

FEM Modeling Of A Stent-Retriever Device

The Development Of In-Silico Thrombectomy Stent-Retriever

MECHANICAL ENGINEERING

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by

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Abstract

Ischaemic stroke remains a leading cause of death and disability worldwide, and mechanical thrombectomy using stent retrievers is the current standard of care for its treatment. Bringing new thrombectomy devices to market, however, relies on costly and time-consuming preclinical and clinical trials that struggle to capture the full variability of patient anatomy and thrombus composition. In-silico clinical trials (ISCTs) offer a way to circumvent these constraints, provided the underlying device models are computationally efficient and demonstrably credible. This thesis, conducted within the T-SIM project, addresses this need by developing and validating a finite element model of the Trevo XP ProVue stent retriever, following the ASME V&V 10/40 framework.

A high-fidelity solid-element (C3D8I) model of the stent geometry was constructed from microscopy measurements and converted into a computationally efficient beam-element (B31) representation. An initial comparison revealed discrepancies of up to 33% in stiffness properties between the two representations, traced to an under-stiffened connector–cell junction in the beam model; introducing an additional beam element at this location reduced the discrepancy to within 1–4%, while reducing the element and node count by more than an order of magnitude. The complete model, including end features and platinum–tungsten braided wires, was then validated against in-vitro flat-plate compression and three-point bending tests. The initial model (Version 1) showed poor agreement with experimental data (NRMSE of 36.0% and 27.0%, respectively); a sensitivity analysis identified strut width and depth as the dominant contributing parameters, motivating refined measurements and a revised model (Version 2), which improved agreement to 16.8% and 22.1% NRMSE. Neither version met the 10% acceptance criterion required under the model’s assigned Risk Level 5 classification. Finally, four Context-of-Use simulations comparing the stent with and without the braided wires showed that the wires have negligible influence on radial mechanical behaviour but measurably restrict axial elongation during retraction.

These results show that a computationally efficient beam-element model can reproduce the structural response of a high-fidelity solid model with good accuracy, but that full experimental validation against the required 10% threshold has not yet been achieved, leaving the central research question only partially answered. The findings nonetheless provide a reusable model-development pipeline and a provisional simplification rule – omitting braided radiopacity wires for radial-loading applications – that can support the broader device library envisioned within the T-SIM project.

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Chapter 1

Introduction

1.1 Clinical Situation

Stroke (disruption of the blood flow to the brain) remains one of the leading causes of death and disability worldwide. According to the most recent Global Burden of Disease (GBD) 2021 study, stroke was the third most common cause of death globally in 2021, responsible for approximately 7.3 million deaths (10.7% of all deaths), and the fourth most common cause of disability-adjusted life-years (DALYs), accounting for 160.5 million DALYs (5.6% of all DALYs) worldwide [GBD 2021 Stroke Risk Factor Collaborators \(2024\)](#). Of all incident strokes, ischaemic stroke accounted for the large majority (65.3%), followed by intracerebral haemorrhage (28.8%) and subarachnoid haemorrhage (5.8%). The economic burden associated with stroke is similarly substantial, with the global cost of stroke estimated at over US\$890 billion annually, equivalent to 0.66% of global GDP [Feigin et al. \(2025\)](#).

Between 1990 and 2021, the global burden of stroke increased markedly: incident strokes rose by 70.0%, stroke-related deaths by 44.0%, stroke prevalence by 86.0%, and DALYs by 32% [Feigin et al. \(2025\)](#). This upward trend is projected to continue. Based on GBD 2021 data, [Cheng et al. \(2024\)](#) forecast that by 2050 the global number of stroke cases will reach 21.43 million annually, with 159.31 million stroke survivors, 12.05 million deaths, and 224.86 million DALYs attributable to stroke. Although age-adjusted rates of incidence, death and DALYs are expected to decline as a result of improved prevention and treatment, population growth and ageing are expected to drive the absolute burden of stroke steadily upward, particularly in low- and middle-income countries.

Given the scale and continuing growth of this global health problem, together with the fact that the large majority of strokes are ischaemic in nature, effective and continuously improving treatment of ischaemic stroke is of substantial clinical and societal importance.

1.2 State of the Art Treatment – Thrombectomy

Ischaemic stroke, the largest contributor to the overall stroke burden, is most commonly treated using endovascular mechanical thrombectomy (the removal of a blood clot via a mechanical device), either in combination with or as an alternative to intravenous thrombolysis. Two main mechanical thrombectomy strategies are used in current clinical practice: aspiration-based thrombectomy and stent-retriever-based thrombectomy, which can also be combined into a single, hybrid technique.

In aspiration-based thrombectomy, a large-bore aspiration catheter is advanced to the face of the thrombus and continuous suction is applied to extract the clot. In the original ADAPT FAST study, aspiration alone achieved successful reperfusion (TICI 2b/3) in 78% of cases, rising to 95% when a stent retriever was subsequently added as an adjunct device [Turk et al. \(2014\)](#).

The alternative approach, stent-retriever thrombectomy, deploys a self-expanding metal stent within the thrombus to entrap it before both are withdrawn together. The randomised ASTER trial directly compared first-line contact aspiration with first-line stent-retriever thrombectomy and found no significant difference between the two approaches in terms of final successful reperfusion or first-pass effect [Lapergue et al. \(2017\)](#).

More recently, attention has shifted towards combining both techniques within a single procedure, using a stent retriever together with continuous aspiration (an approach reported under names such as SAVE and CAPTIVE). A meta-analysis of ten comparative studies (1,495 patients treated with combined aspiration and stent retriever versus 1,864 treated with stent retriever alone) found that the combined approach achieved a significantly higher first-pass effect (40.8% vs. 32.6%, $p < 0.0001$; OR = 1.63), but no significant difference in overall successful reperfusion or 90-day functional independence ([Schartz et al., 2022](#)). Comparable findings emerged from a direct comparison of the SAVE technique with ADAPT: SAVE achieved a substantially higher first-pass reperfusion rate (59.6% vs. 33.3%, $p = 0.019$) and a higher overall rate of successful reperfusion (93.5% vs. 75.0%, $p = 0.006$) [Brehm et al. \(2019\)](#).

Taken together, these results suggest that combining a stent retriever with continuous aspiration improves the likelihood of achieving successful reperfusion after a single pass, thereby reducing the number of device passes required and the associated risk of vessel injury. Stent retrievers, whether used alone or in combination with aspiration, therefore continue to occupy a central role in the endovascular treatment of ischaemic stroke. Most commonly to retrieve thrombi located in the internal carotid artery (ICA) terminus, the M1 and M2 segments of the middle cerebral artery, and the basilar artery, the vessel segments frequently affected by large-vessel occlusion ([Turk et al., 2014](#)). An overview of the most important cerebral arteries affected by ischaemic stroke can be seen in Figure 1.1, ([Rodriguez-Calienes et al., 2023](#))

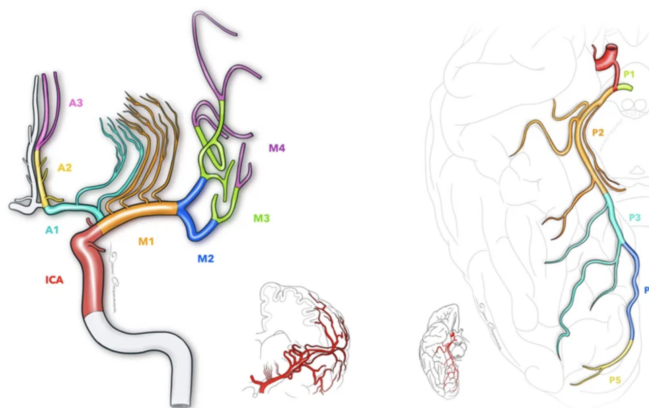


Figure 1.1: Schematic overview cerebral arteries

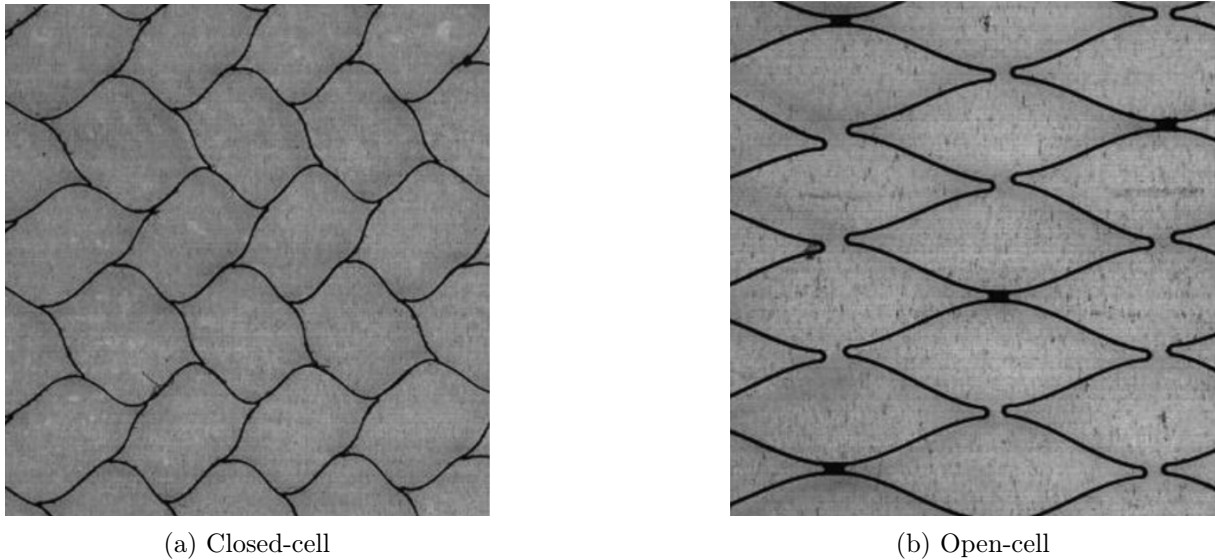
1.3 Device types

Stent retrievers used in mechanical thrombectomy can be broadly categorised along two largely independent design axes: their cell structure (open-cell versus closed-cell) and their manufacturing method (braided versus laser-cut).

1.3.1 Open-cell versus closed-cell design

In an open-cell design (1.2b), the interconnecting struts of the stent are not continuously joined at every intersection, whereas in a closed-cell (1.2a) design all strut junctions are connected. This structural difference has a direct effect on the stent's mechanical behaviour: closed-cell stents behave more predictably during deployment and retrieval but are less flexible, making it more difficult for them to conform to tortuous, curved vessel anatomy; open-cell stents, conversely, are more flexible and adapt more readily to vessel curvature, at the cost of a less predictable expansion behaviour.

Figure 1.2: Open vs closed cell in flattened configuration [Wakhloo et al. \(2009\)](#)



Direct clinical comparisons of open-cell and closed-cell success rates are lacking; however, finite element (FE) simulation studies have compared the two designs. [Wu et al. \(2025\)](#) modelled thrombectomy with an open-cell stent (Solitaire FR) and a closed-cell stent (Trevo XP ProVue) in a patient-specific vessel geometry. The open-cell Solitaire achieved successful thrombus retrieval, consistent with in vitro validation, whereas the closed-cell Trevo failed to retrieve the thrombus in the simulation; the Solitaire also generated substantially higher stress and strain on the thrombus (3.19 and 1.45 times higher, respectively) and higher contact pressure on the vessel wall (2.83 times higher) than the Trevo. This illustrates a broader mechanical trade-off: greater device–thrombus and device–vessel-wall interaction (staying in contact with the wall) can increase the likelihood of successful clot capture, but simultaneously increases the potential for thrombus fragmentation and vessel-wall injury.

Radial force, the outward force exerted by the stent against the vessel wall, is a key mechanical property underlying this trade-off. Clinical evidence indicates that a lower radial force is associated with a reduced incidence of vessel-wall-related complications, such as subarachnoid

haemorrhage, although this may come at the cost of weaker clot integration in firm, fibrin-rich thrombi (Ishiguro et al., 2026).

1.3.2 Braided versus laser-cut design

Radial force is, in turn, strongly influenced by the manufacturing method. Braided stent retrievers, constructed from woven wires, are generally more flexible and exhibit a lower radial force, since the individual wires can move more freely relative to one another; laser-cut stent retrievers, machined from a single tube of nitinol, are structurally more rigid and typically exert a higher radial force (Katz et al., 2019). Bench testing by Katz et al. (2019) confirmed that a braided thrombectomy-assist device exerted a uniformly low radial force (≤ 1 N) across simulated M1 and M2 vessel diameters, whereas all tested laser-cut stent retrievers exceeded 1 N at the smaller, simulated M2 diameters. Furthermore laser-cut devices are also less prone to foreshortening (axial shortening upon expansion) than braided devices, which improves the accuracy and predictability of their final deployed position.

Overall, no single stent-retriever design is unambiguously superior: open-cell, closed-cell, braided, and laser-cut designs each represent a different balance between flexibility, radial force, predictability of deployment, and thrombus-capture efficacy. Device selection in clinical practice therefore reflects a trade-off between these mechanical properties in relation to the target vessel anatomy and thrombus characteristics. A comparative overview of public available thrombectomy stent retrievers including known design characteristics is provided in Table 7.2 in the appendix.

1.4 Device Development Process – Before Approval to Market

Bringing a new stent-retriever device to clinical use requires it to pass through a formal regulatory approval pathway. The US regulatory pathway, overseen by the Food and Drug Administration (FDA), is the pathway considered in this thesis.

In the United States, the FDA distinguishes Class I, II and III devices according to risk. Class III devices generally requiring the extensive Premarket Approval (PMA) pathway and Class II devices typically following the less burdensome 510(k) pathway, in which substantial equivalence to an already-marketed predicate device must be demonstrated (Amaral et al., 2024). Notably, neurovascular mechanical thrombectomy devices for acute ischaemic stroke were reclassified by the FDA from Class III to Class II in 2016, following a request by Concentric Medical, Inc. for the Trevo stent retrievers (US Food and Drug Administration, 2016). This reclassification meant that such devices no longer require a full PMA, provided that a defined set of special controls is satisfied, spanning biocompatibility, non-clinical performance testing, sterility and shelf-life, clinical performance testing, and labelling (21 CFR 882.5600) (US Food and Drug Administration, 2016). Since the Trevo reclassification set a precedent for the device category as a whole, comparable stent retrievers, including the device considered in this thesis, can generally be brought to the US market via the 510(k) pathway under these special controls rather than through a full PMA submission. The remainder of this section examines how these special controls are organised around risk, and how each is satisfied in practice through a layered pathway of evidence.

1.4.1 Safety and Performance: A Tiered Evidence Pathway

Underlying the special controls set out above is a single guiding principle: safety and performance must be demonstrated in proportion to the risks a device presents. The FDA’s 2016 classification order makes this explicit through a risk-mitigation table linking each identified risk: adverse tissue reaction, infection, vessel or tissue damage, stroke progression, and embolisation, to the category or categories of evidence required to mitigate it (US Food and Drug Administration, 2016). Adverse tissue reaction is mitigated through biocompatibility evaluation of all patient-contacting components, and infection through sterility testing, shelf-life testing, and labelling; the remaining risks are addressed through the three testing tiers discussed below, with labelling operating throughout as a further, complementary risk-mitigation measure rather than a merely passive information requirement. This risk-proportionate logic translates into a layered pathway of evidence that moves from the bench, through the animal model, to the clinic.

In-vitro device testing. This forms the first tier of non-clinical evidence and is required to demonstrate that the device performs as intended under anticipated conditions of use. It comprises mechanical testing of the tensile, torsional and compressive forces the device can withstand, mechanical testing of the radial force it exerts, verification of device dimensions, simulated delivery to and retrieval of thrombus from the target location, confirmation that the device is sufficiently radiopaque to be visualised under fluoroscopy, and evaluation of coating integrity and particulate generation under simulated use conditions (US Food and Drug Administration, 2016). In the FDA’s risk-mitigation table, this category of evidence is identified as the primary mitigation for the risk of vessel dissection. Such testing is performed under standardised, repeatable bench conditions well suited to characterising a device’s fundamental mechanical behaviour; the radial force differences between braided and laser-cut stent retrievers discussed in Section 1.3, for instance, were themselves established through this type of bench testing (Katz et al., 2019).

Preclinical testing. Bench testing alone cannot fully capture the biological response of the vessel wall to a device, which is why animal testing, evaluating device safety including any damage to the vessel wall or surrounding tissue under anticipated use conditions, is itself a required sub-item of the same non-clinical performance testing special control described above, rather than a separate, discretionary tier of evidence (US Food and Drug Administration, 2016). Katz et al. (2019) similarly note that *in vivo* animal studies are needed to establish the relationship between a device’s mechanical properties, such as radial force, and clinically relevant complications such as vessel wall injury. Preclinical animal studies therefore occupy an intermediate position in the evidence pathway, bridging mechanical bench data and clinical performance in humans.

Clinical studies. Clinical studies constitute the final and most direct tier of evidence. The special controls require clinical performance testing to demonstrate that the device performs as intended for the treatment of acute ischaemic stroke, capturing any device- or procedure-related adverse events (US Food and Drug Administration, 2016). Whereas non-clinical testing is identified as the primary mitigation for dissection, the FDA’s risk-mitigation table identifies clinical performance testing as the primary, and in some cases sole, mitigation for the more severe risks of vessel perforation, stroke progression, and distal embolisation, reflecting the fact that these outcomes depend on the interaction between the device and a living, perfused vascular

system in ways that bench and animal testing cannot fully replicate. Clinical performance testing must follow Good Clinical Practice (GCP) guidelines, with data collected and submitted to the FDA for review before market authorisation is granted (Amaral et al., 2024). Because the device has not yet received marketing clearance at this stage, such testing is conducted under an Investigational Device Exemption (IDE, 21 CFR Part 812), which permits the use of an unapproved device in human subjects strictly for research purposes, subject to institutional review board approval and patient informed consent, and without the device being commercially marketed or sold. Only once this clinical evidence, together with the remaining special controls, has been compiled into the 510(k) submission can the FDA grant marketing clearance. Together, these successive tiers, in-vitro bench testing, preclinical animal studies, and clinical studies, generate the layered body of safety and performance evidence required before a stent retriever can reach clinical use via the public market.

1.4.2 In-Silico Clinical Trials

The generation of the clinical data required to support device approval is time-consuming and expensive, and can significantly delay the availability of new devices to patients, a phenomenon that has been described, particularly in the context of the Japanese regulatory system, as “medical device lag” (Amaral et al., 2024). This has motivated growing interest in computational alternatives, in particular in-silico clinical trials (ISCT), in which validated computational models are used to generate data on device performance and safety that can complement, or in some contexts partially substitute for, traditional clinical data collection.

An early demonstration of this concept applied to thrombectomy is the work of Luraghi et al. (2021), who created the first fully virtual, patient-specific replication of a mechanical thrombectomy procedure. Using a cerebral vasculature reconstructed from computed tomography images and a thrombus composition derived from histological analysis, the simulation replicated the real clinical procedure with high fidelity: as observed clinically, two attempts were needed to remove the clot in the simulation, owing to the position of the stent retriever relative to the thrombus, and no clot fragmentation occurred because the thrombus deformation remained predominantly compressive.

Building on this type of high-fidelity simulation, Miller et al. (2023) developed an in-silico trial (IST) framework incorporating a surrogate thrombectomy model, a device-specific logistic-regression classifier trained on finite-element simulation data, to predict the probability of successful recanalisation for a given virtual patient. This surrogate model was validated against clinical data from the MR CLEAN Trial: the mean recanalisation rate predicted by the model (85.2%) fell within the 95% confidence interval of the observed MR CLEAN cohort rate (81.9%). The framework was subsequently used to run two exploratory in-silico trials, one comparing recanalisation success between thrombi of differing fibrin composition, and one comparing the performance of two commercially available stent-retriever devices, illustrating how such frameworks could, in principle, support the comparison and pre-clinical evaluation of thrombectomy devices.

A prerequisite for running such trials at scale is the ability to generate large, realistic, and patient-specific virtual cohorts. Bridio et al. (2023) addressed part of this challenge by developing an automated, statistical-shape-modelling-based method for reconstructing three-dimensional, patient-specific cerebral vasculature models from vascular centreline and diameter data, enabling

the efficient generation of virtual cohorts for use in the in-silico simulation of stroke treatments.

Despite this promising body of work, it is important to note that these computational models combined are not yet formally validated to a standard that would allow them to fully replace clinical data collection; their credibility must instead be systematically established using structured verification, validation and uncertainty quantification (VVUQ) frameworks, such as the ASME V&V40 standard, which provides a risk-based methodology for establishing the credibility of computational models used to support regulatory decision-making for medical devices.

