Figure 3: Crush resistance close-up photo of the stent under compression (a) and three-point bending (b) test set-up.

The stent has a strut thickness of 0.22 mm and a strut width of 0.14 mm, while there are three closed cells per ring, and each ring is connected to the adjacent ones with three axial struts.

Two experimental tests were conducted using a uniaxial tensile machine (Galdabini SUN 500). The test reproduces the CR condition and the BC test as prescribed by the standards. The first one is vertical compression between two rigid plates up the 50% of the diameter reduction

(Figure 3a), while the second one is a three-point bending on 8 mm rollers with a vertical displacement of 6.5 mm (Figure 3b).

3.2 Numerical model fit of the experimental results

The numerical model is based on the geometry already shown in Figure 2a. The real stent has three radiopaque tantalum marks in the ends which are not added to the model since they do not change the system behavior. The stent is modeled using shells in Abaqus software, with linear formulation (S4). The first model resembles the experimental test for BC and CR and they were used to fit the material model parameters. A Souza-Auricchio superelastic material model fitting procedure was used to retrieve the parameter reported in Table 1.

The mesh has at least 5 elements in the strut width, and, after a converging procedure, we set the average element dimension at 0.025 mm. Thanks to the shell approach, the model counts only around 200k nodes, and it takes a reasonable time to run. The comparison between the experimental results and the numerical fit is reported in Figure 4a for the CR test, where the force is provided in N/mm to be independent of the stent length and in Figure 4b for the BC test, where it is not possible to scale the force.

Table 1: Material parameters used in the simulation with Abaqus superelastic model

Parameter	Symbol	Value	Parameter	Symbol	Value
Austenite Elastic Modulus, MPa	E_A	69000	Start of transf. loading stress, MPa	σ_{ST_L}	240
Austenite Poisson's ratio	ν_A	0.3	End of transf. loading stress, MPa	σ_{E_L}	310
Martensite Elastic Modulus, MPa	E_M	22000	Start of transf. unloading stress, MPa	σ_{ST_U}	180
Martensite Poisson's ratio	ν_M	0.3	End of transf. unloading stress, MPa	σ_{E_U}	120
Transformation strain	ε_L	0.04	Start of transf. stress in compression, MPa	σ_{ST_C}	330

3 NUMERICAL RESULTS

The results shown in Figure 4 confirm that the proposed material model provides good agreement with the experimental results. Therefore, a parametric analysis is carried out to find out the influence of the main geometrical parameters on the system behavior in terms of CR and BC, while RRF and COF will be considered in future studies.

3.2 Crush Resistance

The crush resistance numerical results provide not only the force but also an estimate of the stresses occurring in the stent. The parametric analysis considered the following values for the thickness of the strut: 0.198, 0.220, 0.242 mm and 0.112, 0.120 and 0.132 mm for the width. The combination of these values leads to 9 configurations for each of the outputs considered. The numerical set-up of the model is the same as in paragraph 3.2. The stress contour map is provided in Figure 5, where it is possible to note that the material reaches the stress plateau and completely transforms in almost all the struts, which is something expected in a destructive test. In terms of force by unit length, as shown in the chart of Figure 6, the effect of the width is stronger compared to the thickness in increasing the CR figures of merit.