1.5 The T-Sim project

It is precisely this credibility gap, the need for in-silico models that are fast and patient-specific enough to support large-scale virtual trials, yet rigorously verified and validated enough to be trusted by regulators, that motivates the T-SIM project, within which the model development work presented in this thesis is situated. The T-SIM project (“A digital twin based platform for simulating thrombectomy procedures”) is a public-private partnership, running from September 2025 to September 2029. The consortium consists of TU Delft (Biomechanical Engineering), 4ReSim, InSteps, and Erasmus MC (Radiology & Nuclear Medicine). The project addresses a key clinical problem: current thrombectomy procedures for acute ischemic stroke achieve only moderate first-pass success rates, despite being the preferred treatment for removing thrombi from occluded cerebral vessels. Thrombi vary substantially in composition, ranging from fibrin-dominant to red-blood-cell-dominant structures, resulting in widely differing mechanical properties. A one-size-fits-all approach to device selection therefore fails to account for this patient-specific variability. A major driver behind T-SIM is the limitation of evaluating new thrombectomy devices through conventional routes. Preclinical and clinical trials are expensive, time-consuming, labour-intensive, and frequently fail to generate sufficient data on device performance across the full range of patient anatomies and thrombus types, partly due to patient privacy restrictions and the practical difficulty of recruiting large, representative patient cohorts. In-silico clinical trials (ISCTs), evaluating device performance on large virtual patient populations through simulation rather than physical trials, offer a way to circumvent these constraints, provided the underlying models are sufficiently fast, robust, and credible. To realize this, T-SIM pursues three integrated objectives, each corresponding to a work package: WP1 – Virtual patient population generation: development of an in-silico platform that generates realistic virtual vessel lumens, vessel walls, and thrombi using generative AI methods, producing synthetic patient cohorts with clinically representative anatomical and biomechanical variability, without relying on scarce and privacy-restricted real patient datasets. WP2 – In-silico thrombectomy (device evaluation): development of a computational platform featuring efficient finite element (FE) models of thrombectomy devices, such as stent retrievers and aspiration catheters, capable of rapidly simulating device deployment and device-thrombus-vessel interaction across many virtual cases. WP3 – Platform evaluation and integration: combination of the virtual patient and device platforms into a unified ISCT environment, including rigorous verification, validation, and uncertainty quantification (VVUQ) in line with the ASME VV-40 standard and FDA guidance, to establish the credibility required for the simulation results to be trusted as a substitute for (part of) real-world testing. The overarching goal of T-SIM is therefore not only to build a simulation platform, but to make it credible and efficient enough to meaningfully replace or complement costly and slow clinical evaluation routes, enabling device manufacturers to test and compare many devices across large,

diverse virtual patient populations quickly, and helping clinicians select the optimal device for an individual patient based on rapid, patient-specific simulation rather than population-averaged clinical statistics.

1.5.1 Thesis Project

The work presented in this thesis contributes directly to WP2 of the T-SIM project, specifically to the development of the device model library that underpins the in-silico thrombectomy platform. A central motivation of T-SIM is to reduce reliance on slow, costly, and data-scarce clinical and preclinical trials by replacing part of this evaluation process with fast, validated in-silico testing. For this substitution to be justified, however, each device model included in the platform must be both computationally efficient and demonstrably credible.

This thesis focuses on establishing exactly this foundation for a single device: a computationally efficient and thoroughly validated stent retriever model. This gives rise to the central research question guiding this work: **How can a computationally efficient finite element model of a thrombectomy device be developed that remains sufficiently realistic and validated to represent the device’s mechanical behaviour in the intended in-silico thrombectomy application?** Beyond answering this question for the specific device considered here, this thesis also aims to set up a first pipeline for the development of such stent retriever models, so that the approach followed here can later be re-applied to other devices within the broader device library envisioned in WP2. In this sense, the model and methodology developed in this thesis form a first building block on which the wider T-SIM platform can be constructed.

Chapter 2

Model Development

2.1 General

2.1.1 Goal

The in-silico model developed in this work will be used to evaluate the performance and safety of the device in a virtual patient cohort under challenging clinical conditions. It is intended to generate regulatory-grade, model-based evidence that will accompany in-vitro test data, pre-clinical data, and clinical data in a device submission and design evaluation study's.

As described above, the overarching goal is to develop a model of a thrombectomy device that is robust while remaining computationally efficient. To achieve this, it is essential to consider how the device is used during the procedure and which mechanical aspects of its behaviour are relevant. The model represents the stent retriever manufactured by Stryker, the Trevo XP ProVue, size 6×25.

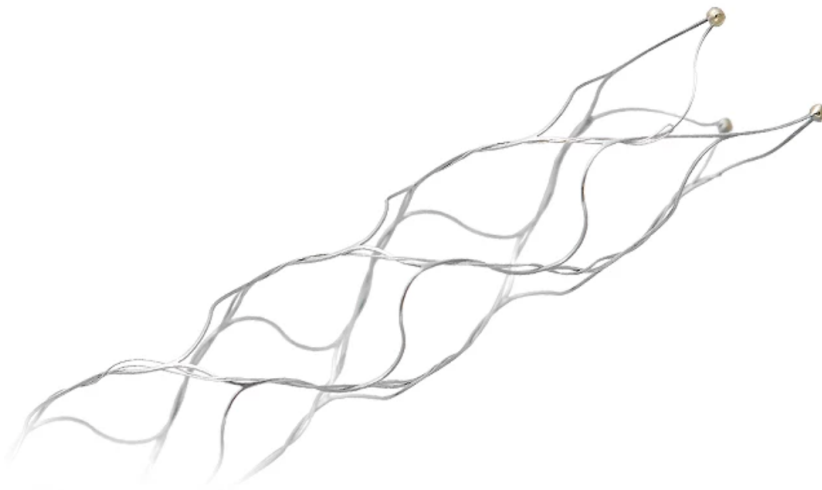


Figure 2.1: Stent retriever thrombectomy device: Trevo XP ProVue

2.1.2 Context of Use Simulations

The final Context of Use (COU) simulations will only be performed once the model has been sufficiently validated for the aspects of stent behaviour relevant to its clinical use. The physical

device consists of a laser-cut nitinol structure through which platinum–tungsten braided wires are threaded. Whether these wires may be omitted from the model is an open question, since they could introduce additional stiffness in the stent that affects its mechanical behaviour.

The wires are included in the device to improve visibility under fluoroscopy during the procedure. They are wound around the both ends of the laser-cut stent and tied on the start of the stent. It is possible that this configuration introduces additional axial stiffness, and possibly also affects the radial stiffness of the stent. To investigate this, the intention is to use a validated stent model to run three Context of Use simulations comparing the stent with and without the braided wires. This is done by simulating (i) crimping of the stent into a catheter, (ii) deployment into a rigid vessel, and (iii) retraction of the stent back into the catheter. The following outputs are of interest because these are important mechanical characteristics during a thrombectomy procedure:

- The radial outward forces of the stent during crimping;
- The radial forces on the vessel wall during deployment;
- The axial forces on the catheter during retraction
- The difference in stent length during retraction into the catheter.

2.1.3 Question of Interest

The Question of Interest (QOI) for this part of the work is therefore: what is the influence of the platinum–tungsten braided wires on the mechanical behaviour of the stent, specifically on (i) the radial force exerted on the vessel wall/catheter and (ii) the axial stiffness of the stent? If the wires are found to have no, or only a minor, influence on this behaviour, they could potentially be omitted from the model, which would further improve its computational efficiency.

2.1.4 Model Credibility

Credibility is central to the development of this model. If the model is not developed and validated in accordance with the relevant standards, it cannot be assumed to be adequate for use in in-silico trials. Development of the model therefore closely follows the ASME V&V 10/20/40 framework, together with the relevant ISO standards and FDA guidance documents. The full set of standards and guidance documents underpinning the credibility assessment is listed below.

- ASTM F2514-21 – Standard Guide for Finite Element Analysis (FEA) of Metallic Vascular Stents Subjected to Uniform Radial Loading
- ASME V&V 10-2019 – Standard for Verification and Validation in Computational Solid Mechanics
- ASME V&V 20-2009 – Standard for Verification and Validation in Computational Fluid Dynamics and Heat Transfer
- ASME V&V 40-2018 – Assessing Credibility of Computational Modelling through Verification and Validation: Application to Medical Devices

- ISO 25539-1:2017 – Cardiovascular implants – Endovascular devices – Part 1: Endovascular prostheses
- ISO 25539-2:2020 – Cardiovascular implants – Endovascular devices – Part 2: Vascular stents
- FDA (2016) – Guidance for Industry and Food and Drug Administration Staff: Reporting of Computational Modelling Studies in Medical Device Submissions, FDA-2013-D-1530
- FDA (2023) – Assessing the Credibility of Computational Modelling and Simulation in Medical Device Submissions, FDA-2021-D-0980

According to these standards, model credibility is evaluated by defining and executing a risk-based Verification, Validation, and Uncertainty Quantification (VVUQ) assessment, as illustrated in Figure 2.2.

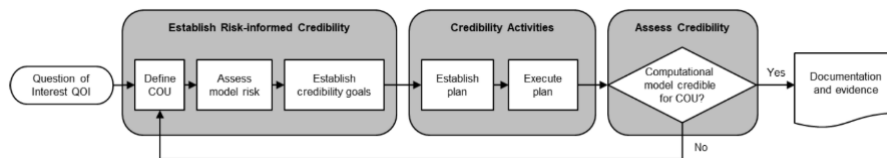


Figure 2.2: Process for defining and conducting a risk-based VVUQ assessment, according to ASME V&V 40.

2.2 Summary on Approach

The final model represents the vascular stent geometry of the Trevo XP ProVue 6×25 (Stryker), intended for finite element analysis. The stent consists of a repeating pattern of interconnected struts arranged in a cylindrical configuration, composed of a laser-cut nitinol structure providing the primary mechanical support and self-expanding functionality, and a braided platinum–tungsten component that enhances radiopacity under fluoroscopic imaging.

A central aim of this work is to assess whether a computationally efficient model can retain sufficient fidelity to a high-resolution solid model, motivated by the requirements of an in-silico platform (e.g. T-Sim) for models that are both fast and reliable. Development therefore started with a high-fidelity solid-element (C3D8I) model of the repeating stent geometry only, without end features or braided wires, which was subsequently converted into a beam-element (B31) representation to reduce computational cost. A mesh convergence study was performed for both representations at this stage.

Comparing the beam and solid representations across four key mechanical properties initially revealed notable discrepancies, traced to the connectivity at each cell bifurcation and resolved by introducing an additional beam element at these locations; the corrected beam model then agreed with the solid model to within a few percent (Section 2.4.6).

The stent end features (crowns/tip) and braided wires were subsequently added, based on a micro-CT scan, to form the first complete model (Model Version 1). Validation against in-vitro flat-plate compression and three-point bending data showed insufficient agreement (Section 3.5). A sensitivity analysis (Section 3.4) identified strut width and depth as the dominant contributing

parameters, motivating a repeated, more detailed microscopy measurement and a revised model (Model Version 2), assessed in Chapter 4.

2.2.1 Model VVUQ

A series of VVUQ activities were carried out on Model Version 1 in accordance with the ASME V&V standards. A VVUQ plan was drawn up (see appendix 7.3), describing which steps of the ASME V&V process were planned to be followed. The model risk was assessed as high–high, based on the model influence and decision consequence; all VVUQ activities were therefore planned at the highest rigor level specified in the VVUQ plan. The credibility matrix in the appendix 7.1 shows the achieved levels.

Model Risk Assessment

The model risk assessment was conducted in accordance with ASME V&V-40.

1. Model Influence. Model influence is assigned one of three gradation levels, as suggested by ASME V&V-40: (a) simulation outputs are a minor factor in the decision; (b) simulation outputs are a moderate factor in the decision; (c) simulation outputs are a significant factor in the decision. Since the finite element model will be used within an in-silico platform to evaluate device performance and safety in a virtual patient cohort under challenging clinical conditions, a high model influence level (Level C) was assigned. The simulation outputs constitute a significant factor in the decision-making process, as they provide regulatory-grade, model-based evidence supporting device design evaluation and regulatory submission. Although this model evidence can be accompanied by in-vitro, pre-clinical, and clinical data, the simulation results play a critical role in assessing device behaviour across a wide range of conditions that cannot be fully captured through physical testing alone. Consequently, a high level of confidence in the model predictions is required.

2. Decision Consequence. Decision consequence is likewise assigned one of three gradation levels: (a) an incorrect decision would not adversely affect patient safety or health, but might cause a nuisance to the physician or have other minor impact; (b) an incorrect decision could result in minor patient injury, the need for physician intervention, or other moderate impact; (c) an incorrect decision could result in severe patient injury or death, or other significant impact. A high design consequence level (Level C) was assigned because the model supports evaluation of the safety and performance of a medical device intended for clinical use. An incorrect decision based on the model evidence could lead to an inaccurate assessment of device behaviour, potentially resulting in the use of a device that does not meet the required safety or performance standards. Given the intended application in the neurovascular domain, such an outcome could result in severe patient injury, death, or other significant adverse consequences. The consequence of an incorrect decision is therefore considered high.

3. Model Risk. Based on the ASME V&V-40 risk framework, a risk matrix was constructed using the assigned model influence and design consequence levels (Figure 2.3). Given the high model influence (Level C) and high design consequence (Level C) associated with the intended Context of Use, the model was classified as Risk Level 5 – the highest credibility risk category.

Consequently, a high degree of model credibility is required to provide sufficient confidence in the simulation results and to support their use in device evaluation and regulatory decision-making.

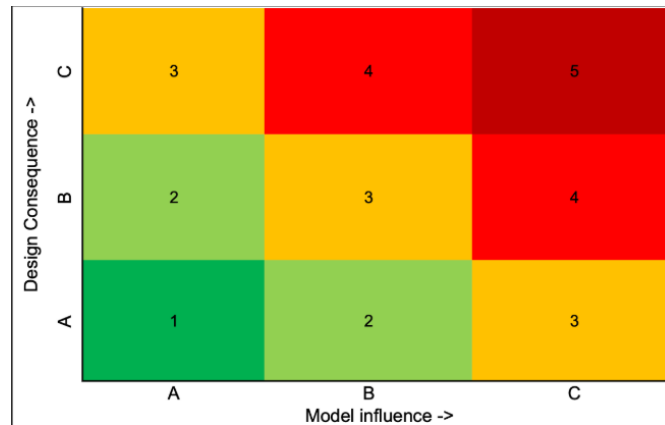


Figure 2.3: Model risk matrix, based on model influence and design consequence (ASME V&V-40).

Credibility

Model Risk Level 5 defines the required level of rigor for the output comparison. This highest risk category requires a stringent validation process to ensure sufficient model credibility. A quantitative comparison between computational and experimental data is therefore required as part of the model validation, with relative differences between simulation results and experimental measurements required to remain below 10%. This acceptance criterion is used to assess the predictive capability of the model under relevant loading conditions and device configurations.

Table 2.1: Rigor of output comparison required per model risk level (ASME V&V-40).

Risk level	Rigor of output comparison
1	Visual comparison concludes good agreement.
2	Quantitative comparison; differences between computational and experimental results are less than 50%.
3	Quantitative comparison; differences between computational and experimental results are less than 20%.
4	Comparison with uncertainty estimated and incorporated from the comparator or the computational model; differences are less than 10%; some uncertainty is considered, but statistical distributions for further uncertainty quantification are unknown.
5	Comparison with uncertainties estimated and incorporated from both the comparator and the computational model, including comparison error; differences are less than 10%; statistical distributions are known, enabling rigorous treatment of uncertainty.

2.3 High Fidelity Model

2.3.1 Approach

The high-fidelity model was built based on microscopy measurements. The stent was measured using a Keyence microscope at TU Delft. The stent geometry was analysed and found to be composed of a symmetric, repeating pattern: the majority of the stent consists of a single repeating unit cell. The repeating cell was reconstructed in a 2D plane and subsequently extruded into a 3D flat mesh structure. This cell was then used to build an assembly forming a flat 3D structure, which was mapped into a single cylindrical geometry in Abaqus using scripting (see figure 2.4). This constitutes the high-resolution model, built from solid elements. Three stent sizes from the same Trevo XP ProVue were generated in this way: 3×20 mm, 4×30 mm and 6×25 mm. In figure 2.5 the models for the three different sizes can be seen. Furthermore the table 2.2, shows the configuration of the three different models. The T3 is fabricated out of a row of 7 cells, stacked 4 times, with in total 28 repeating parts. Also the size of each model can be seen. Because as expected the T3 has the least amount of elements and nodes, we used this model for mesh convergence analysis. This analysis was done on output for four different relevant simulations.

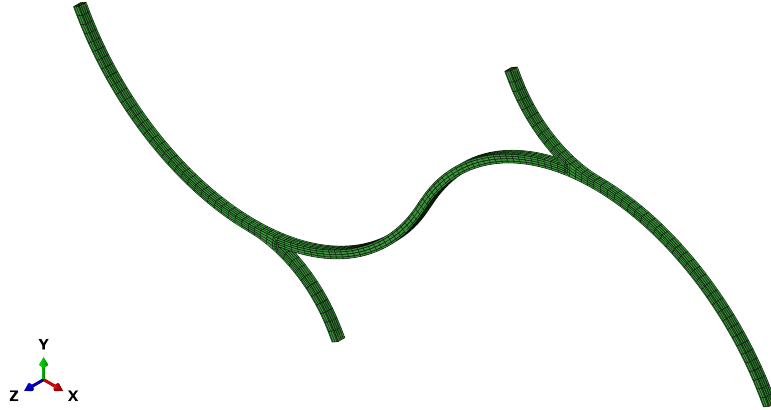
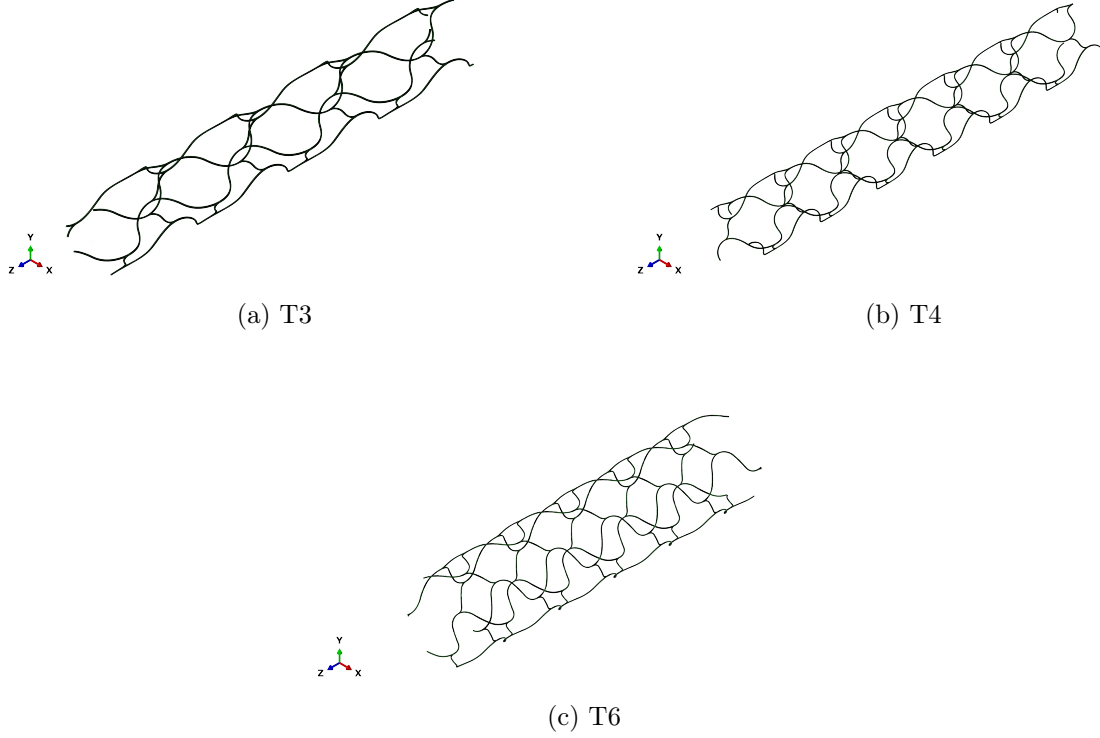


Figure 2.4: Model of single cell (T3) in abaqus

Table 2.2: Mesh characteristics of the high-resolution (solid element) model for the three stent sizes (T3, T4, T6), across mesh levels ML1–ML3.

		T3 (3×20 mm)	T4 (4×30 mm)	T6 (6×25 mm)
Parts (Element divisions)		7×4	7×4	7×5
Elements (C3D8I)	ML1	39,324	68,296	76,136
	ML2	131,682	229,272	256,584
	ML3	447,786	780,858	868,167
Nodes	ML1	61,040	105,965	118,250
	ML2	178,500	310,737	348,005
	ML3	551,020	961,300	1,069,260

Figure 2.5: Hight fidelity models T3, T4, T6



2.3.2 Material model

The stent is made of nitinol (Wu et al., 2025), which was assigned a material model using the superelastic parameters listed in Table 2.3.

Table 2.3: Superelastic nitinol material parameters used for the laser-cut structure.

Material parameter	Unit	Value
Austenite Young's modulus	MPa	56,000
Austenite Poisson's ratio	—	0.3
Martensite Young's modulus	MPa	23,700
Martensite Poisson's ratio	—	0.3
Transformation strain	—	0.063
Loading start of transformation stress	MPa	635
Loading end of transformation stress	MPa	677
Unloading start of transformation stress	MPa	288
Unloading end of transformation stress	MPa	254
Loading start of transformation stress (compression)	MPa	952.5
Temperature	°C	37
Density	g/cm ³	6.45×10^{-9}

2.3.3 Data acquisition

Model input data were obtained from several sources. The dimensions of the repeating unit cell were derived from the microscopy measurements showed in figure 2.6, more measurements included in the appendix 7.3 The nitinol material model parameters were taken from a published

study in which these parameters were determined based on radial testing of the Trevo XP ProVue 6x25 (Wu et al., 2025). The compression-stress parameter is a difficult parameter and can not easily be tested, therefore a value of 1.5 times the loading stress was taken based on studies internal data from 4RealSim and literature (Paranjape et al., 2025)). The overall diameter of the stents were taken from the latest FDA report U.S. Food and Drug Administration (2020)

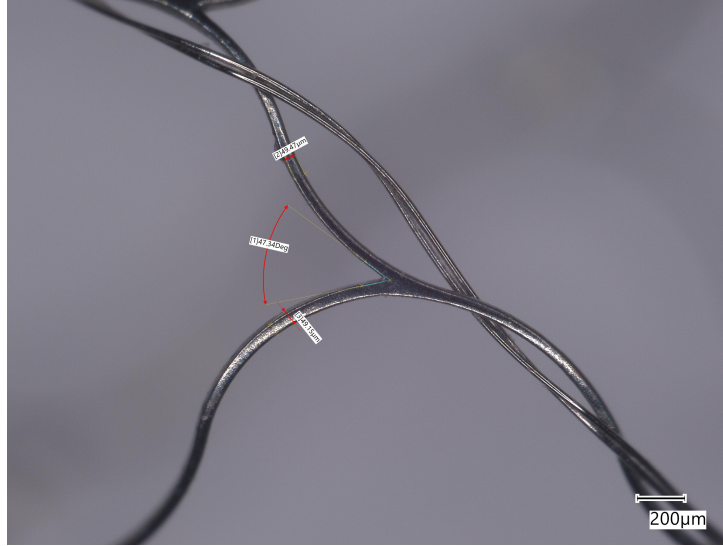


Figure 2.6: Microscopy images of the stent and the repeating unit cell used to reconstruct the geometry.

2.3.4 Test cases

The smallest stent size (T3) was used for the test cases, since it contains the fewest elements and nodes and can therefore be simulated fastest. Four simulation tests, all done with abaqus implicit (static steps), were performed on this model:

- **Axial extension** – the stent was axially stretched by 2 mm (10% of length) and the reaction forces recorded. The axial stiffness was defined as

$$k_a = \frac{\Delta F}{\Delta L} \quad (2.1)$$

- **Bending** – the stent was bent by 0.2 rad and the moment at the end of the stent recorded. The bending stiffness was defined as

$$k_b = \frac{\Delta M}{\Delta \theta} \quad (2.2)$$

- **Torsion** – the stent was twisted by 0.3 rad and the moment at the end of the stent recorded. The torsional stiffness was defined as

$$k_t = \frac{\Delta M}{\Delta \phi} \quad (2.3)$$

- **Radial crimp** – a cylindrical surface was used to crimp the stent to a diameter of 2.25 mm (25% decrease of the diameter). The total reaction force on the surface was recorded

as a function of diameter, and the radial stiffness was defined as

$$k_r = \frac{\Delta F}{\Delta D} \quad (2.4)$$

As outlined in the context of use described in Section 2.1, the selection of these four test cases is directly motivated by the clinical procedure the device is intended to perform. During a thrombectomy procedure, the stent retriever is first crimped into the delivery catheter and advanced through the vessel system to the site of the thrombus. Once the guiding catheter is withdrawn, the stent is deployed and expands radially into contact with the vessel wall and the thrombus. The stent is subsequently retracted, together with the entrapped thrombus, back through the vessel. Each of these procedural steps subjects the device to a distinct and clinically relevant mechanical loading condition. Radial stiffness governs the interaction between the stent and both the delivery catheter (during crimping) and the vessel wall (during deployment and retrieval). Axial stiffness is relevant during retraction of the device, when tension is applied along its length. Bending stiffness determines the ability of the stent to conform to the curvature of the vessel while maintaining radial contact with the vessel wall. Finally, torsional deformation occurs during manipulation and retraction of the device within the tortuous vessel anatomy. Given that these four mechanical characteristics – radial, axial, bending, and torsional stiffness – correspond directly to the loading conditions experienced throughout the procedure, they were selected as the most relevant mechanical properties for evaluation within this context of use.

To apply the loading conditions described above, the stent was coupled to reference points located on its central axis at both ends. At each end, all nodes of the stent terminal cross-section were connected to a reference point (RP) positioned on the axis of the stent, using a distributed coupling constraint. Distributed coupling relates the displacement and rotation of the reference point to the average, weighted displacement of the coupled node set, allowing the applied load or displacement to be distributed evenly over the node set while permitting local deformation of the cross-section. This approach was used at both ends of the stent, enabling boundary conditions and loads to be applied directly to the reference points rather than to individual nodes. See figure 2.7 for the coupling constraint.

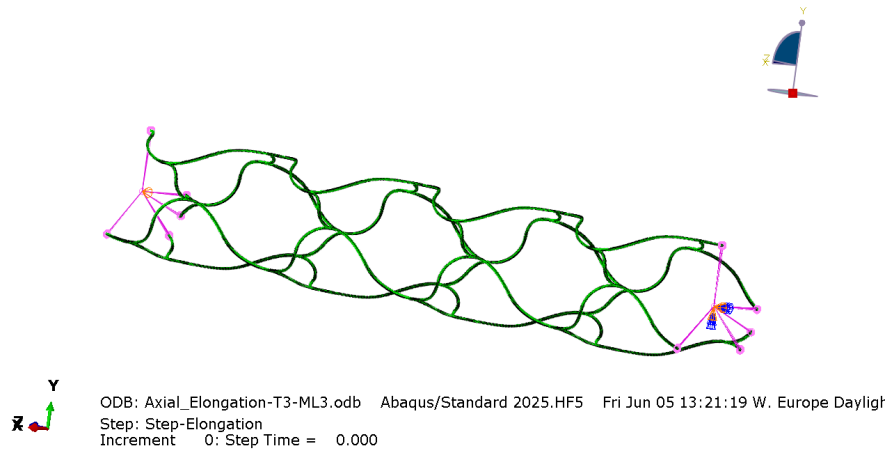


Figure 2.7: Stent model T3 in Abaqus showing distributed coupling constraint

For each of the test cases except radial compression, the reference point at the right-hand end of the stent (RP-R) was fully constrained in all three translational directions (x, y, z) and

the corresponding rotational degrees of freedom, effectively fixing this end of the stent. The reference point at the left-hand end of the stent (RP-L) was then used to apply the relevant loading condition for each test. For Axial extension a displacement boundary condition of 10% of the stent length was applied to RP-L along the axial (U3) direction of the stent. For the T3 size (nominal length 20 mm), this corresponds to a displacement of 2 mm. For bending a rotation boundary condition of 0.2 rad was applied to RP-L about the x-axis (UR1). For torsion a rotation boundary condition of 0.3 rad was applied to RP-L about the z-axis (UR3).

For the radial compression test, a different setup was used. Radial crimping was applied using a cylindrical surface surrounding the stent, with contact defined between the cylindrical surface and the outer surface of the stent (penalty stiffness of 1000 for normal behavior, tangential behavior friction penalty coefficient 0.05). A displacement boundary condition was applied to the cylindrical surface to reduce its diameter from the nominal stent diameter of 3 mm to 2.25 mm, corresponding to a 25% reduction in diameter (i.e. 75% of the original diameter). The total reaction force exerted on the surface, in the radially outward direction, was recorded as a function of the imposed diameter reduction.

Figure 2.8 shows the simulation setup for each of the four test cases at the end of each step, including the boundary conditions applied at the reference points and, for the radial compression test, the crimping surface used to compress the stent.

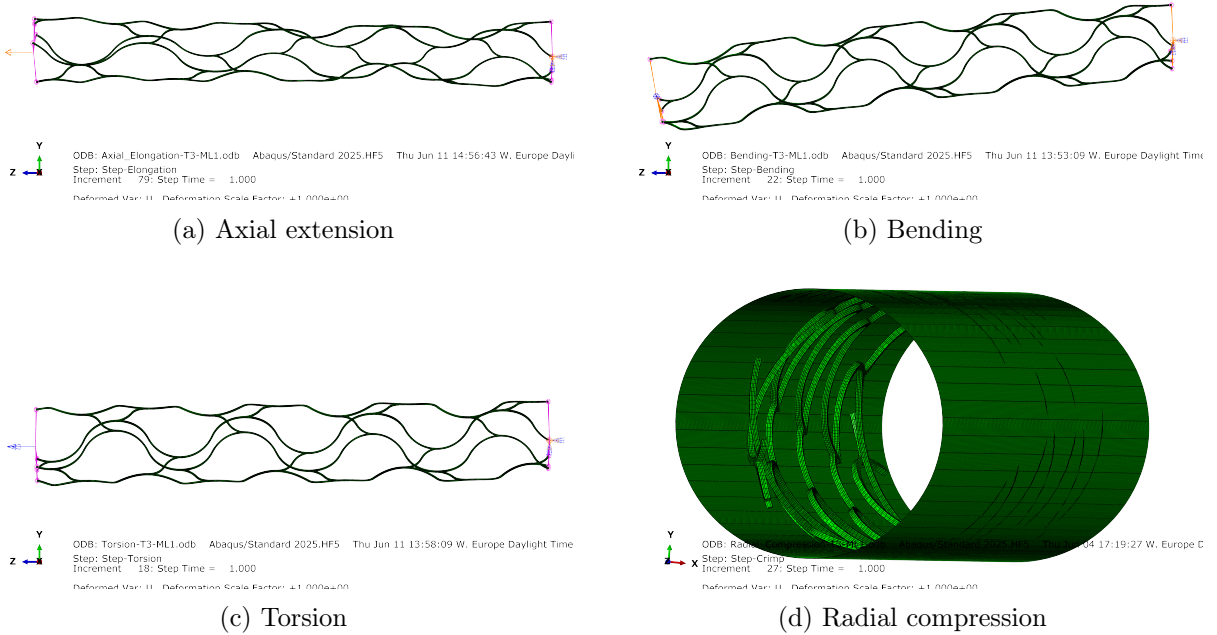
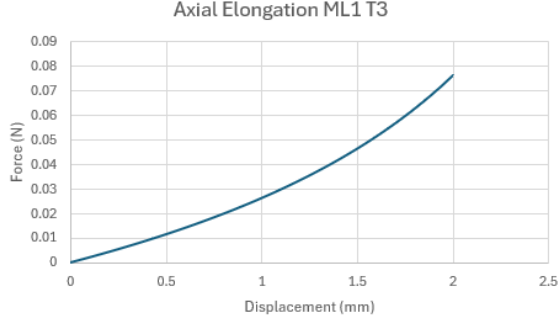


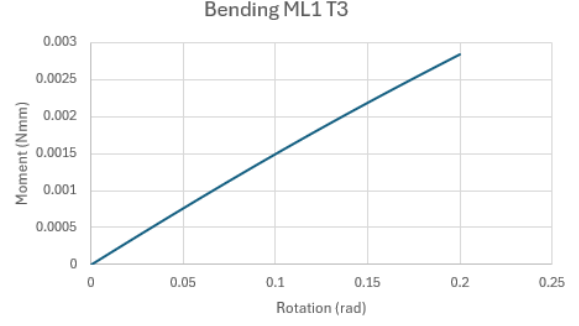
Figure 2.8: Simulation setup for the four test cases performed on Model T3 (ML1): (a) axial extension, (b) bending, (c) torsion, and (d) radial compression.

The load-displacement responses obtained from the four simulation tests on the high fidelity model, T3 (ML1) are shown in Figure 2.9. For each test, the relevant reaction quantity (force or moment) is plotted against the corresponding applied displacement or rotation, illustrating the mechanical response of the stent under axial elongation, bending, torsion, and radial compression.

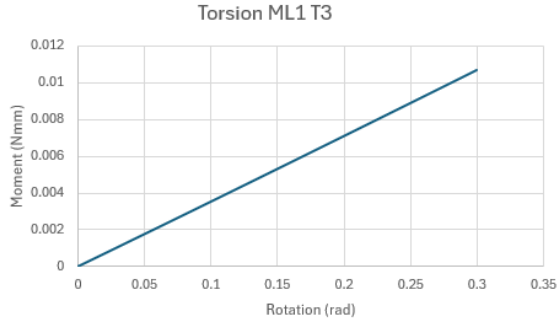
Table 2.4 summarises the applied displacement/rotation, the resulting reaction force/moment,



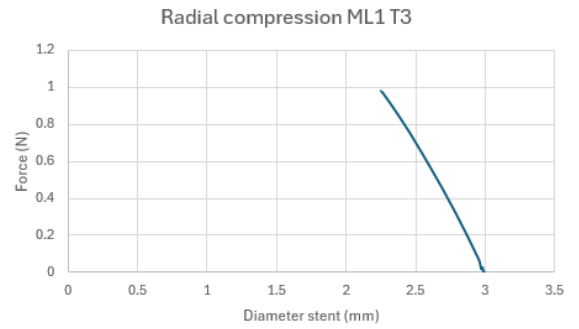
(a) Axial elongation



(b) Bending



(c) Torsion



(d) Radial compression

Figure 2.9: Reaction force/moment as a function of applied displacement/rotation for T3 (ML1), for the four test cases: (a) axial elongation, (b) bending, (c) torsion, and (d) radial compression.

and the corresponding stiffness obtained from the four simulation tests, T3 (ML1), calculated from the load-displacement curves shown in Figure 2.9.

Table 2.4: Applied displacement/rotation, resulting reaction force/moment, and mechanical stiffness values obtained from the four simulation tests on Model T3 (ML1).

Test	Applied	Value	Force/Moment	Stiffness	Value
Axial elongation	ΔL	2 mm	0.0764 N	k_a	0.0382 N/mm
Bending	$\Delta \theta$	0.2 rad	0.00284 N·mm	k_b	0.0142 N·mm/rad
Torsion	$\Delta \phi$	0.3 rad	0.0107 N·mm	k_t	0.0356 N·mm/rad
Radial compression	ΔD	0.75mm	0.981 N	k_r	1.31 N/mm

The axial and radial stiffness are expressed in units of force per unit displacement (N/mm), whereas the bending and torsional stiffness are expressed in units of moment per unit angle (N·mm/rad), consistent with the definitions given in Equations (1)–(4).

2.3.5 Model verification

Software Quality Assurance. The Abaqus bug list and the limitations of the specific features used were reviewed. Custom Python scripts implemented for model generation and analysis were checked by simple testing of the scripts for every step separately.

Discretization Error. A mesh convergence study was performed for the model. Three mesh levels were generated using a constant refinement factor of $r = 1.5$, resulting in element (C3D8I) sizes of 0.05 mm (ML1), 0.0333 mm (ML2), and 0.0222 mm (ML3), corresponding to 4, 6, and 9 elements across the strut width and strut height (SW, SH), respectively, with ML3 representing the finest mesh. The resulting meshes are shown in Figure 2.10, and the corresponding output stiffnesses are reported in Table 2.5.

The discretization error was quantified using the Grid Convergence Index (GCI) method, following the procedure of Roache (1994) as summarized by Baker, Kelly, and O’Sullivan [Baker et al. \(2019\)](#). For three systematically refined grids with solutions f_1 , f_2 , and f_3 (fine, medium, and coarse, respectively — i.e. ML3, ML2, and ML1 in this study), the error between two consecutive grid levels, ε_{mn} , is combined into a root-mean-square error over k output points as:

$$\varepsilon_{rms\ mn} = \left(\frac{\sum_{i=1}^k \varepsilon_{mn}^2}{k} \right)^{1/2} \quad (2.5)$$

which, for a single scalar stiffness output ($k = 1$), reduces to $\varepsilon_{rms\ mn} = |\varepsilon_{mn}|$, with $\varepsilon_{21} = f_2 - f_1$ and $\varepsilon_{32} = f_3 - f_2$. The observed order of accuracy $\hat{p}$ is then calculated as:

$$\hat{p} = \frac{\ln \left| \frac{\varepsilon_{32}}{\varepsilon_{21}} \right|}{\ln(r)} \quad (2.6)$$

Monotonic convergence requires ε_{21} and ε_{32} to have the same sign; a sign change indicates oscillatory convergence, while a negative $\hat{p}$ indicates monotonic divergence rather than convergence. The GCI is then given by:

$$GCI = F_s \frac{\varepsilon_{rms\ mn}}{r^{\hat{p}} - 1} \quad (2.7)$$

with a safety factor $F_s = 1.25$, applicable when the observed order $\hat{p}$ agrees with the formal order within the range recommended by Oberkampf and Roy (2010), i.e. $0.5 \leq \hat{p} \leq p$.

Applying this method to the four stiffness outputs, a valid GCI could only be obtained for the torsional stiffness K_t , for which the mesh solutions converge monotonically, yielding **GCI = 0.079%** for ML3. For the remaining stiffnesses, $\hat{p}$ either fell outside the valid range or could not be meaningfully defined: K_a and K_r both yielded a negative observed order, indicating that the solutions do not converge monotonically towards a single value across the three mesh levels but instead diverge slightly with refinement, while K_b exhibited a sign change between ε_{21} and ε_{32} , characteristic of oscillatory convergence, for which the GCI expression is not defined (Roache, 1994; Longest & Vinchurkar, 2007).

Notably, the absolute difference in all four stiffness values across the three mesh levels is small figure 2.11 (well under 2% of the reported value), even where a formal GCI could not be computed. This indicates that the mesh resolution already being sufficiently fine that the discretization error has become comparable to, or smaller than, other numerical error sources

rather than indicating an unresolved or poor-quality mesh. Longest and Vinchurkar (2007) note that when the differences between successive grid solutions (ε_{21} , ε_{32}) approach zero, the resulting ratio becomes dominated by numerical noise rather than by the true discretization error, producing oscillatory or non-monotonic apparent convergence. It is therefore concluded that K_a , K_b , and K_r are effectively mesh-converged at the resolutions considered, and that the mesh used for ML3 provides a mesh-independent solution suitable for further analysis.

Figure 2.10: Mesh levels ML1–ML3 for Model T3.

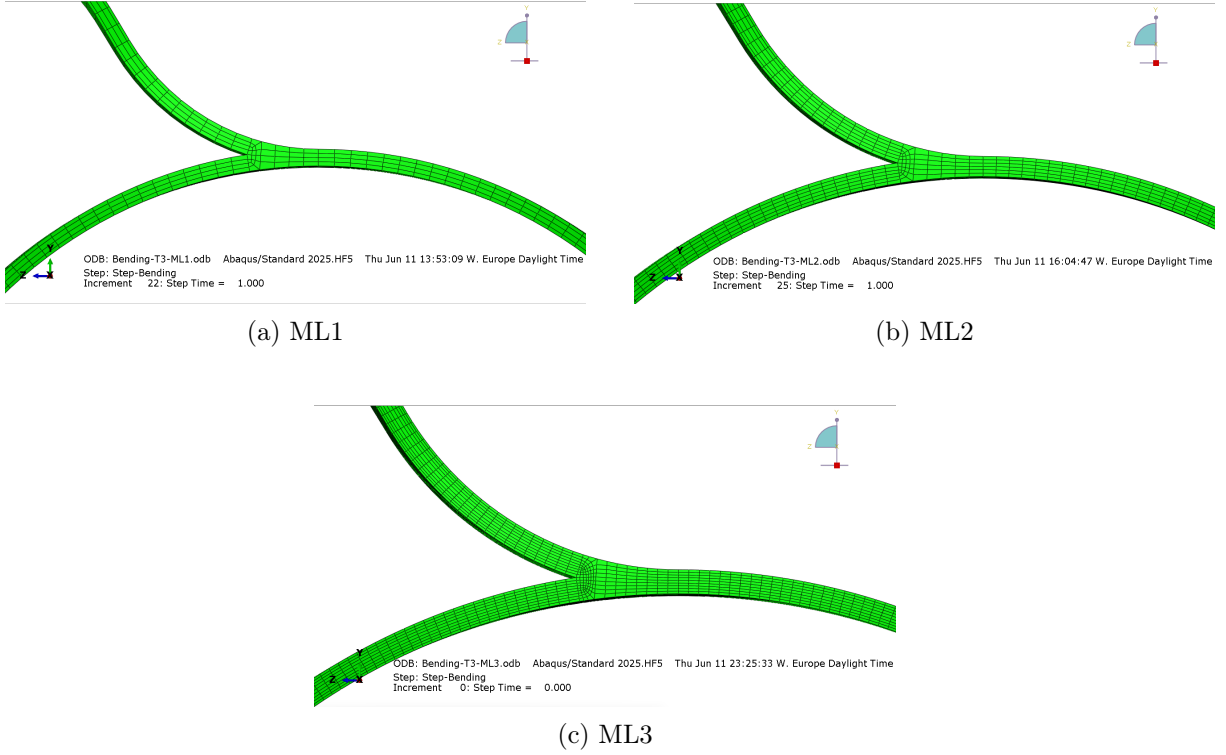


Table 2.5: T3 stiffness values (solid-element model) across mesh levels ML1–ML3.

Stiffness		ML1	ML2	ML3
T3	K_a [N/mm]	0.0382	0.0381	0.0379
	K_b [Nmm/rad]	0.0142	0.0140	0.0141
	K_t [Nmm/rad]	0.0356	0.0352	0.0350
	K_r [N/mm]	1.3082	1.2998	1.2900

Use Error. Model inputs were verified by internal peer review.