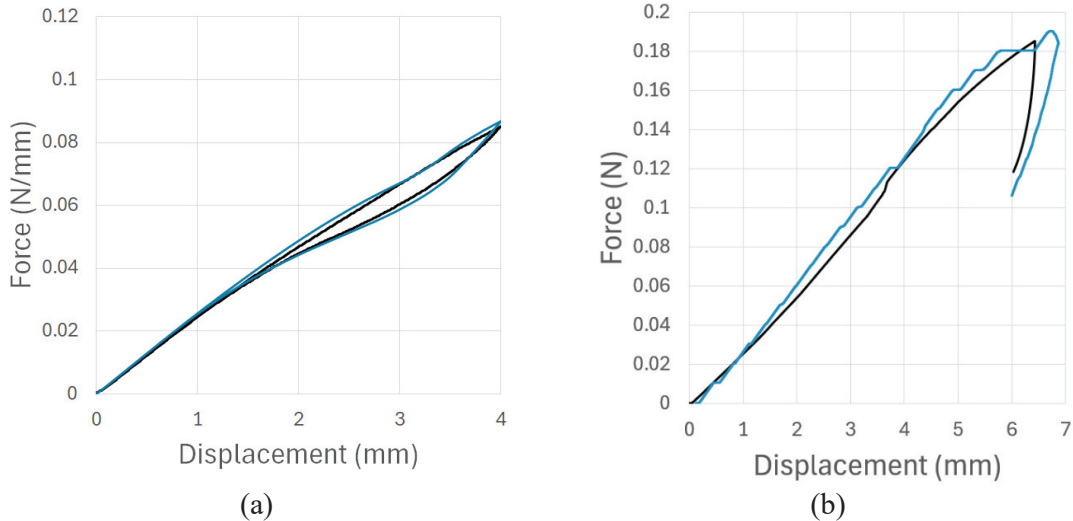


Figure 4: Experimental curves (blue) and numerical curves (black) for CR (a) and BC (b) tests.

3.2 Bending Compliance

The bending compliance of a stent is crucial to allow the surgeon an easy endovascular deployment, even in districts where the vessels are particularly complex, such as the popliteal or carotid ones. The numerical set-up of the three-point bending model is the same as in paragraph 3.2. The bending compliance numerical results provide not only force but also an estimate of the stresses occurring in the stent when subjected to the biomechanical force due to the gait or the patient motion. The parametric analysis considered the following values for the thickness of the strut: 0.198, 0.220, 0.242 mm and, 0.120, 0.132 and 0.144 mm for the width.

It must be noted that these values are different from the CR tests, only the exact width of the real device (0.120 mm) is kept as the previous design. The lower value (0.122 mm) is too small to be obtained through AM, and it greatly lowers the CR, while the upper value (0.168 mm) has been found to be too high to provide adequate compliance in some preliminary studies, not reported here for the sake of brevity. The stress contour map of the stent undergoing a three-point bending with a 4 mm central displacement is provided in Figure 7, where it is possible to note that the material reaches the stress plateau and completely transforms in all the central struts, while it is unloaded in the rest of the stent. The most stressed region, reported in the magnified view of Figure 7, presents stress above 700 MPa and strains around 6-7%, which is close to the material limit fatigue properties [14] and could explain the disappointing results found in [13]. The results of the analysis in terms of force force-deflection diagram carried out for this figure of merits is reported in Figure 8.

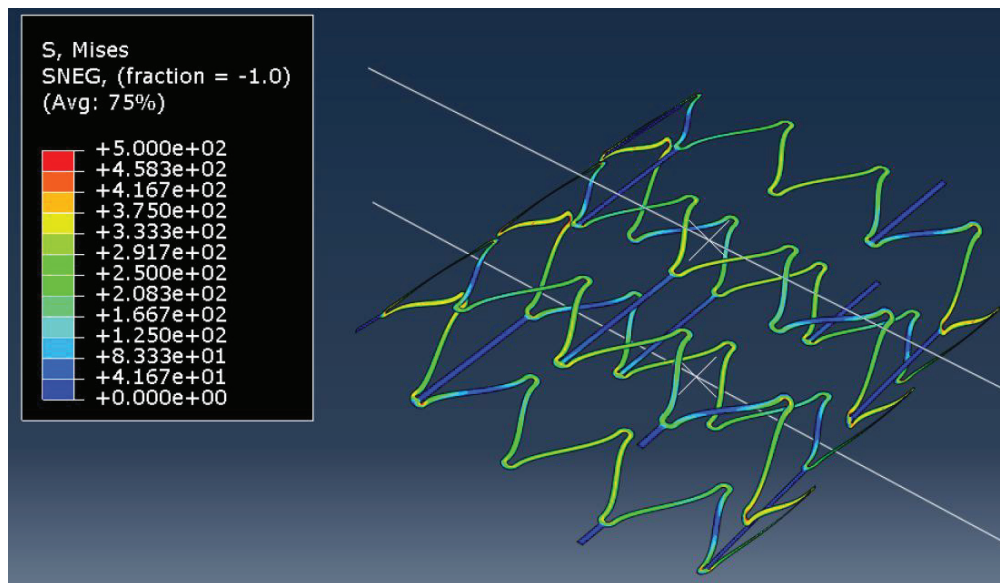


Figure 5: Equivalent stress contour of the stent at maximum deflection, upper limit 500 MPa.

4 DISCUSSION

The CR and BC tests clearly show that both the strut width and thickness play a role in the system behavior and the use of additive manufacturing techniques could lead to an optimization of the system. The influence of the strut width is particularly important in increasing the CR, while the thickness seems to play a crucial role in changing the BC. The optimal combination of these two variables could lead to a stent that can provide enough support when compressed while remaining flexible enough to be deployed endovascularly with enough ease. Another interesting parameter which could be extracted from Figure 6 is the radial crush stiffness, which is closely related to the RRF and it is reported in Table 2 along with the maximum values of the absolute CR force and the bending compliance. Further studies will expand the search toward the optimum values to effectively increase the mechanical performance of a stent without compromising its deployment behaviour.

Additive Manufacturing of NiTi Stents: Opportunities and Challenges

Laser-based powder bed fusion (LB-PBF) has emerged as a groundbreaking method for producing nickel-titanium (NiTi) stents. The main advantages of this technique are the following.

- Patient-specific customization, obtained through the creation of stents tailored to individual anatomies using 3D models derived from CT or MRI scans;
- Material Efficiency, since LB-PBF is a net shape method and the unused powder can be reused with very low waste;
- Functional Performance: obtained through customization of the shape and dimensions of the stent based on the patient's needs, including the possibility of treating bifurcations and complex shapes of the vessel [15].

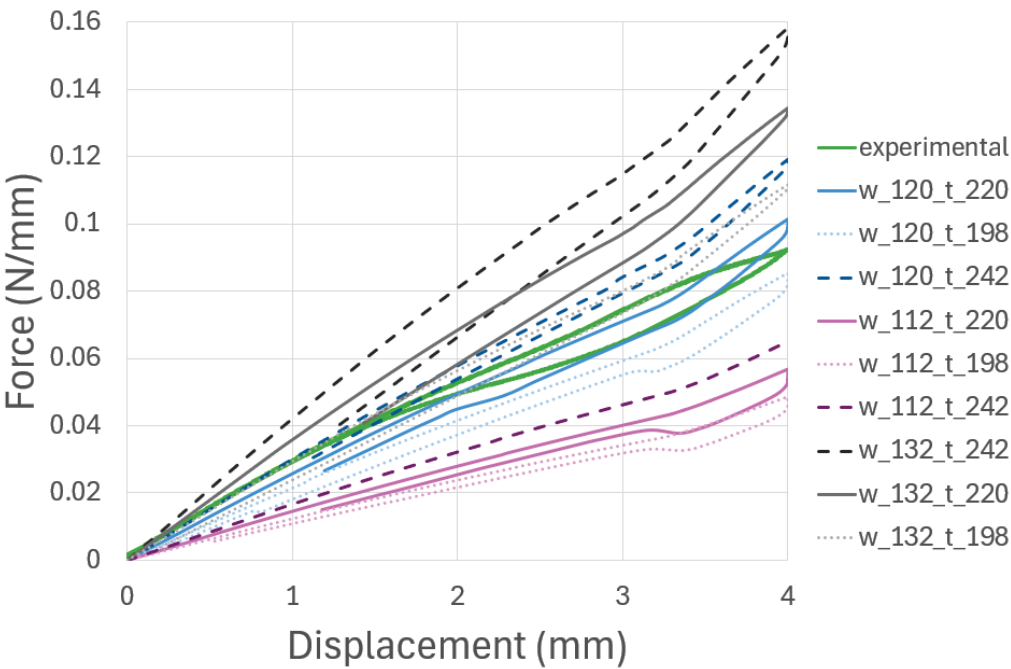


Figure 6: CR force for all the configurations considered.