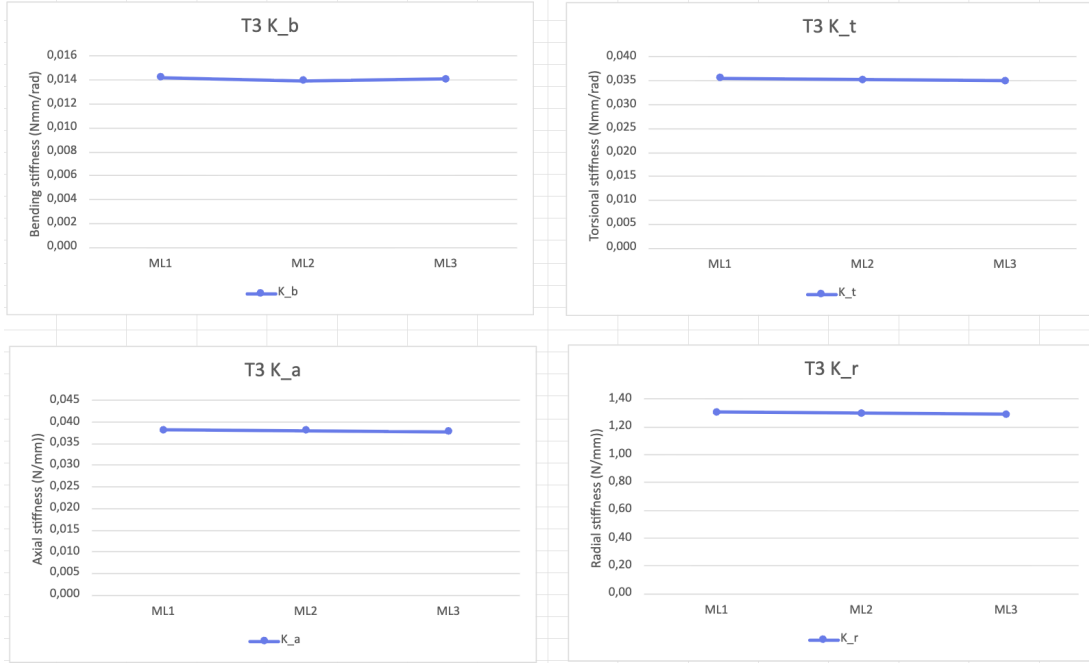


Figure 2.11: Axial (K_a), bending (K_b), torsional (K_t) and radial (K_r) stiffness of the T3 solid-element model across mesh levels ML1–ML3.

2.4 Simplification Model

2.4.1 Approach

One of the key requirements for the model developed in this work is that it should be computationally efficient, enabling fast simulation while retaining sufficient fidelity to the high-resolution solid model. To this end, a simplified model was constructed using beam elements (B31) instead of the solid elements (C3D8I) used in the high-fidelity model.

The fundamental difference between these two element formulations lies in how the geometry and deformation of the structure are represented. Solid elements (C3D8I) discretise the full three-dimensional volume of the strut into a mesh of hexahedral elements, each defined by eight nodes with three translational degrees of freedom per node. This allows the full three-dimensional stress and strain state within the cross-section to be captured, but requires a relatively fine mesh across the strut width and thickness to resolve local gradients such as bending stresses, resulting in a large number of elements and nodes for a given geometry.

Beam elements (B31), by contrast, represent the strut as a one-dimensional line of elements along its centerline, with the cross-sectional geometry (e.g. width and height) defined separately through an assigned beam section profile rather than being explicitly meshed. Each node of a B31 element has six degrees of freedom – three translations and three rotations – allowing the element to capture axial, bending, shear, and torsional deformation of the cross-section analytically, based on beam theory, rather than through explicit discretisation of the volume. Figure 2.12 illustrates this difference, showing the substantially larger number of elements and nodes required to represent a single strut segment using solid elements compared to the equivalent beam representation.

This difference in discretisation directly explains the reduction in computational cost. Because the beam representation requires only a single row of elements along the centerline rather

Table 2.6: Comparison of mesh resolutions for different models.

		T3 (3×20 mm)	T4 (4×30 mm)	T6 (6×25 mm)
Parts		7×4	7×4	7×5
Elements (C3D8I vs B31)	ML1	39,324 vs 2,460	68,296 vs 4,245	76,136 vs 4,811
	ML2	131,682 vs 3,756	229,272 vs 6,470	256,584 vs 7,128
	ML3	447,786 vs 5,516	780,858 vs 9,621	868,167 vs 10,747
Nodes	ML1	61,040 vs 2,449	105,965 vs 4,225	118,250 vs 4,792
	ML2	178,500 vs 3,745	310,737 vs 6,450	348,005 vs 7,109
	ML3	551,020 vs 5,505	961,300 vs 9,600	1,069,260 vs 10,728

than a full three-dimensional mesh across the cross-section, the total number of elements and degrees of freedom in the model is drastically reduced (see table 2.6). Since computation time scales with the number of elements, nodes, and the associated system of equations to be solved at each increment, this substitution makes the model considerably faster to simulate, while still capturing the same characteristic deformation modes (axial, bending, torsional, and radial) through the underlying beam theory.

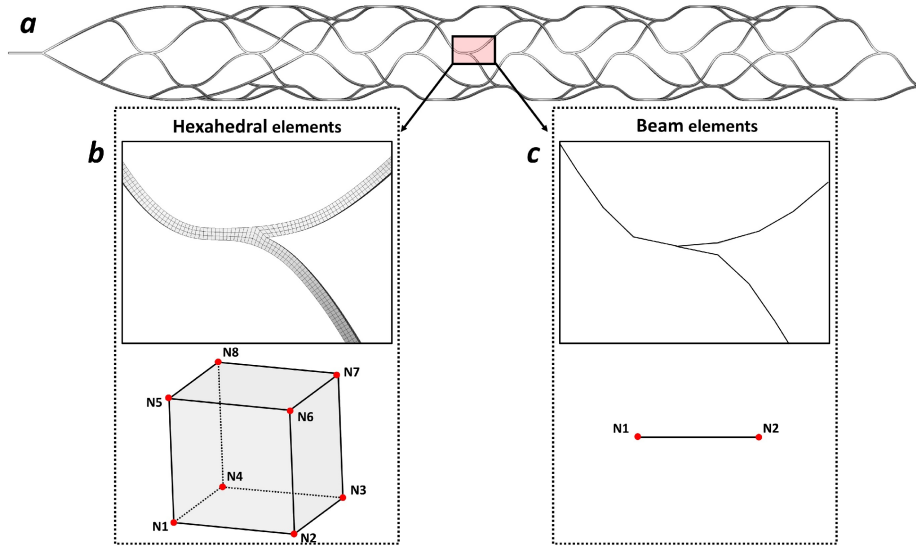


Figure 2.12: Comparison between the solid element (C3D8I) mesh and the beam element (B31) representation for a single strut segment, illustrating the difference in the number of elements and nodes required for each formulation.

To construct the beam model, the centerline was extracted from the sketch used to define the repeating unit cell of the solid model. Using this centerline, the same assembly procedure as for the solid model was followed, ensuring that the overall stent geometry (unit cell pattern, dimensions, and circular assembly) remained consistent between the two representations. A beam section, corresponding to the strut cross-sectional dimensions, was then assigned along the centerline, giving the beam model the same global structure as the solid model while using B31 elements instead of C3D8I elements. In addition, a script was developed to automatically assign the correct local orientation to each beam element, ensuring that the cross-sectional axes were consistently aligned with the actual geometry of the stent along its circular and helical path.

2.4.2 Material model

The same nitinol material model was used for the beam elements as for the solid elements (see Table 2.3). In model version 1, the braided wires were added. For the braided wires, the material model listed in Table 2.7 was used.

Table 2.7: Material properties of the platinum–tungsten alloy (92–8) used for the braided wires.

Material parameter	Unit	Value
Density	g/cm ³	21.2
Young’s modulus	MPa	138,000
Poisson’s ratio	–	0.3

2.4.3 Data acquisition

All data sources are identical to those used for the solid model, with the addition of the wire cross-sectional dimensions and the wire material model, based on the California Fine Wire Platinum–8% Tungsten Alloy (Alloy 436) [MatWeb, LLC](#).

2.4.4 Test cases

The same test cases as for the high-fidelity model were used: axial elongation, bending, torsion, and radial crimping, with identical loading protocols and stiffness definitions. Results of the test cases can be seen in figure 2.13

2.4.5 Model verification

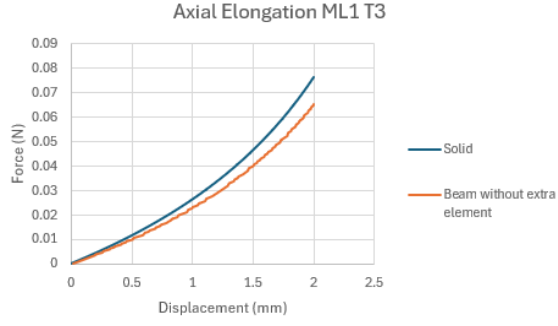
A mesh convergence study was also performed for the beam model. Since beam elements do not require discretisation across the cross-section, only the element length along the centerline could be varied, unlike the solid model where both the number of elements across the strut cross-section and the element length changed between mesh levels. To allow a direct comparison with the solid model, the same element lengths as used in the solid mesh convergence study were applied here, namely 0.05 mm, 0.0333 mm, and 0.0222 mm for ML1, ML2, and ML3, respectively. The resulting mesh convergence analysis is shown in Figure 2.14, and the final stiffness values are given in Table 2.8.

Table 2.8: T3 stiffness values, initial beam-element model, mesh levels ML1–ML3.

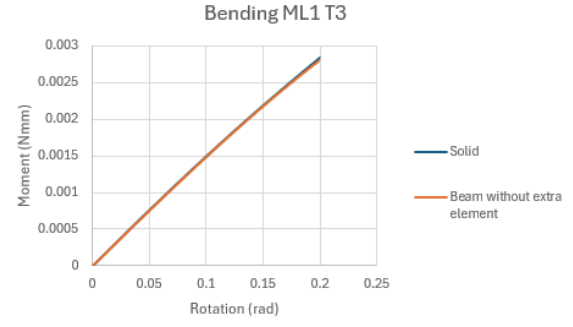
	Stiffness	ML1	ML2	ML3
T3-Beam	K_a [N/mm]	0.0328	0.0327	0.0329
	K_b [Nmm/rad]	0.0140	0.0130	0.0133
	K_t [Nmm/rad]	0.0319	0.0319	0.0321
	K_r [N/mm]	0.8581	0.8580	0.8985

2.4.6 Identification of discrepancy with continuum model

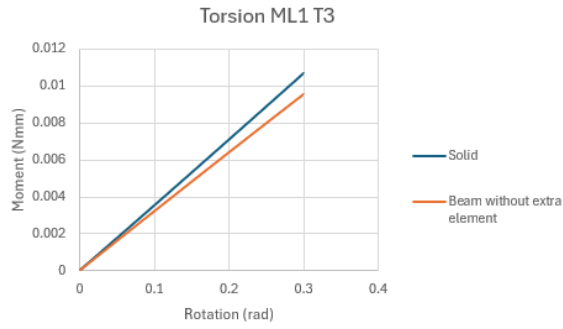
The stiffnesses of the beam and solid models were compared across all test cases. For this comparison, the stiffness values obtained from the finest mesh level of the solid model (ML3)



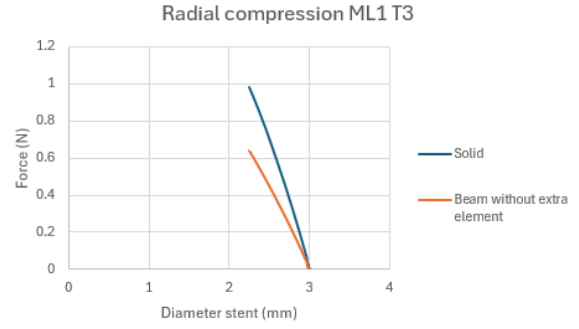
(a) Axial elongation



(b) Bending



(c) Torsion



(d) Radial compression

Figure 2.13: Reaction force/moment as a function of applied displacement/rotation for T3 (ML1) beam model and high fidelity model, for the four test cases: (a) axial elongation, (b) bending, (c) torsion, and (d) radial compression.

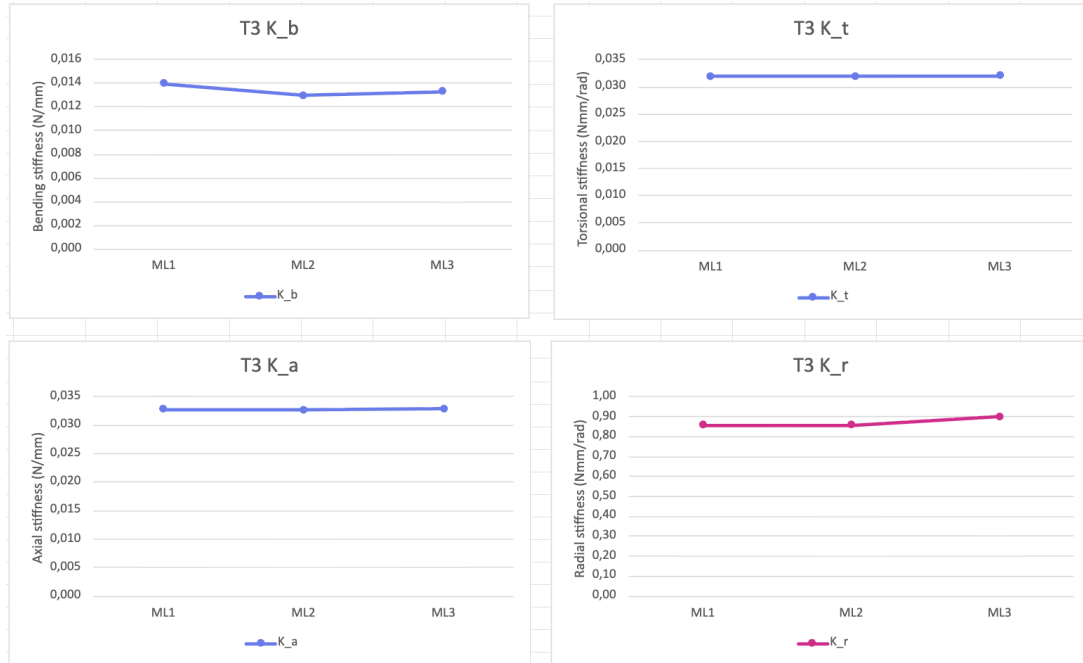


Figure 2.14: Axial (K_a), bending (K_b), torsional (K_t) and radial (K_r) stiffness of the T3 beam-element model (initial version, without the additional connecting beam element) across mesh levels ML1–ML3.

Table 2.9: Relative error of the initial beam-element model versus the solid-element model (T3).

	K_a (%)	K_b (%)	K_t (%)	K_r (%)
ML1	13.33%	0.56%	8.80%	33.48%
ML2	13.68%	7.90%	8.79%	33.49%
ML3	13.21%	5.47%	8.28%	30.34%

were taken as the reference values, against which the stiffness values obtained at each mesh level of the beam model (ML1, ML2, ML3) were compared. The resulting relative error between the two representations was found to be substantial (see Table 2.9). The largest discrepancy with the finest mesh was found for the radial stiffness, at approximately 30%.

The root cause of this discrepancy was investigated by examining the deformation of a single unit cell, which showed that the cell deforms considerably more in the beam model than in the solid model. Figure 2.15 shows the deformed beam and solid representations of the finest mesh (ML3) overlaid for the axial extension test case, under identical loading conditions. The beam model can be seen to deform noticeably different than the solid model, despite representing the same nominal geometry and boundary conditions.

The conclusion drawn from this investigation was that, in the beam model, the split between the connector element and the sinusoidal main body of the cell is represented by only a single node. In the solid model, by contrast, this same location is represented by a larger number of elements, which locally resist the simple local bending that otherwise occurs unopposed at a single-node split in the beam model.

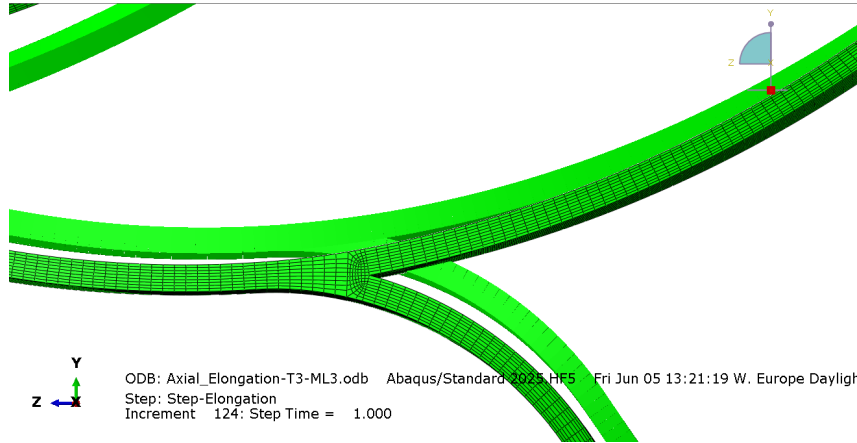


Figure 2.15: Overlay of the deformed beam and solid model representations (finest mesh, ML3) for the axial elongation test case, under identical loading conditions

As a solution, an additional beam element was introduced at the split location to increase its local rigidity, see figures 2.16

The test cases were repeated with this corrected beam model. The results 2.10 confirmed that this was indeed the source of the discrepancy: the new errors, shown below 2.11, are substantially reduced compared to the initial beam model.

With these corrected results, the optimal mesh size was re-examined. The mesh study showed that the corrected beam model was already reasonably well converged at the mesh sizes previously used for the solid model comparison. Since the model showed good agreement at these relatively

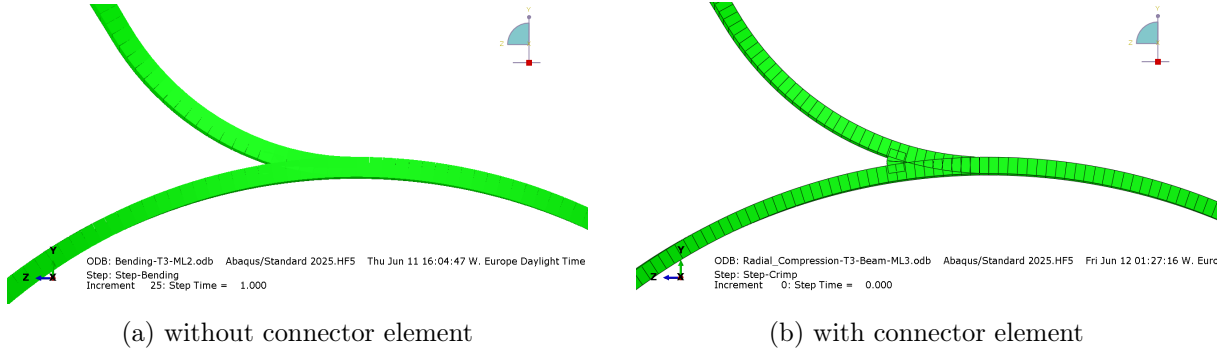


Figure 2.16: Beam model ML3 with connector element vs without connector element

Table 2.10: T3 stiffness values, corrected beam-element model (with additional connecting beam element at the split location), mesh levels ML1–ML3.

Stiffness		ML1	ML2	ML3
T3	K_a [N/mm]	0.0386	0.0386	0.0382
	K_b [Nmm/rad]	0.0146	0.0143	0.0142
	K_t [Nmm/rad]	0.0361	0.0361	0.0357
	K_r [N/mm]	1.3193	1.3207	1.3191

Table 2.11: Relative error of the corrected beam-element model versus the solid-element model (T3).

	K_a (%)	K_b (%)	K_t (%)	K_r (%)
ML1	2.0%	3.6%	3.3%	2.3%
ML2	1.8%	1.6%	3.2%	2.4%
ML3	1.0%	0.7%	2.2%	2.3%

fine mesh sizes, the mesh study was extended to larger element sizes (mesh levels ML -3 to ML0, in addition to ML1–ML3) to evaluate whether coarser meshes could still provide sufficiently accurate results. This is of particular interest since a coarser mesh would substantially reduce the computational time of the model, thereby improving its overall efficiency.

The relative error at each mesh level compared to ML3 is shown in Table 2.13, with the corresponding convergence graphs presented in Figure 2.17. The resulting stiffness values for the coarser mesh sizes are given in Table 2.12, and Table 2.14 lists the element lengths corresponding to all mesh levels, generated using a reduction factor of 1.5.