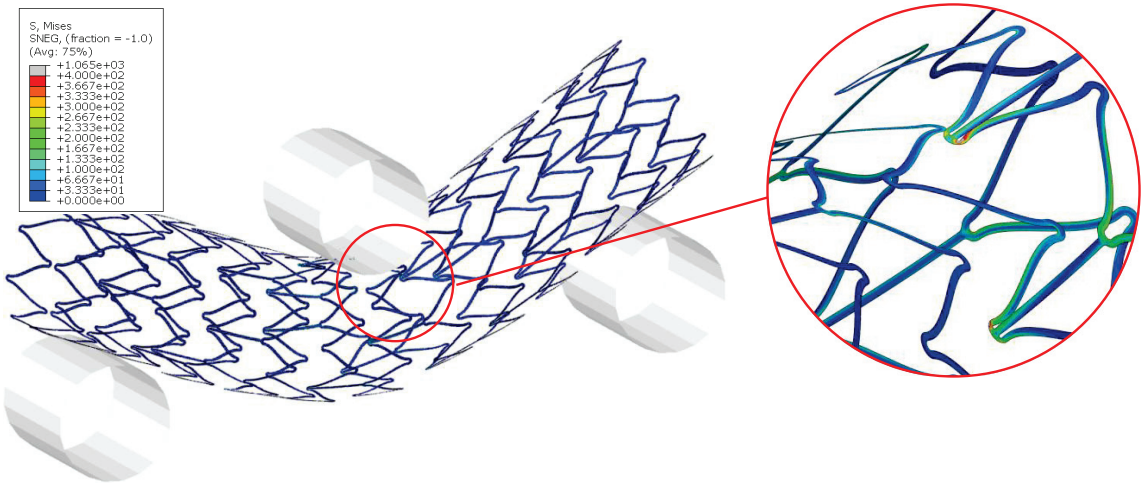


Figure 7: Stress contour of the equivalent stress at maximum bending and detail of the most stressed struts, in the magnified circle within grey the region above 400 MPa.

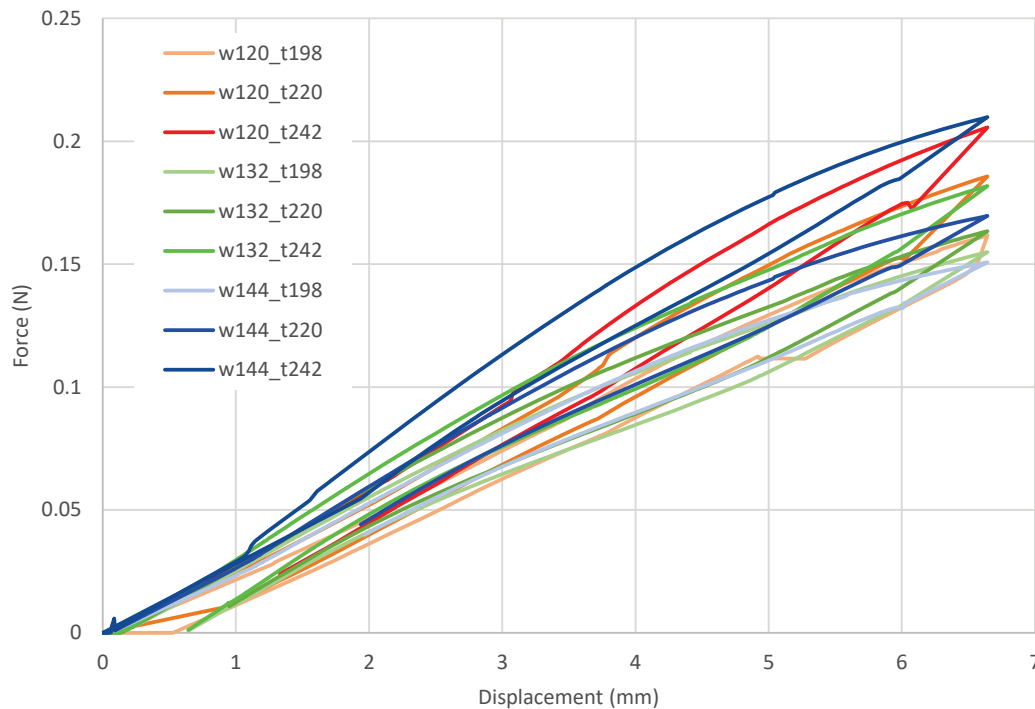


Figure 8: Force–deflection chart for the parametric condition considered. Reddish curve for 0.120 mm width, greenish curves for 0.132 mm and bluish curve for 0.144 mm width.

These advantages are balanced by some open challenges, such as surface quality and dimensional precision, a major concern, especially since strut thicknesses (100–500 μm) are similar to the size of NiTi powder particles (10–60 μm) and the laser beam diameter. Etching and electropolishing are needed as a post-process. [5], [7]. Moreover, the composition of the alloy can be affected by the process, the high-energy laser can evaporate nickel during melting, shifting the phase transformation temperatures. Residual stress, porosity and slight anisotropic behavior are side effects which can be effectively controlled by post-heat and pressure treatment. [16]. The strongest open challenge is related to the supports and the design constraints. [17], which are present also with this technology and limits the possibility of the designer, especially due to the need of a self-supporting lattice in most cases. The findings of this study could help in making the right decision and support the designer of the structure with quantitative information.

Table 2: Results of the CR and BC simulations in terms of Max absolute force, crush stiffness and bending compliance

w	t	Max Force (N)	Crush stiffness (N/mm)	Bending compliance (mm/N)
112	198	0.5667	0.1417	-
112	220	0.6620	0.1655	-
112	242	0.7587	0.1897	-

120	198	0.9888	0.2472	41.092
120	220	1.1743	0.2936	35.777
120	242	1.3800	0.3450	32.308
132	198	-	-	42.894
132	220	-	-	40.659
132	242	-	-	36.551
144	198	-	-	44.072
144	220	-	-	39.166
144	242	-	-	31.663
168	198	1.2834	0.3208	-
168	220	1.5457	0.3864	-
168	242	1.8197	0.4549	-

5 CONCLUSIONS

This work studies NiTi stents for endovascular applications. This study explores the potential of combining additive manufacturing (AM) with advanced simulations to optimize the stent design by focusing on specific figures of merit. The results show that integrating experimental and computational methods can lead to enhanced fabrication processes and more effective performance evaluations, particularly in terms of bending stiffness and crush resistance. This study shows that the strut width has a stronger influence on the CR than the strut width on the BC, while future studies will integrate these findings also with the effect on RRF and COF. By leveraging these values, the study provides valuable insights into stent mechanical responses and highlights the potential for optimizing stent design through AM, offering improved performance compared to traditional methods. AM holds transformative potential for NiTi stents, but overcoming its technical limitations requires interdisciplinary collaboration across materials science, biomechanics, and clinical medicine.

REFERENCES

- [1] A. R. Pelton, "Nitinol fatigue: A review of microstructures and mechanisms," *J Mater Eng Perform*, vol. 20, no. 4–5, pp. 613–617, 2011, doi: 10.1007/s11665-011-9864-9.
- [2] A. Kapoor, N. Jepson, N. W. Bressloff, P. H. Loh, T. Ray, and S. Beier, "The road to the ideal stent: A review of stent design optimisation methods, findings, and opportunities," *Mater Des*, vol. 237, p. 112556, Jan. 2024, doi: 10.1016/J.MATDES.2023.112556.
- [3] Funakubo, *Shape Memory Alloys*. Boca Raton, Florida, USA: CRC Press, 1987.
- [4] S. W. Robertson, "On the mechanical properties and microstructure of Nitinol for biomedical stent applications," PhD thesis, University of California, Berkeley, 2006.
- [5] J. Dong, M. Pacella, Y. Liu, and L. Zhao, "Surface engineering and the application of laser-based processes to stents - A review of the latest development," *Bioact Mater*, vol. 10, pp. 159–184, Apr. 2022, doi: 10.1016/J.BIOACTMAT.2021.08.023.
- [6] A. Lantada *et al.*, "Additive Manufacturing of Nitinol for Smart Personalized Medical Devices: Current Capabilities and Challenges," Scitepress, Feb. 2024, pp. 123–134. doi: 10.5220/0012363900003657.
- [7] O. M. McGee *et al.*, "An investigation into patient-specific 3D printed titanium stents and