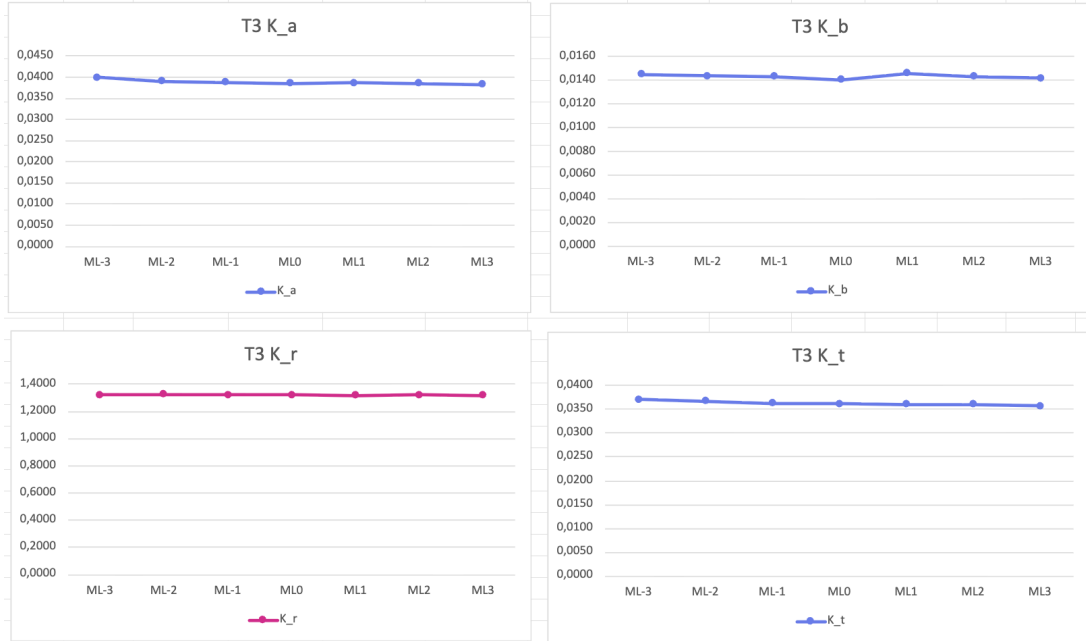


Figure 2.17: Mesh convergence of the corrected beam model for axial (K_a), bending (K_b), radial (K_r) and torsional (K_t) stiffness, across the extended mesh range ML-3 to ML3.

Table 2.12: T3 stiffness values, corrected beam-element model, coarser mesh levels ML -3 to ML0.

Stiffness		ML-3	ML-2	ML-1	ML0
T3	K_a [N/mm]	0.0399	0.0390	0.0388	0.0385
	K_b [Nmm/rad]	0.0145	0.0144	0.0143	0.0141
	K_t [Nmm/rad]	0.0371	0.0368	0.0363	0.0362
	K_r [N/mm]	1.3211	1.3259	1.3229	1.3207

The error at mesh level ML-1 remains sufficiently close to the finest mesh level. For practical convenience, a beam mesh element size of 0.1 mm was therefore adopted for the beam model.

2.4.7 Model Version 1

To arrive at the complete stent geometry, the two end features of the stent (crowns/tip) were constructed based on the micro-CT scan. In addition, the braided wires were modelled and added to the geometry. With these additions, the model is now complete as Model Version 1 (V1).

Table 2.13: Relative change in stiffness at each mesh level, expressed relative to the finest level (ML3).

Stiffness	ML-3→ML3	ML-2→ML3	ML-1→ML3	ML0→ML3	ML1→ML3	ML2→ML3
K_a	-4.29%	-1.99%	-1.32%	-0.73%	-0.95%	-0.80%
K_b	2.30%	-1.35%	-1.15%	0.84%	-2.86%	-0.91%
K_t	-3.77%	-2.91%	-1.62%	-1.23%	-1.08%	-1.01%
K_r	-0.15%	-0.52%	-0.28%	-0.12%	-0.02%	-0.12%

Table 2.14: Overview of the beam mesh element sizes corresponding to each mesh level (refinement factor 1.5).

Mesh level	Mesh size [mm]
ML-3	0.253125
ML-2	0.16875
ML-1	0.1125
ML0	0.075
ML1	0.05
ML2	0.03333
ML3	0.02222

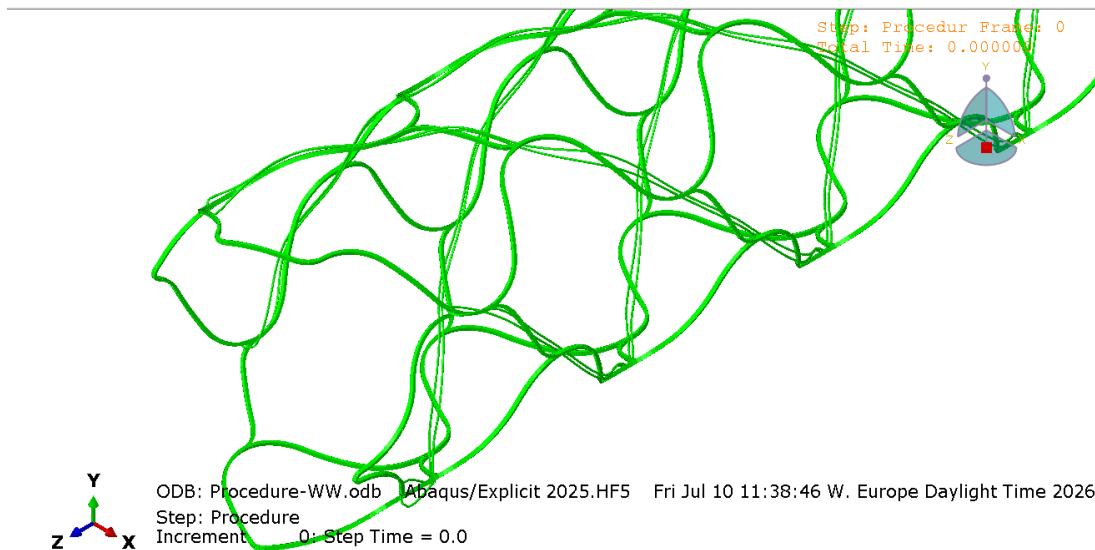


Figure 2.18: Model version 1

Chapter 3

Model Validation

3.1 Comparators: Experimental Tests

To validate the model, it is essential to compare its predictions against relevant experimental (comparator) tests. In line with the ASME V&V-40 framework, these tests must be selected such that they are representative of the intended context of use of the device. Two experimental tests were therefore performed: flat-plate compression and three-point bending. Flat-plate compression was selected because the stent is frequently subjected to radial compression within the vessel, both during deployment and while in contact with the vessel wall. Three-point bending was selected because the stent must navigate through curved vessel anatomy, subjecting it to significant bending deformation during use. Both tests were performed for all three stent sizes (T3, T4, T6) including braided wires.

3.1.1 Flat-Plate Compression

Flat-plate compression tests were performed using a Mark-10 tensile/compression testing machine at TU Delft lab with a consistent temperature of 20.5 °C. The setup consisted of two flat, circular aluminium plates with a diameter of 56 mm, mounted parallel to one another in the testing machine, see figure 3.1

The zero position of the plates was first calibrated by lowering the top plate until contact with the bottom plate was detected via a measurable increase in force and then set to zero. The top plate was then raised by approximately 5–8 mm (depending on stent size) to create sufficient clearance for the stent to be placed between the plates. The stent was subsequently positioned between the plates, and the top plate was moved downward to compress the stent radially, until the distance between the plates equalled half of the nominal stent diameter (e.g. 3 mm for a nominal diameter of 6 mm). After compression, the plate was moved back upward until contact between the stent and the top plate was lost, as indicated by the recorded force returning to zero.

Throughout both the downward (loading) and upward (unloading) motion of the top plate, the force exerted on the plate was recorded as a function of plate displacement, allowing the loading and unloading response of the stent to be captured within a single test cycle.

The applied velocity of the top plate was 1.6 mm/min, and a 2.5 N load cell (accuracy $\pm 0.1\%$, [Mark-10 Corporation \(2026\)](#)) was used to record the compressive force.

For each stent size, three compression cycles were performed under different conditions:

1. An initial test on the stent in its as-received condition.
2. A second test performed immediately after the first, in order to assess the effect of repeated loading; a reduction in the recovered stent diameter was observed following the first cycle, indicating a degree of permanent (plastic or non fully-recovered) deformation.
3. A third test performed after resetting the stent in water at 37 °C, corresponding to the stent manufacturing temperature, in order to allow the nitinol shape-memory effect to recover the original stent geometry before retesting.

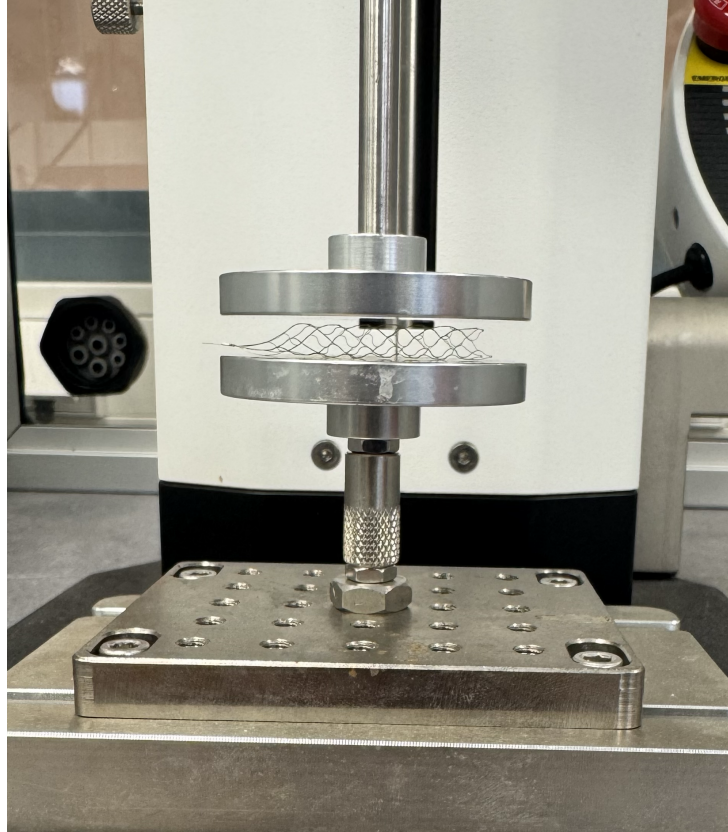


Figure 3.1: Flat plate compression test setup

The results of the flat-plate compression tests are shown in Figure 3.2. Test 1 corresponds to the stent in its as-received condition, having been used once in a real thrombectomy procedure. Test 2 was performed directly following Test 1, and clearly showed that the stent had undergone a degree of permanent deformation, resulting in a slightly flattened, reduced-diameter configuration. To assess whether this apparent deformation could be recovered, a third test was performed after placing the stent in water at 37 °C, allowing it to return to its unconstrained (stress-free) configuration through the nitinol shape-memory effect. In this third test, the stent diameter was indeed observed to have increased again, as indicated by the plate distance at which contact between the top plate and the stent first occurred.

In Figure 3.2, the horizontal axis shows the distance between the two plates, starting from an initial separation of 6 mm, while the vertical axis shows the reaction force recorded on the top plate. Across all three tests, the plate distance at which the stent first made contact with the top plate did not correspond to the nominal 6 mm diameter reported in the FDA documentation.

Furthermore, the diameter at which contact occurred was largest for Test 3 (following the 37 °C water conditioning), and notably smaller for Test 2, which was performed directly after Test 1 without any conditioning step, consistent with permanent deformation observed after the first loading cycle. In addition, all three tests exhibit a clear hysteresis effect, with the recorded force during unloading being consistently lower than during loading at the same plate distance.

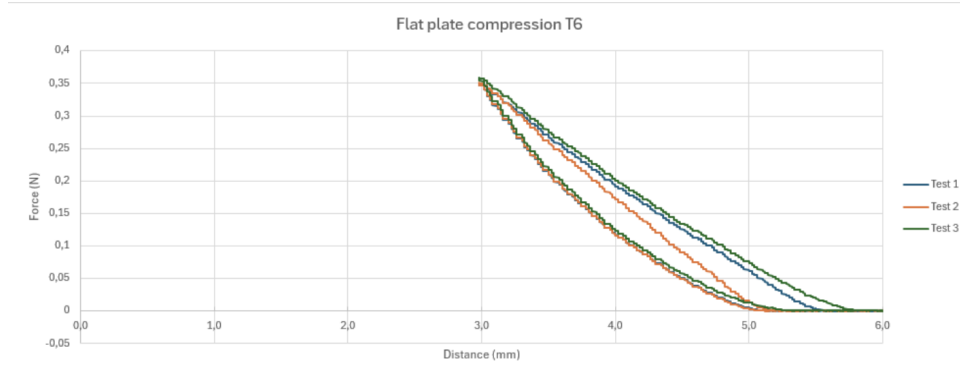


Figure 3.2: Force-displacement response of the flat-plate compression Test 1, Test 2 and Test 3 for T6.

3.1.2 Three-Point Bending

The three-point bending test setup is shown in Figure 3.3. The setup consisted of two supporting cylinders, each with a diameter of 10 mm, positioned at the bottom of the fixture with a horizontal centre-to-centre distance of 20 mm. A loading punch was positioned above the two supporting cylinders and was first calibrated relative to the cylinders to establish the zero (contact) position.

The punch was then raised to create sufficient clearance, after which the stent was placed on top of the two supporting cylinders, centred between them. The punch was subsequently moved downward, midway between the two supports, applying a displacement equal to half the nominal diameter of the respective stent size, after which the punch was moved back upward to its original position. The same Mark-10 testing machine, velocity (1.6 mm/min), and load cell (2.5 N) were used as for the flat-plate compression tests.

As with the flat-plate compression tests, the force exerted on the punch was recorded as a function of its displacement during both the downward (loading) and upward (unloading) motion, capturing the full loading-unloading response of the stent for each cycle.

This loading cycle was repeated twice for each stent, in order to assess repeatability of the mechanical response. Unlike the flat-plate compression tests, the stent was not reset in 37 °C water between the two repetitions; instead, the two cycles were performed consecutively without any intermediate conditioning step because an decrease in diameter was not seen.

The results of the two three-point bending tests are shown in Figure 3.4. The horizontal axis shows the displacement of the top punch, measured from the point of first contact with the stent, while the vertical axis shows the resulting reaction force on the punch. The punch was displaced downward to a distance from the top of the supporting cylinders equal to half the nominal diameter of the stent (i.e. 3 mm for a nominal diameter of 6 mm).

Since the tested stent had previously been used in a thrombectomy procedure, it was no longer perfectly straight, but exhibited a slight upward bow along its length. As a result, when placed between the two supporting cylinders, the stent made initial contact with the punch at a



Figure 3.3: Three-point bending test setup, showing the two supporting cylinders (10 mm diameter, 20 mm centre-to-centre spacing) and the loading punch positioned midway between them.

position elevated relative to a perfectly straight reference stent. This is reflected in Figure 3.4, where the total downward displacement of the stent exceeds the nominal 3 mm target.

Furthermore, because the stent was not fixed in place on the supporting cylinders, it was free to rotate and slide during the test. This is visible in the second test, where a sudden jump in the recorded force is present, corresponding to the stent rotating about its own axis – shifting from a configuration with its convex (bowed) side facing upward to one with its convex side facing downward – partway through the test. This rotation caused an abrupt change in the local contact and loading conditions, and is reflected as a discontinuity in the recorded force-displacement curve.

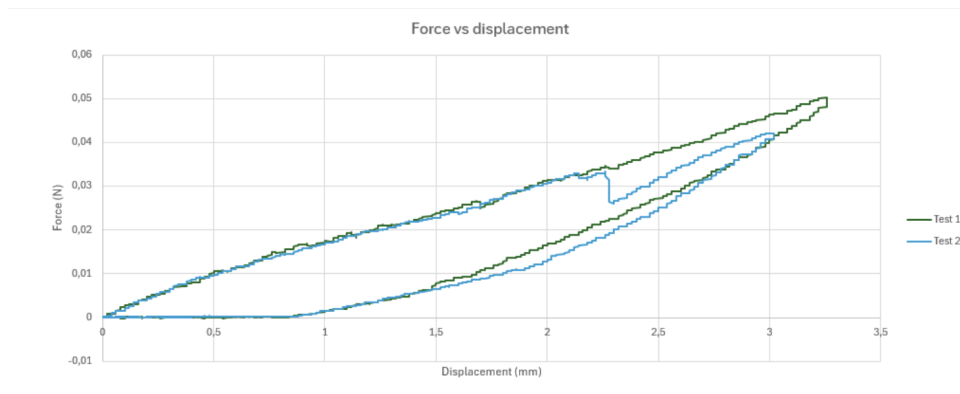


Figure 3.4: Force-displacement response of Test 1, Test 2 of the three-point bending tests for T6.

3.2 Simulation

To validate the model, simulations were performed that replicate the in-vitro test setups as closely as possible. Simulations were therefore carried out for both the flat-plate compression test and the three-point bending test, using the same loading conditions, geometric dimensions (with braided wires), temperature, and boundary conditions as described for the corresponding in-vitro tests in Section 3.1.

3.2.1 Flat-Plate Compression

The simulation setup for the flat-plate compression test is shown in Figure 3.5. The resulting reaction force on the top plate, recorded in the direction opposite to the plate motion (i.e. y -direction), is shown as a function of plate displacement in Figure 3.6.

The simulation was performed using Abaqus/Explicit with $\alpha = 1$ and $\beta = 1 \times 10^{-9}$, rather than Abaqus/Standard (implicit), due to the extensive contact interactions involved between the stent and the two plates, which are considerably more challenging to resolve robustly using an implicit solver. For contact interaction, a penalty friction coefficient between stent-plate and wire-plate of 0.1 was given. To improve the stability and convergence of the explicit simulation, both plates were moved simultaneously towards each other, with the top surface moving downward by 1.5 mm and the bottom surface moving upward by 1.5 mm, rather than moving only the top plate while keeping the bottom plate fixed, as was done in the in-vitro test. This differs from the physical test setup; however, since the relevant quantity is the relative displacement between the two plates (and hence the resulting radial compression of the stent), this modification is not expected to affect the resulting force-displacement response.

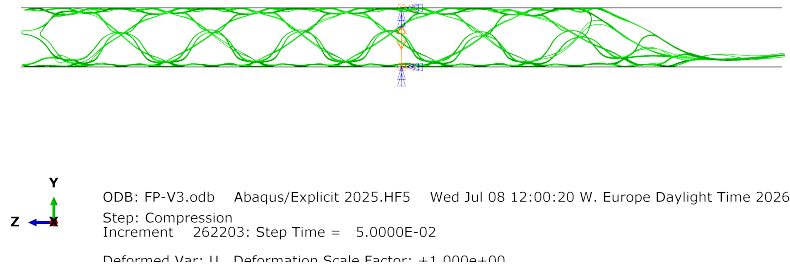


Figure 3.5: Simulation setup for the flat-plate compression test for model version 1, showing the stent positioned between the two analytical surface plates.

3.2.2 Three-Point Bending

The three-point bending simulation was performed in Abaqus/Standard, using a static general step. The simulation setup is shown in Figure 3.7. Three reference points were defined along the central axis of the stent. A central reference point was coupled, using a distributed coupling constraint, to all nodes of the stent located at the corresponding axial position. Two additional

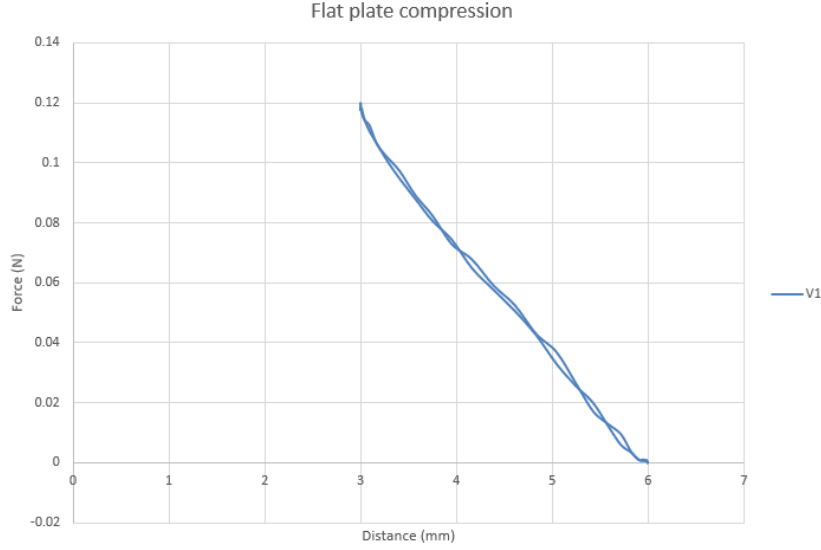


Figure 3.6: Simulated force-displacement response for the flat-plate compression test, showing the reaction force on the top plate as a function of plate displacement for model version 1.

reference points were defined 10 mm to the left and right of the central reference point, respectively, each similarly coupled via distributed coupling to the stent nodes at their respective axial positions. This configuration reproduces the same support span (20 mm) used in the in-vitro three-point bending setup.

The most accurate way to represent this setup would be to model explicit contact between the stent and the two supporting cylinders. However, such a contact-based simulation is considerably more computationally expensive and numerically challenging to converge, and, moreover, the friction coefficients governing the interaction between the stent and the cylinders are not known. A simplified boundary condition was therefore adopted instead: the left and right reference points were fully constrained in the x -, y -, and z -directions, as well as in rotation about the z -axis, in order to approximate the supporting condition provided by the two cylinders in the physical test as closely as possible without explicitly modelling the contact interaction. A displacement boundary condition was then applied to the central reference point, displacing it 3 mm downward, corresponding to half the nominal diameter of the stent. The reaction force at the central reference point, recorded in the direction opposite to the applied displacement, was extracted as a function of the applied downward displacement. The resulting force-displacement curve is shown in Figure 3.8.

3.3 Uncertainty Quantification

Uncertainty quantification (UQ) is the activity within the model validation process that establishes how uncertainty in the model inputs translates into uncertainty in the simulation outputs, and is a prerequisite (depending on risk level) for a meaningful quantitative comparison between simulation and experimental results. Two broad categories of uncertainty are typically distinguished. *Aleatory* uncertainty, also referred to as inherent variability, arises from natural, irreducible variation in a physical quantity – for example, specimen-to-specimen variability in material properties or manufacturing tolerances – and cannot be reduced by acquiring additional

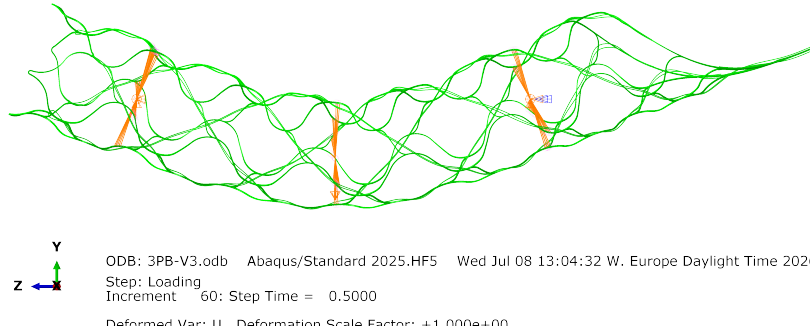


Figure 3.7: Simulation setup for the three-point bending test with distributed couplings and boundary conditions of model version 1.

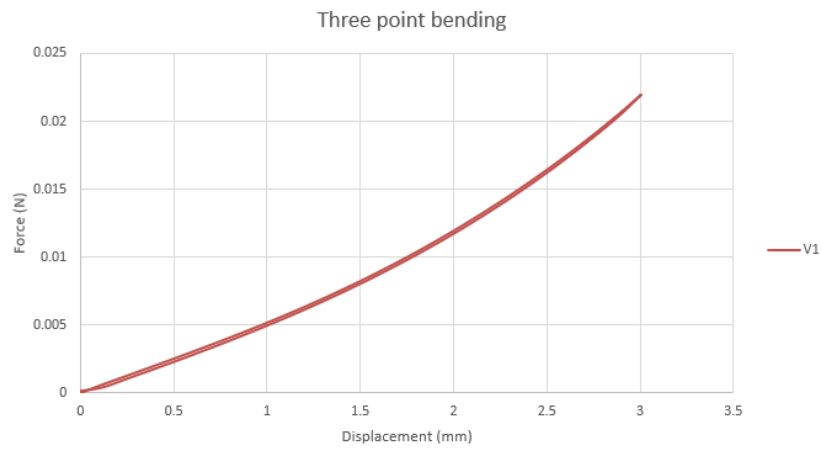


Figure 3.8: Simulated force-displacement response for the three-point bending test, showing the reaction force at the central reference point as a function of applied downward displacement of model version 1.

information. *Epistemic* uncertainty, on the other hand, results from a lack of complete knowledge, such as limited characterisation data or simplifying modelling assumptions, and can in principle be reduced through additional measurements or refined models.

Several approaches exist to propagate input uncertainty through a computational model to the output quantities of interest. Sampling-based methods, such as Monte Carlo or Latin Hypercube sampling, propagate the full input distributions through repeated model evaluations to build an output distribution, but require a large number of simulations and are therefore time consuming. Sensitivity-based methods instead rely on the local sensitivity of the output to each input parameter, evaluated around a baseline configuration, to approximate the resulting output uncertainty. Given the number of input parameters considered and the computation time of a single finite element simulation, a sensitivity-based, first-order uncertainty propagation approach was adopted in this work, combining the one-at-a-time sensitivity analysis described in Section 3.4 with a first-order propagation of the individual input uncertainties, as detailed in that section.

For each model input, an associated uncertainty was established, expressed as a range of variation around its baseline (nominal) value. Depending on the parameter, this range was derived from a comparison across multiple independent sources reporting the same material property, from microscopy measurements, or, in the absence of any measured or reported reference, from an assumed range based on engineering judgement. The following subsections describe how the uncertainty was established for each category of input; the resulting baseline values, ranges, and standard deviations are summarised in Table 3.1.

Nitinol material parameters

The baseline parameters for the Nitinol superelastic material model were obtained from a study in which the model was calibrated to match the radial support force of the specific stent considered in this work (Trevo XP ProVue 6x25), measured experimentally using a crimping/radial force test rig. As this calibration is a deterministic fitting procedure, no associated uncertainty is reported for the resulting parameter values. In the absence of a reported uncertainty, the variability associated with each Nitinol parameter was instead estimated from the spread across multiple independently reported parameter sets for Nitinol stent alloys: generic literature values [Finotello et al. \(2017\)](#), an equivalent calibration performed for a different commercial stent (Solitaire FR) [Wu et al. \(2025\)](#), and three additional independent literature sources (dataset 4RealSim). For each parameter, the applied range of variation was taken as the minimum-to-maximum interval spanned by these independent estimates, with the calibrated baseline value falling within this range, and was conservatively treated as epistemic with an assumed uniform distribution. The full set of values reported across all sources for each Nitinol parameter is provided in Appendix 7.4.

For parameters not explicitly reported in the Trevo-specific calibration (compressive transformation stress, stress–temperature slopes), the generic literature value was assumed as baseline. It should further be noted that calibration of superelastic material parameters to a single radial force curve is subject to a degree of equifinality, whereby different parameter combinations can reproduce a similar global force response; the inter-source spread used here may therefore partly reflect this non-uniqueness rather than physical material variability alone.

Platinum-tungsten wire material parameters

The exact tungsten content of the platinum-tungsten wire used in the device modelled in this work was not specified in the available source information. A baseline composition of Pt92/W8 was therefore adopted, as this is the most commonly reported platinum-tungsten composition for wire used in medical devices [Chen and Lee \(2022\)](#), and the associated baseline elastic properties were taken from a manufacturer datasheet for this composition (California Fine Wire, Alloy 436, [MatWeb, LLC](#)). As this datasheet does not report a measurement uncertainty, the variability of each property was estimated from the spread across two additional independent sources reporting nominally the same Pt92/W8 composition, explicitly intended for medical device or intravascular applications: a manufacturer datasheet (Goodfellow, [Goodfellow \(2004\)](#)) and reference wire properties reported in a patent describing intravascular devices. The reported Young’s modulus shows considerable spread across sources (138–230 GPa), attributed to the strong dependence of the elastic response of fine-drawn precious-metal wire on the degree of cold work and annealing state, which is not always consistently reported alongside the corresponding modulus value.

It should also be noted that this range reflects variability across sources reporting the same nominal Pt92/W8 composition, and does not account for the possibility that the true tungsten content of the wire in the modelled device differs from 8 wt%. Since increasing tungsten content in platinum–tungsten alloys is known to substantially increase stiffness [USP \(2022\)](#), an unverified composition represents an additional, unquantified source of epistemic uncertainty beyond the applied range reported here.

Contact friction coefficients

For the friction coefficients, no experimental characterisation or directly applicable literature values were available for the specific contact pairs considered in the model. Four contact pairs were considered. For the stent-to-plate and wire-to-plate contacts, a baseline friction coefficient of $\mu = 0.1$ was assumed, and the sensitivity of the model output was assessed at $\mu = 0.05, 0.2, 0.4, 0.8$. For the wire-to-wire and wire-to-stent contacts, a baseline value of $\mu = 0$ (frictionless) was assumed, and the sensitivity was assessed at $\mu = 0.05, 0.1, 0.2, 0.4, 0.8$. All baseline values were based on engineering judgement, and the tested values were chosen to bound the physically plausible range for these contact types, from near-frictionless to dry, unlubricated metal-on-metal contact ($\mu = 0.8$, [RoyMech](#)).

For these friction coefficients, no basis was available to assign a credible probability distribution to the true (unknown) value within the tested range. Rather than computing a corresponding standard deviation for use in the first-order uncertainty propagation, the friction coefficients were therefore treated purely as a sensitivity study: the tested range illustrates the maximum plausible influence of an unknown friction coefficient on the model output, without contributing a quantified term to the propagated output uncertainty σ_k^2 in Section 3.4. This is noted as a limitation of the present uncertainty quantification: because no distributional assumption could be justified for these parameters, their contribution to the total predicted output uncertainty is justified since Section 3.4 shows their influence on the output to be negligible.

Test temperature

The Nitinol material model additionally requires a reference (manufacturing/transformation) temperature, fixed at 37 °C; this value was not varied in the present analysis, as it represents a fixed material model parameter rather than an experimentally variable condition, and is therefore not included in the uncertainty quantification. The temperature that was included as an uncertain input is the predefined field temperature applied to the model, representing the ambient laboratory temperature at which the physical test was performed, $T = 20.5$ °C. A range of $\pm 5\%$ around this value was assumed, based on the precision of the laboratory temperature measurement.

Geometric parameters

For the geometric parameters, microscopy measurements were performed. The strut width was measured from a top-down view, for which the edge is directly and unambiguously visible; nonetheless, because the strut cross-sections are not perfectly rectangular, identifying the precise start and end of the edge involved a degree of subjective interpretation, which – combined with the potential use error and the small scale of the acquired images – was judged to introduce a non-negligible uncertainty. A range of $\pm 20\%$ around the measured value was therefore assumed.

The strut height was also measured, but with a substantially larger assumed uncertainty ($\pm 40\%$) than the strut width. This is because an unobstructed, perpendicular view onto the strut side wall – required for an accurate height measurement – was difficult to achieve without sectioning the sample; the height was therefore estimated from an oblique viewing angle, introducing a perspective foreshortening error in addition to the edge-identification uncertainty already affecting the width measurement.

For the wire radius, a smaller range of $\pm 5\%$ was assumed. Unlike the strut cross-sections, the wire has a circular cross-section, for which the outer edge forms an unambiguous geometric boundary in the microscopy images; the associated measurement uncertainty was therefore judged to be substantially smaller than for the strut width and height, and closer to the intrinsic resolution limit of the microscope. All geometric uncertainties were treated as epistemic, with an assumed uniform distribution.

3.4 Sensitivity Analysis

An important part of the model validation process is to assess the influence of uncertainty in the model inputs on the relevant model outputs. Since every input to a finite element model is associated with some degree of uncertainty – whether from measurement limitations, material characterisation, or assumptions made during model development – it is necessary to quantify how strongly each input affects the predicted response.

For both the flat-plate compression and three-point bending test cases, the output of interest was defined, consistent with the definitions used throughout this work, as the stiffness

$$k = \frac{\Delta F}{\Delta U} \quad (3.1)$$

where ΔF is the change in reaction force over the full displacement and ΔU the corresponding

Table 3.1: Overview of all model input uncertainties considered in this work: baseline (nominal) value, applied minimum–maximum range, resulting standard deviation assuming a uniform distribution ($\sigma_{x_i} = (x_{max} - x_{min})/\sqrt{12}$), type of uncertainty, and basis for the estimate.

Category	Parameter	Baseline	Min	Max	σ_{x_i}	Type	Basis
Nitinol	Austenite E [MPa]	56,000	51,700	68,212	4,767	Epistemic	Multi-source comparison (App. 7.3)
	Austenite ν [-]	0.30	0.30	0.33	0.0087	Epistemic	Multi-source comparison (App. 7.3)
	Martensite E [MPa]	23,700	23,700	47,800	6,958	Epistemic	Multi-source comparison (App. 7.3)
	Martensite ν [-]	0.30	0.30	0.33	0.0087	Epistemic	Multi-source comparison (App. 7.3)
	Transformation strain [-]	0.063	0.0421	0.063	0.0060	Epistemic ^a	Multi-source comparison (App. 7.3)
	Loading start stress [MPa]	635	463.04	635	49.64	Epistemic	Multi-source comparison (App. 7.3)
	Loading end stress [MPa]	677	498.54	677	51.52	Epistemic	Multi-source comparison (App. 7.3)
	Unloading start stress [MPa]	288	270	380	31.75	Epistemic	Multi-source comparison (App. 7.3)
	Unloading end stress [MPa]	254	221.96	343	34.94	Epistemic	Multi-source comparison (App. 7.3)
	Compressive stress (start) [MPa]	952.5	590	952.5	104.63	Epistemic	Multi-source comparison (App. 7.3)
	Stress/temp slope, loading [MPa/°C]	6.5	6.0	6.5	0.144	Epistemic	Multi-source comparison (App. 7.3)
	Stress/temp slope, unloading [MPa/°C]	6.5	6.0	6.5	0.144	Epistemic	Multi-source comparison (App. 7.3)
Pt92/W8 wire	Density [g/cm ³]	21.2	21.2	21.3	0.0289	Epistemic	Multi-source comparison
	Young's modulus [GPa]	138	138	230	26.56	Epistemic	Multi-source comparison
	Poisson's ratio [-]	0.30	0.30	0.40	0.0289	Epistemic	Literature Goodfellow (2004)
Contact friction	Stent–plate	0.1	0.05	0.8	n/a ^c	Epistemic	SA only, no distributional basis
	Wire–plate	0.1	0.05	0.8	n/a ^c	Epistemic	SA only, no distributional basis
	Wire–wire	0.0	0.0	0.8	n/a ^c	Epistemic	SA only, no distributional basis
	Wire–stent	0.0	0.0	0.8	n/a ^c	Epistemic	SA only, no distributional basis
Test conditions	Test temperature [°C]	20.5	19.475	21.525	0.592	Aleatory	Lab measurement, $\pm 5\%$
Geometry	Strut width [mm]	0.05	−20%	+20%	0.00575	Epistemic	Single measurement, edge ambiguity
	Strut height [mm]	0.05	−40%	+40%	0.01155	Epistemic	Single measurement, oblique view
	Wire radius [mm]	0.02	−5%	+5%	0.00058	Epistemic	unambiguous circular edge

change in displacement. For the flat-plate compression test, this corresponds to the reaction force on the moving plate over its displacement; for the three-point bending test, this corresponds to the reaction force on the central loading point over its downward displacement.

To perform the sensitivity analysis, a baseline model was defined for each test case, with each input parameter set to its nominal (best-estimate) value. Subsequently, a large number of simulations were performed in which each input parameter was varied individually – via direct modification of the corresponding value in the Abaqus input file – while keeping all other parameters fixed at their baseline value. The resulting change in this defined stiffness, relative to the baseline model, was used to quantify the sensitivity of the model output to that specific input. Based on the relative magnitude of this change, each input was classified into one of three qualitative levels of model influence: *Low*, *Medium*, or *High*. This resulted in only strut width, strut height, wire radius and Austenite Young's modulus as High (more than 2.5 percent) and Friction between stent-plate and wire-plate as medium (between 1 and 2.5 percent).

For each input, the representative range of variation defined in Section 3.3 was applied. Table 3.2 and the corresponding table in the appendix summarise the model inputs considered for the flat-plate compression and three-point bending sensitivity analyses, respectively, together with their baseline values, applied range of variation, and the source used to determine this range. The full sensitivity analysis, including the resulting stiffness values obtained for each individual input variation, is presented in Appendix 7.4.

First-order uncertainty propagation

To translate the qualitative sensitivity classification into a quantitative estimate of the resulting uncertainty on the model output, a first-order (Taylor-series based) uncertainty propagation was performed. For each input (x), the sensitivity coefficient S_i from equation 3.2 was determined from simulations in which the parameter was perturbed by $\pm 5\%$ (or $\pm 10\%/\pm 20\%$ for a small

number of parameters) around its baseline value, sufficient to estimate the local slope of the model response while remaining within the approximately linear regime around the baseline. This sensitivity coefficient was subsequently combined with the uncertainty range established for that parameter in Section 3.3 via the first-order propagation described in equation 3.3

$$S_i = \left. \frac{\partial k}{\partial x_i} \right|_{x_0} \approx \frac{k(x_i) - k_0}{x_i - x_{i,0}} \quad (3.2)$$

Assuming the input parameters are mutually independent and that the model response varies approximately linearly over the considered range of variation, the variance of the output (σ_k) can be approximated, following a first-order Taylor expansion of $k(x_1, x_2, \dots, x_n)$ about the baseline, as

$$\sigma_k^2 \approx \sum_{i=1}^n S_i^2 \sigma_{x_i}^2 \quad (3.3)$$

where σ_{x_i} denotes the uncertainty of input parameter x_i , as reported in Table 3.1. This root-sum-square combination is a standard sensitivity-based, first-order propagation approach and is appropriate here given the moderate number of inputs and the one-at-a-time design of the sensitivity analysis. Note that the friction coefficients (Section 3.3) are excluded from the calculation in Eq. (3.3), as no σ_{x_i} could be justified for these parameters; their influence is reported separately as a qualitative sensitivity result only.

The relative contribution of each input parameter to the total (quantified) output variance was subsequently computed as

$$C_i = \frac{S_i^2 \sigma_{x_i}^2}{\sum_{j=1}^n S_j^2 \sigma_{x_j}^2} \times 100\% \quad (3.4)$$

providing a quantitative counterpart to the qualitative Low/Medium/High classification, and allowing the dominant sources of uncertainty in the predicted stiffness k to be identified for both test cases.

Table 3.2: Sensitivity analysis and first-order uncertainty propagation for the flat-plate compression test case. Baseline stiffness $k_0 = 0.0398$. S_i computed via Eq. (3.2), σ_{x_i} from Table 3.1, contribution $S_i^2 \sigma_{x_i}^2$ and C_i via Eq. (3.4). Friction coefficients are excluded from the propagation (marked n/a) per Section 3.3.

Category	Parameter	Baseline	Tested values	Resulting k	S_i	σ_{x_i}	$S_i^2 \sigma_{x_i}^2$	C_i (%)
Geometry	Strut width	0.05 mm	0.0525	0.0441	1.720	0.00575	9.783E-05	37.68
	Strut height	0.05 mm	0.0525	0.0424	1.040	0.01155	1.443E-04	55.57
	Wire radius	0.02 mm	0.021	0.0409	1.100	0.00058	4.070E-07	0.157
Contact / friction	Friction stent-plate	0.1	0.05, 0.2, 0.4, 0.8	0.0395;0.0404;0.0406;0.0411	n/a	n/a	n/a	n/a (SA only)
	Friction wire-plate	0.1	0.05, 0.2, 0.4, 0.8	0.0393;0.0401;0.0407;0.0412	n/a	n/a	n/a	n/a (SA only)
	Friction wire-wire	0.0	0.05, 0.1, 0.2, 0.4, 0.8	0.0397;0.0398;0.04;0.0401;0.0401	n/a	n/a	n/a	n/a (SA only)
	Friction wire-stent	0.0	0.05, 0.1, 0.2, 0.4, 0.8	0.0401;0.0400;0.0402;0.0404;0.0409	n/a	n/a	n/a	n/a (SA only)
	Test temperature	20.5	21.525	0.0400	1.951E-04	0.592	1.334E-08	0.0051
Nitinol material model	Austenite E	56,000	58,800	0.0419	7.500E-07	4.767	1.278E-05	4.923
	Austenite ν	0.33	0.3465	0.0397	-6.061E-03	0.0087	2.780E-09	0.0011
	Martensite E	23,700	24,885	0.0399	8.439E-08	6.958	3.448E-07	0.133
	Martensite ν	0.30	0.315	0.0399	6.667E-03	0.0087	3.364E-09	0.0013
	Transformation strain	0.063	0.0662	0.0401	9.375E-02	0.0060	3.164E-07	0.122
	σ_{LS}	635	667	0.0403	1.563E-05	49.64	6.020E-07	0.232
	σ_{LE}	677	711	0.0403	1.471E-05	51.52	5.745E-07	0.221
	σ_{US}	288	302	0.0401	2.143E-05	31.75	4.629E-07	0.178
	σ_{UE}	254	267	0.0401	2.308E-05	34.94	6.503E-07	0.251
Pt-W wire	Young's modulus	138,000	144,900	0.0401	4.348E-08	26,560	1.333E-06	0.513
	Poisson's ratio	0.30	0.315	0.0399	6.667E-03	0.0289	3.712E-08	0.014

The total propagated uncertainty on the predicted stiffness follows from Eq. (3.3) as

$$\sigma_k = \sqrt{\sum_i S_i^2 \sigma_{x_i}^2} = 0.01611 \quad (\text{flat-plate compression}) \quad (3.5)$$

$$\sigma_k = \sqrt{\sum_i S_i^2 \sigma_{x_i}^2} = 0.004599 \quad (\text{three-point bending}) \quad (3.6)$$

3.5 Simulation Results vs Vitro-tests - First Validation

The simulation results obtained in Section 3.2 were compared against the corresponding in-vitro test data described in Sections 3.1 (flat-plate compression and three-point bending). For the flat-plate compression comparison, Test 3 was selected as the reference in-vitro dataset, since this test was performed after conditioning the stent in 37 °C water, allowing it to return as closely as possible to its stress-free, as-manufactured configuration. This is more consistent with the nominal diameter of 6 mm used as the initial (undeformed) geometry in the simulation, making Test 3 the most representative comparator. For the three-point bending comparison, Test 1 was selected, since in this test the stent remained in a stable position between the two supporting cylinders throughout loading, without the rotation and associated force discontinuity observed in Test 2 (discussed in Section 3.1).