- the use of etching to overcome Selective Laser Melting design constraints,” *J Mech Behav Biomed Mater*, vol. 134, p. 105388, Oct. 2022, doi: 10.1016/J.JMBBM.2022.105388.
- [8] P. Jamshidi *et al.*, “Development, characterisation, and modelling of processability of nitinol stents using laser powder bed fusion,” *J Alloys Compd*, vol. 909, p. 164681, Jul. 2022, doi: 10.1016/J.JALLCOM.2022.164681.
 - [9] M. Bernini *et al.*, “Oversizing of self-expanding Nitinol vascular stents – A biomechanical investigation in the superficial femoral artery,” *J Mech Behav Biomed Mater*, vol. 132, p. 105259, Aug. 2022, doi: 10.1016/J.JMBBM.2022.105259.
 - [10] T. W. Duerig and M. Wholey, “A comparison of balloon- and self-expanding stents,” *Minimally Invasive Therapy & Allied Technologies*, vol. 11, no. 4, pp. 173–178, Aug. 2002, doi: 10.1080/136457002760273386.
 - [11] F. Hoseini, A. Bellelli, L. Mizzi, F. Pecoraro, and A. Spaggiari, “Self-expanding Nitinol stents for endovascular peripheral applications: A review,” *Mater Today Commun*, vol. 41, p. 111042, Dec. 2024, doi: 10.1016/j.mtcomm.2024.111042.
 - [12] L. de O. Harduin *et al.*, “Safety and efficacy of a new covered stent in hemodialysis vascular access outflow stenosis: A Brazilian multicenter retrospective study,” *Journal of Vascular Access*, 2024, doi: 10.1177/11297298231226259/ASSET/EBEF75CA-CCC9-4041-8898-76ADEAC51EFE/ASSETS/IMAGES/LARGE/10.1177_11297298231226259-FIG3.JPG.
 - [13] E. M. Marone, C. Brioschi, C. Barra, and L. F. Rinaldi, “Disappointing results of popliteal aneurysm endovascular treatment with a new self-expandable covered stent,” *Asian Cardiovasc Thorac Ann*, vol. 32, no. 4, pp. 227–230, May 2024, doi: 10.1177/02184923241251887.
 - [14] S. W. Robertson, A. R. Pelton, and R. O. Ritchie, “Mechanical fatigue and fracture of Nitinol,” *International Materials Reviews*, vol. 57, no. 1, pp. 1–37, 2012, doi: 10.1179/1743280411Y.0000000009.
 - [15] V. Finazzi, F. Berti, R. J. Guillory, L. Petrini, B. Previtali, and A. G. Demir, “Patient-specific cardiovascular superelastic NiTi stents produced by laser powder bed fusion,” in *Procedia CIRP*, Elsevier B.V., 2022, pp. 244–248. doi: 10.1016/j.procir.2022.06.044.
 - [16] M. Somireddy and A. Czekanski, “Anisotropic material behavior of 3D printed composite structures – Material extrusion additive manufacturing,” *Mater Des*, vol. 195, p. 108953, Oct. 2020, doi: 10.1016/J.MATDES.2020.108953.
 - [17] V. Finazzi *et al.*, “Design Rules for Producing Cardiovascular Stents by Selective Laser Melting: Geometrical Constraints and Opportunities,” *Procedia Structural Integrity*, vol. 15, pp. 16–23, Jan. 2019, doi: 10.1016/J.PROSTR.2019.07.004.

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