The simulated and experimental force-displacement curves for both test cases are shown together in Figure 3.9 (flat-plate compression) and Figure 3.10 (three-point bending).

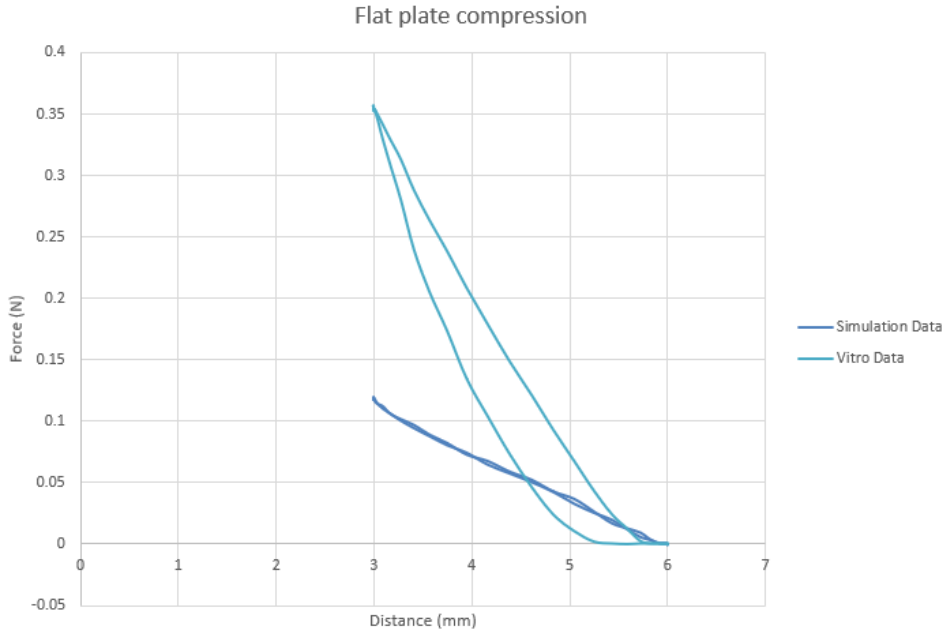


Figure 3.9: Comparison between the simulated (Model Version 1) and experimental (Test 3) force-displacement response for the flat-plate compression test.

3.5.1 Comparison Metrics

To quantitatively assess the agreement between simulation and experiment, two complementary metrics were used: the normalised root-mean-square error (NRMSE) of the force response, and

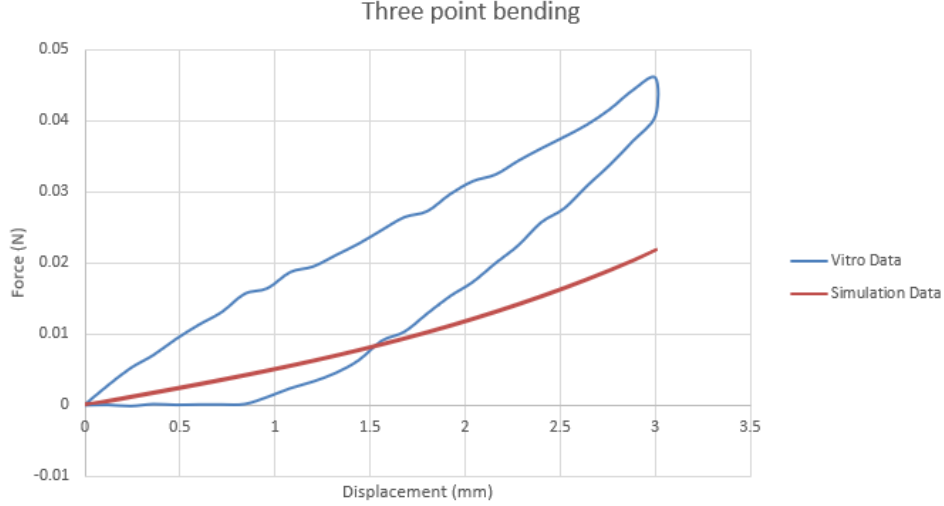


Figure 3.10: Comparison between the simulated (Model Version 1) and experimental (Test 1) force-displacement response for the three-point bending test.

the relative error in the local slope (stiffness) of the loading and unloading curves.

The root-mean-square error (RMSE) between the simulated and experimental force values is defined as

$$\text{RMSE} = \sqrt{\frac{1}{n} \sum_{i=1}^n (F_{\text{sim},i} - F_{\text{exp},i})^2} \quad (3.7)$$

where $F_{\text{sim},i}$ and $F_{\text{exp},i}$ are the simulated and experimental force values at displacement point i , and n is the number of compared data points. The RMSE was normalised by the range of the experimental force data to obtain the NRMSE:

$$\text{NRMSE} = \frac{\text{RMSE}}{F_{\text{exp,max}} - F_{\text{exp,min}}} \quad (3.8)$$

Normalising in this way allows the error to be expressed as a percentage of the total experimental force range, making it possible to compare the magnitude of the error across test cases with different force scales. The NRMSE was calculated in three ways: over the full loading-unloading cycle (*Overall*), over the loading part of the cycle only, and over the unloading part of the cycle only. Separating loading and unloading allows any discrepancy in hysteretic behaviour between simulation and experiment – i.e. a difference in how well the model captures the unloading response relative to the loading response – to be identified, rather than being averaged out over the full cycle.

In addition to the NRMSE, the local slope of the force-displacement curve was compared between simulation and experiment. The slope was calculated using linear regression (equivalent to the `SLOPE` function in Excel) over a selected displacement range for each test case: between 5.5 mm and 3 mm plate distance for the flat-plate compression test, and between 0 mm and 3 mm punch displacement for the three-point bending test. This slope corresponds to the local stiffness of the response and was calculated separately for the loading and unloading segments, for both the simulated and experimental curves:

$$\text{error}_{\text{slope}} = \frac{k_{\text{sim}} - k_{\text{exp}}}{k_{\text{exp}}} \times 100\% \quad (3.9)$$

where k_{sim} and k_{exp} are the local slopes (stiffnesses) obtained from linear regression of the simulated and experimental curves, respectively, over the specified displacement range. While the NRMSE provides an overall measure of agreement across the full curve, the local slope comparison isolates whether the model correctly captures the characteristic stiffness of the response over a specific, well-defined displacement range, independent of any offset or overall curve-shape mismatch.

3.5.2 Results

The resulting comparison metrics for Model Version 1 against the in-vitro data are summarised in Table 3.3 for the flat-plate compression test case, and Table 3.4 for the three-point bending test case. Based on these criteria, insufficient agreement was found between the simulation and the in-vitro data for both test cases. For flat-plate compression as well as three-point bending, the overall NRMSE and the loading and unloading segments all showing a NRMSE of far above 10%, while the local slope comparison showed even bigger deviations for the loading and unloading segments. In both test cases, the model consistently underestimates the stiffness of the stent relative to the experimental data, indicating that Model Version 1 does not provide an adequate representation of the in-vitro mechanical response.

As established in Section 2.2.1, the model was classified as Risk Level 5 under the ASME V&V-40 framework, requiring relative differences between simulation and experimental results to remain below 10% in order to achieve adequate validation. The errors obtained for Model Version 1 – with NRMSE and local slope deviations ranging from approximately 19% to 75% across both test cases – substantially exceed this acceptance criterion. Consequently, Model Version 1 is considered **not validated** for its intended context of use, and further refinement of the model is required before it can be considered credible for the intended application.

Table 3.3: Comparison metrics (RMSE, NRMSE, and local slope error) between Model Version 1 and the in-vitro flat-plate compression data (Test 3).

Model Version 1		
RMSE		0.128839
Force	Overall NRMSE	36.0%
	Loading NRMSE	39.2%
	Unloading NRMSE	34.4%
Stiffness	Loading error	−71.4%
	Unloading error	−74.9%

3.6 Root Cause Analysis

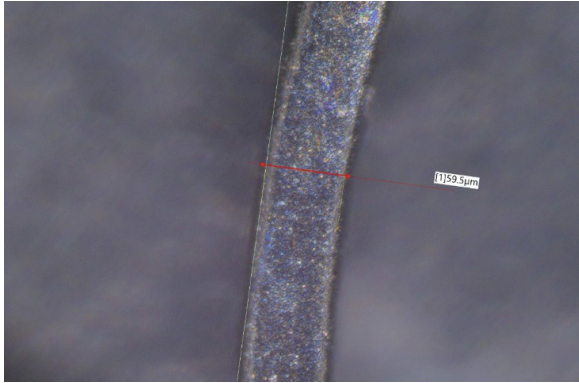
Following the failed validation of Model Version 1, the underlying cause of the observed discrepancy was investigated. Given the magnitude of the error, it was considered likely that one or more model inputs with a substantial influence on the output were incorrectly characterised.

Table 3.4: Comparison metrics (RMSE, NRMSE, and local slope error) between Model Version 1 and the in-vitro three-point bending data (Test 1).

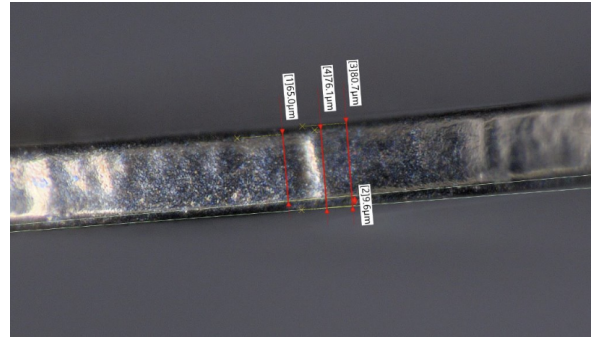
Model Version 1		
RMSE		0.012468
Force	Overall NRMSE	27.0%
	Loading NRMSE	34.5%
	Unloading NRMSE	18.8%
Slope	Loading error	-51.0%
	Unloading error	-48.5%

The sensitivity analysis results presented in Section 3.4 were therefore used to guide this investigation, focusing specifically on the inputs classified with the largest model influence. Both for the flat-plate compression and three-point bending test cases, strut width and strut height consistently emerged as the two dominant contributing parameters.

These two dimensions had originally been measured using microscopy. Since this measurement was performed by someone with limited prior experience in the use of the microscope, a second, independent measurement was performed by a more experienced individual, in order to verify the accuracy of the original values. The resulting measurements, shown in Figures 3.11a and 3.11b, differed noticeably from the values originally used in Model Version 1. Based on this second measurement, updated values of $60\text{ }\mu\text{m}$ for the strut width (SW) and $80\text{ }\mu\text{m}$ for the strut height (SH) were obtained.



(a) Remeasured strut width (SW).



(b) Remeasured strut height (SH)

3.7 Model Update: Model Version 2

Based on the updated strut dimensions obtained from the remeasurement, a new model was constructed using the revised strut width ($60\text{ }\mu\text{m}$) and strut height ($80\text{ }\mu\text{m}$), while keeping all other model inputs unchanged from Model Version 1. This updated model is referred to as Model Version 2. The construction, simulation results, and validation of this new model are discussed in the following chapter.

Chapter 4

Model Revalidation

4.1 Repeated Comparators: Simulation Results with Tests

Model Version 2, as described in Section 3.7, was used to repeat the comparator simulations for both the flat-plate compression and three-point bending test cases. Aside from the updated strut width and strut height values, no other boundary conditions or model inputs were changed relative to Model Version 1, ensuring that any improvement in agreement with the in-vitro data can be attributed specifically to the corrected strut dimensions.

The resulting force-displacement curves for the flat-plate compression and three-point bending simulation results plotted together with the corresponding in-vitro test data (Test 3 for flat-plate compression, Test 1 for three-point bending, as used previously in Section 3.5) are shown in Figures 4.1 and 4.2. As shown in these figures, the agreement between the simulated and experimental responses is considerably improved compared to Model Version 1.

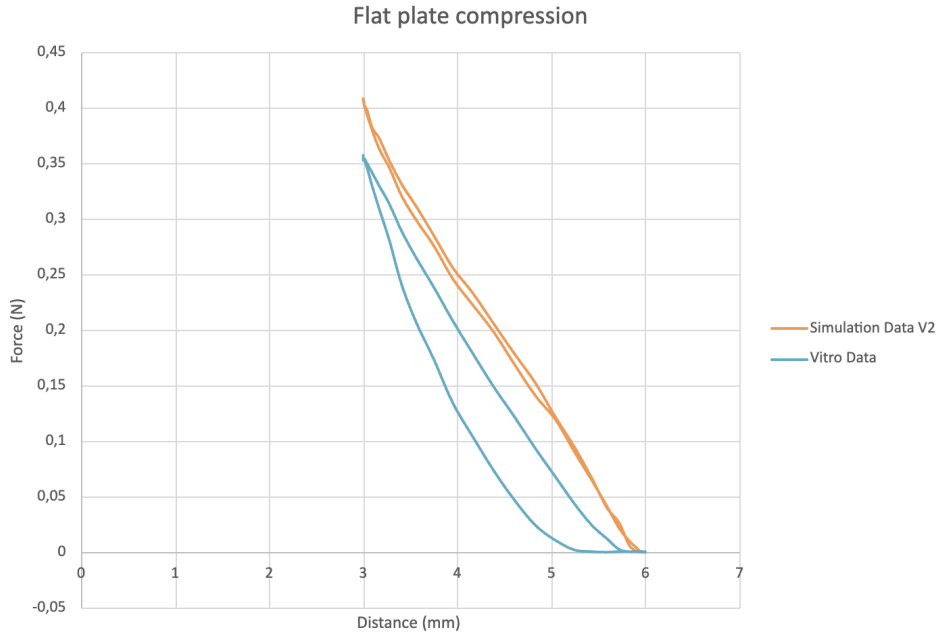


Figure 4.1: Comparison between the simulated (Model Version 2) and experimental (Test 3) force-displacement response for the flat-plate compression test.

The corresponding comparison metrics (RMSE, NRMSE, and local slope error), calculated

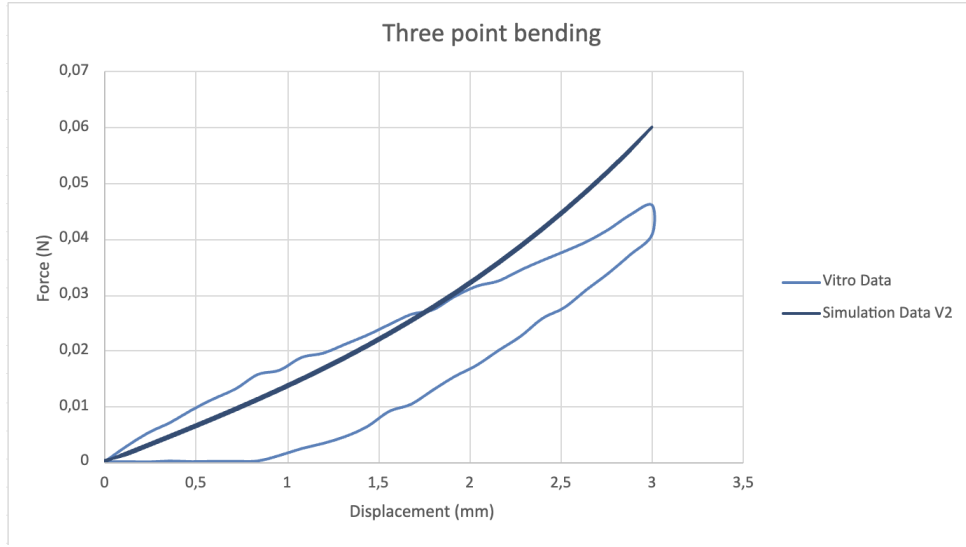


Figure 4.2: Comparison between the simulated (Model Version 2) and experimental (Test 1) force-displacement response for the three-point bending test.

Table 4.1: Comparison metrics (RMSE, NRMSE, and local slope error) between Model Version 2 and the in-vitro flat-plate compression data (Test 3).

Model Version 2		
RMSE		0.060164
Force	Overall NRMSE	16.8%
	Loading NRMSE	11.6%
	Unloading NRMSE	20.7%
Slope	Loading error	−0.30%
	Unloading error	−14%

Table 4.2: Comparison metrics (RMSE, NRMSE, and local slope error) between Model Version 2 and the in-vitro three-point bending data (Test 1).

Model Version 2		
RMSE		0.010195
Force	Overall NRMSE	22.1%
	Loading NRMSE	11.8%
	Unloading NRMSE	32.9%
Slope	Loading error	34.2%
	Unloading error	39.5%

using the same methodology described in Section 3.5, are summarised in Table 4.1 for flat-plate compression and Table 4.2 for three-point bending. For flat-plate compression, the overall NRMSE improved to 16.8%, with the local slope error reduced to -0.3% for loading and -14% for unloading. For three-point bending, the overall NRMSE improved to 22.1%, although the local slope errors remained relatively large, at 34.2% for loading and 39.5% for unloading. Notably, the sign of the slope error has reversed between the two model versions, indicating that the model has moved from underestimating to overestimating the local stiffness in this displacement range.

While these results represent a substantial improvement compared to Model Version 1, the errors – particularly the local slope errors for three-point bending and the unloading NRMSE for both test cases – still exceed the 10% acceptance criterion required for adequate model validation (see Section 2.2.1). This indicates that, although the updated strut dimensions substantially improved the model’s predictive accuracy, further refinement is still required before the model can be considered validated for its intended context of use.

4.1.1 Remaining Discrepancies

Despite the substantial improvement in the overall NRMSE and local slope errors between Model Version 2 and the in-vitro data, a clear and consistent discrepancy remains in the shape of the loading and unloading curves. In the in-vitro data, a pronounced hysteresis loop is visible, with the unloading path following a noticeably different route back than the loading path, at the same displacement. In the simulation results, this hysteresis effect is either absent or considerably smaller: while the loading and unloading paths in the simulation do not overlap perfectly, the resulting loop is far narrower than the hysteresis loop observed experimentally.

Several factors may contribute to this discrepancy, and further investigation is required to determine their relative importance. One possible explanation is that the braided platinum-tungsten wire, which is wound around the nitinol stent structure, may be wrapped more tightly in the physical device than represented in the simulation, introducing additional frictional interaction and energy dissipation not fully captured by the model.

In addition to this hysteresis discrepancy, a further limitation specific to the three-point bending comparison was identified. As discussed in Section 3.1, the tested stent was no longer perfectly straight, but exhibited a slight residual bow due to prior use in a thrombectomy procedure. As a result, the downward-moving punch made contact with the stent earlier than it would have for a perfectly straight stent, as represented in the simulation. Since the punch was displaced until the distance between the top of the supporting cylinders and the bottom of the punch reached 3 mm – rather than until a fixed 3 mm of stent deflection was achieved – the in-vitro test effectively applied a larger total displacement to the stent than the nominal 3 mm applied in the simulation. This geometric mismatch between the simulated and tested configurations makes a perfectly one-to-one comparison between the two datasets inherently difficult, and should be taken into account when interpreting the remaining discrepancies in the three-point bending results.

This remaining discrepancy is partly attributable to the fact that the tested stent did not have an exact diameter of 6 mm, and to the residual bow present in the stent due to prior use in a procedure, as discussed in the previous section.

4.1.2 Acceptability

As stated previously, the acceptance criterion for model validation requires the comparison between simulation and in-vitro data to remain below 10% (see Section 2.2.1). Based on the NRMSE comparison, this criterion was not met for either test case, whether considered overall, or separately for the loading and unloading segments. Although the loading NRMSE values for both test cases came close to this threshold (11.6% and 11.8%), they still exceed the required 10%. Despite this, the local slope of the flat-plate compression response, representing the stiffness of the stent under radial compression, was estimated very accurately by the model. Overall, Model Version 2 does not yet meet the acceptance criterion for the high level risk we acquired and is therefore considered not validated, although the results represent a substantial improvement over Model Version 1 and indicate that the model is approaching an acceptable level of agreement, the testing setup and model still needs to be improved.

4.2 Context of Use Simulations

Following model validation, the ultimate goal of this work, as outlined in the Introduction, is to perform simulations representative of the full context of use of the device. In the existing literature and regulatory documentation on this stent, the braided platinum-tungsten wire is generally neglected from a mechanical perspective, since the FDA documentation indicates that its primary purpose is to enhance radiopacity under fluoroscopic imaging. However, since the wire is wound helically around the nitinol stent structure along its entire length, it was investigated whether this component nonetheless has a non-negligible effect on the mechanical behaviour of the stent during use. To this end, four simulations representative of the clinical procedure were performed, each once with and once without the braided wire included in the model, allowing the mechanical contribution of the wire to be isolated.

4.2.1 Procedure

The complete procedure of the context of use is as follows. First, the stent is crimped by the catheter, whereby the catheter surface decreases in the radial direction from 6.4 mm to 1.4 mm, causing the stent to shrink radially from 6 mm to 1.4 mm (Figure 4.3). This step takes place between 0 and 0.1 s of the simulation step. Subsequently, the catheter is withdrawn by -55 mm in the z -direction between 0.1 and 0.3 s of the step, while the stent is held in place in the z -direction at its distal end by means of a reference point. In this way, the stent gradually expands into a vessel with a diameter of 5 mm (Figure 4.4c). Finally, between 0.3 and 0.5 s of the step, the catheter is fixed in the axial direction, and the stent is retracted back into the catheter by displacing the stent itself by -55 mm in the z -direction (Figure 4.4d, 4.4e). The different phases of the simulation are shown in Figure 4.4, in these figures part of the elements around the middle of the vessel have been removed (only in display) to have a better overview of the simulation procedure.

All steps of the procedure are simulated using a dynamic explicit step in Abaqus. Contact is defined between all relevant components of the model, namely stent–wires, wires–wires, catheter–stent, catheter–wires, vessel–wires, and vessel–stent. For all these interactions, tangential behavior is modeled using a penalty friction formulation with a friction coefficient of 0.05. The simulations are performed at a temperature of 37°C, corresponding to physiological body

temperature. Furthermore, alpha and beta damping coefficients of $\alpha = 1$ and $\beta = 1 \times 10^{-9}$ are applied to both the nitinol and the tungsten-platinum material, in order to ensure a numerically stable and smooth simulation.

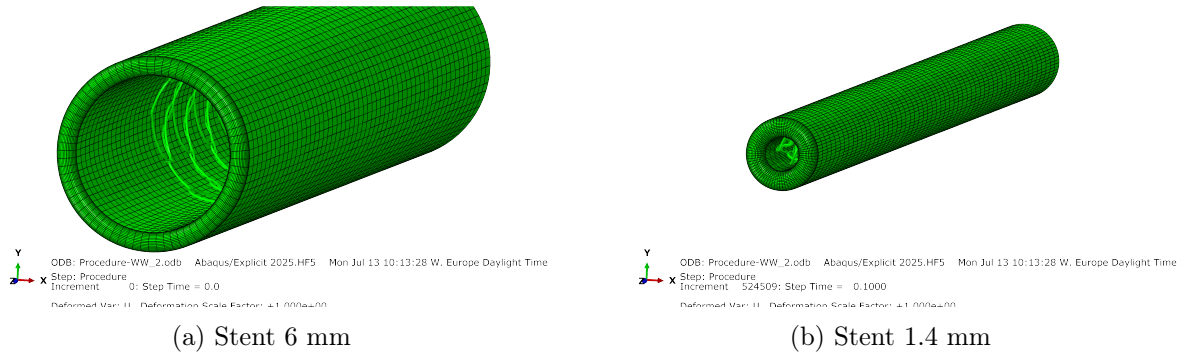


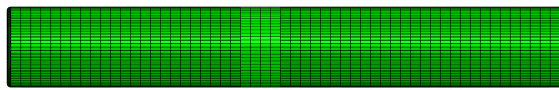
Figure 4.3: Crimping of the stent by the catheter, radial reduction from 6 mm to 1.4 mm.

4.2.2 Simulations With/Without Wires

Radial force during catheter crimping. The first simulation considers the radial force exerted on the delivery catheter as the stent is crimped from its nominal diameter of 6 mm down to 1.4 mm. The total reaction force exerted by the stent on the catheter surface was summed over the full surface and plotted as a function stent diameter, as shown in Figure 4.5. Down to approximately 4 mm diameter, the force response with and without wires is comparable; below this diameter, the two curves begin to diverge, with the radial force of the stent without wires becoming noticeably higher at the smallest diameter (1.4 mm). Some irregular behaviour is visible in the wireless configuration at this stage of crimping. Since this simulation was performed in Abaqus/Explicit using a dynamic step, with mass scaling and alpha/beta damping applied to ensure a stable and efficient simulation, this irregular behaviour is most likely attributable to the numerical damping applied to stabilise the model, rather than representing genuine physical behaviour.

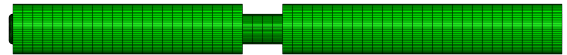
Axial force during retraction. The second simulation considers the axial force exerted by the stent on the catheter during retraction. As shown in Figure 4.6, this response shows considerable fluctuation, caused by individual struts and wire segments repeatedly making and losing contact with the edge of the catheter as the stent is retracted. Despite this fluctuating behavior, the average trend between 10 mm and 50 mm of the force curve appears to be lower for the wire-free configuration than for the stent with braided wire configuration, suggesting that the presence of the wire increases the effective axial stiffness of the stent during this stage of the procedure, the average force for both with and without braided wires was therefore calculated. The average force of the stent with wires was 0.279 N (0.048 STD) and 0.247 N (0.063 STD) for the stent without wires being an decrease of 11.5 % removing the wires.

Force on the vessel wall during deployment. The third simulation considers the radial force exerted by the stent on the vessel wall during deployment. In this procedural simulation, the catheter is retracted starting at $t = 0.1$ s, allowing the stent to expand into a 5 mm diameter vessel; the stent is subsequently retracted back into the catheter starting at $t = 0.3$ s. As shown in



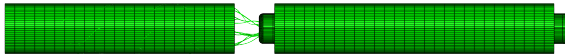
ODB: Procedure-WW_2.odb Abaqus/Explicit 2025.HF5 Mon Jul 13 10:13:28 W. Europe Daylight Time
 Step: Procedure
 Increment: 0; Step Time = 0.0
 Deformed Var: U Deformation Scale Factor: 1.000e+00

(a) Time: 0 s



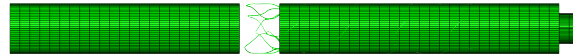
ODB: Procedure-WW_2.odb Abaqus/Explicit 2025.HF5 Mon Jul 13 10:13:28 W. Europe Daylight Time
 Step: Procedure
 Increment: 524509; Step Time = 0.1000
 Deformed Var: U Deformation Scale Factor: 1.000e+00

(b) Time: 0.1 s



ODB: Procedure-WW_2.odb Abaqus/Explicit 2025.HF5 Mon Jul 13 10:13:28 W. Europe Daylight Time
 Step: Procedure
 Increment: 1017747; Step Time = 0.1940
 Deformed Var: U Deformation Scale Factor: 1.000e+00

(c) Time: 0.15 s



ODB: Procedure-WW_2.odb Abaqus/Explicit 2025.HF5 Mon Jul 13 10:13:28 W. Europe Daylight Time
 Step: Procedure
 Increment: 1983013; Step Time = 0.3780
 Deformed Var: U Deformation Scale Factor: 1.000e+00

(d) Time: 0.35 s



ODB: Procedure-WW_2.odb Abaqus/Explicit 2025.HF5 Mon Jul 13 10:13:28 W. Europe Daylight Time
 Step: Procedure
 Increment: 2087969; Step Time = 0.3980
 Deformed Var: U Deformation Scale Factor: 1.000e+00

(e) Time: 0.40 s



ODB: Procedure-WW_2.odb Abaqus/Explicit 2025.HF5 Mon Jul 13 10:13:28 W. Europe Daylight Time
 Step: Procedure
 Increment: 2623263; Step Time = 0.5000
 Deformed Var: U Deformation Scale Factor: 1.000e+00

(f) Time: 0.50 s

Figure 4.4: Context of use simulation during different time frames (s)

Figure 4.7, the resulting force curves with and without wires are nearly identical, with matching slopes during both the deployment and retraction phases. This indicates that the presence of the wire has little to no effect on the radial force exerted on the vessel wall.

Stent length change during the procedure. The final simulation considers the change in stent length throughout the procedure, defined as the axial difference in distance between a reference node at the pulling end of the stent and a corresponding node at the opposite end, where the stent is wrapped by the wire. This distance was tracked as the axial displacement of one end of the stent relative to the other throughout the simulated procedure.

The evolution of this distance can be directly related to the different phases of the procedure. During the crimping phase (0–0.1 s), the distance between the two reference points increases: as the stent is crimped by the catheter, the right end of the stent is held fixed at its reference point, while the left end moves in the positive z -direction as a result of the radial crimping, thereby elongating the stent. At 0.1 s, the catheter starts to withdraw, causing the stent to expand radially. As the stent expands, it simultaneously shortens axially, which is reflected in a decreasing distance between the two reference points. By 0.3 s, the stent has fully expanded into the vessel with a diameter of 5 mm; since the stent is not expanded to its nominal free diameter of 6 mm, the distance between the two points does not return to its original (unloaded) value at this point. Finally, from 0.3 s onward, the stent is retracted back into the catheter, causing the stent to elongate again and the distance between the two reference points to increase once more.

As shown in Figure 4.8, the results with and without wires overlap closely for most of the procedure. However, towards the end of the procedure – once the stent has been fully retracted back into the catheter – the distance between the two reference points is larger for the configuration without wires than for the configuration with wires, indicating that the wire slightly resists axial elongation of the stent during this stage.

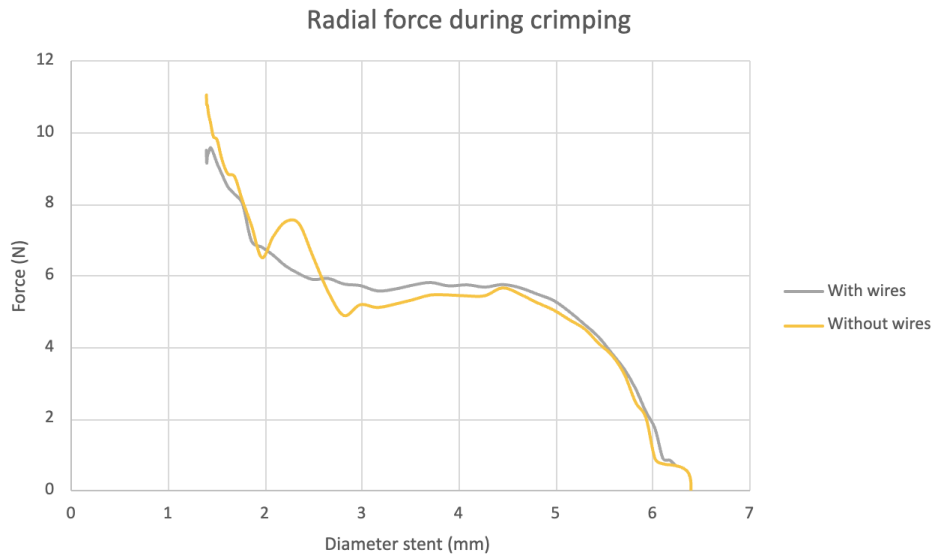


Figure 4.5: Radial reaction force on the catheter surface as a function of stent diameter during crimping, with and without the braided wire.

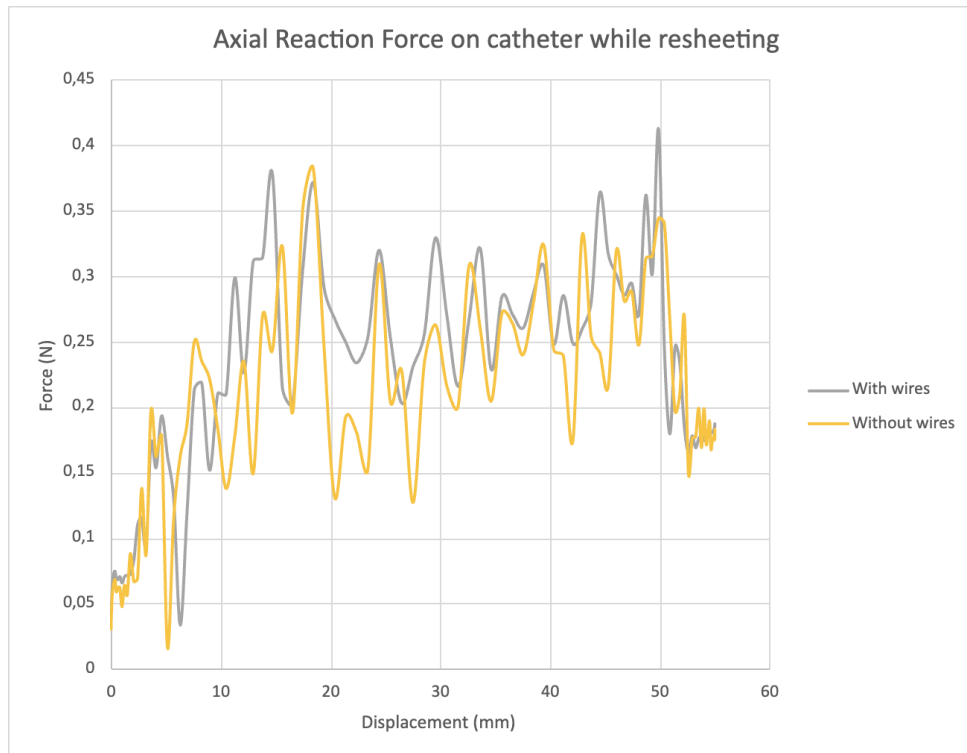


Figure 4.6: Axial reaction force on the catheter during stent retraction, with and without the braided wire.

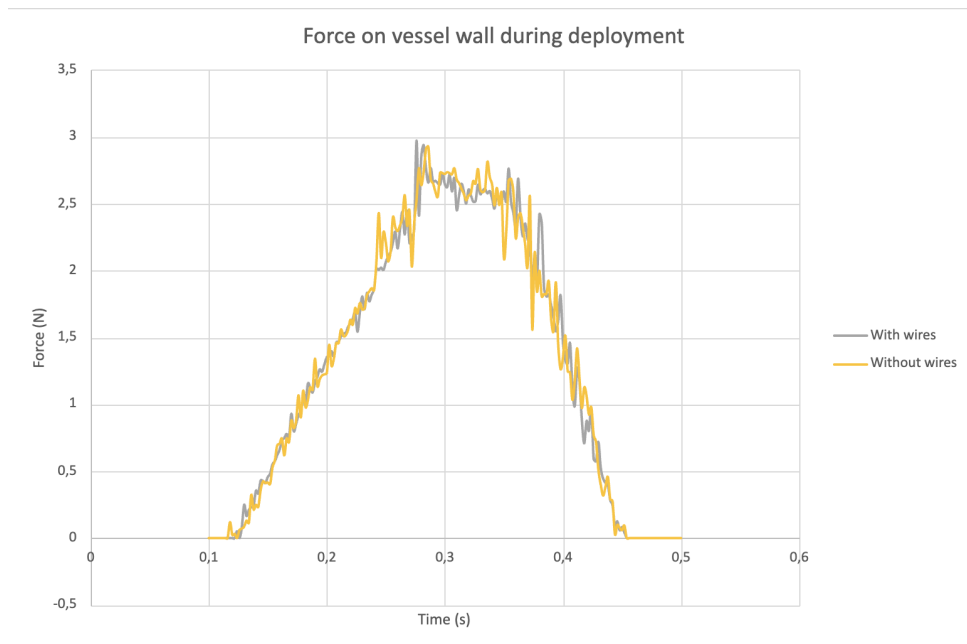


Figure 4.7: Radial reaction force on the vessel wall during deployment and retraction, with and without the braided wire.

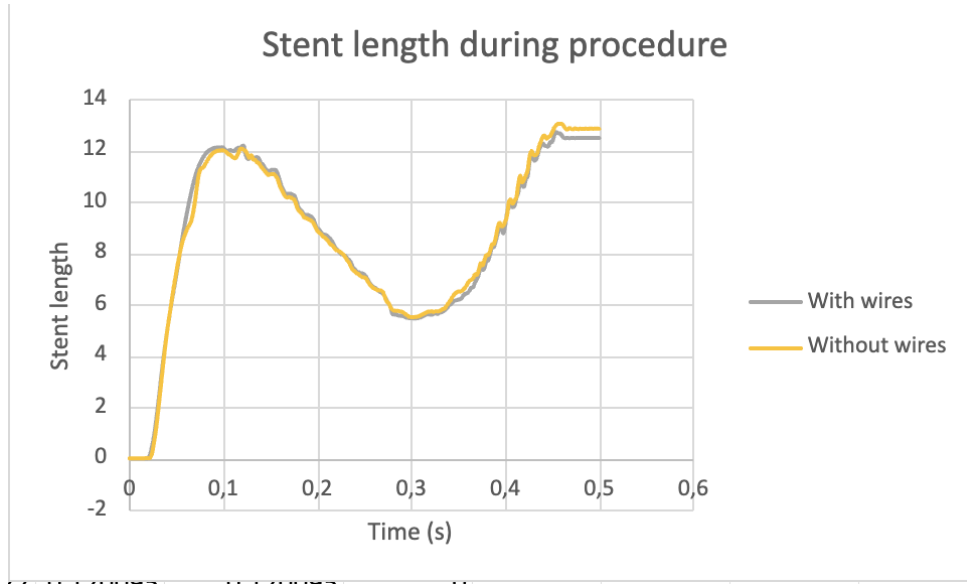


Figure 4.8: Change in stent length between the two end reference nodes throughout the simulated procedure, with and without the braided wire.

4.2.3 Summary

Based on these four context-of-use simulations, the braided wire appears to have little to no influence on the radial mechanical behaviour of the stent, both in terms of the force exerted on the vessel wall during deployment and, for the most part, the radial force during catheter crimping. In contrast, the axial force exerted on the catheter during retraction shows a consistently higher average force for the configuration with wires compared to without, and the stent length results likewise show that the wire slightly limits axial elongation of the stent by the end of the procedure. Together, these results indicate that, while the assumption of neglecting the wire appears reasonable for radial loading conditions, it does have a measurable effect on the axial mechanical behaviour of the stent, and should therefore be taken into account when the axial response of the device is of specific interest within its context of use.

Chapter 5

Discussion

5.1 Interpretation of the Main Results

The correction introduced at the connector–sinusoidal cell split reduced the relative error between the beam- and solid-element models from as much as 33% to within 1–4% across all four stiffness properties (Table 2.11). This is a substantial improvement for a single, localised modelling change, and it is worth being explicit about *why* it worked: in the original beam model, the split between the connector element and the sinusoidal body of the cell was represented by a single node, which offered no local resistance to bending at that location. In the solid model, by contrast, this same region is spanned by many elements, which collectively stiffen the joint. Adding a single additional beam element at the split reproduces this local stiffening effect analytically, without requiring the computational cost of a full three-dimensional mesh. This suggests that the discrepancy was not a general shortcoming of the beam formulation itself, but a localised discretisation artefact at geometric discontinuities – a distinction that matters, because it implies the correction strategy (adding elements at similar discontinuities) may generalise to other stent geometries with comparable joint features, rather than being a fix specific to this device.

The revalidation results (Section 4.1) show a second pattern worth interpreting. For both the flat-plate compression and three-point bending test cases, the *loading* NRMSE of Model Version 2 approached the 10% acceptance threshold (11.6% and 11.8%, respectively), while the *unloading* NRMSE remained substantially higher (20.7% and 32.9%). The model consistently reproduces the forward (loading) mechanical response better than the return (unloading) response. Combined with the visibly narrower hysteresis loop in the simulation compared to the in-vitro data (Figure 4.1), this points to an energy-dissipation mechanism that is under-represented in the model.

This distinction between the loading and unloading agreement is arguably the most important remaining finding of the revalidation, since it isolates where the model’s residual error is concentrated. Given that the loading NRMSE already lies close to the 10% acceptance criterion, the overall NRMSE for both test cases is being pulled above threshold predominantly by the unloading segment. This suggests that the model is, in a meaningful sense, already close to meeting the ASME V&V-40 acceptance criterion, and that resolving the hysteresis discrepancy specifically – rather than further refining the geometry or mesh – may be the single most impactful next step towards a validated model. For this reason, a dedicated investigation into the source of the missing hysteresis width is recommended as a priority for future work.

Taken together, these results indicate that the central research question can only be answered

in part. A computationally efficient beam-element model *can* be constructed that reproduces the stiffness properties of the solid-element reference model to within a few percent, demonstrating that the efficiency requirement of the research question is achievable. However, the same model does not yet reproduce the experimentally observed hysteretic behaviour to within the required 10% margin, meaning the validation requirement of the research question has not yet been fully satisfied. The efficiency and the validation objectives should therefore not be conflated: this thesis demonstrates that the first is achievable and provides a partial, but not yet sufficient, answer to the second.

5.2 A Methodological Inconsistency in the Acceptance Criterion

A point that deserves explicit acknowledgement, is a methodological inconsistency between the model risk classification and the comparison actually performed. As established in Section 4.1, the model was assigned Risk Level 5 under the ASME V&V-40 framework, which, according to Table 2.1, requires “*Comparison with uncertainties estimated and incorporated from both the comparator and the computational model, including comparison error; differences are less than 10%; statistical distributions are known, enabling rigorous treatment of uncertainty.*”. This is a materially stronger requirement than a simple point-to-point comparison against a 10% threshold: it requires the acceptance criterion itself to be evaluated against a propagated uncertainty band on both sides of the comparison.

A full sensitivity-based uncertainty quantification and first-order propagation *was* developed for this purpose, including an explicit derivation of the propagated output variance σ_k . However, the validation and revalidation comparisons themselves evaluate the model deterministically against a single in-vitro dataset (Test 3 for flat-plate compression, Test 1 for three-point bending), using the 10% figure as a flat threshold rather than as a criterion applied to an uncertainty-bounded comparison. Therefore a Risk-Level-5-conformant validation has not yet been performed in this work: what has been performed is closer to a Risk-Level-4 point comparison. This does not invalidate the reported NRMSE and slope-error values, but it does mean that the pass/fail conclusions in Sections validation and revalidation should be read as necessary rather than sufficient evidence of validation under the model’s own assigned risk framework. Completing this chapter would require repeating the comparison in these Sections using the propagated σ_k together with an estimated comparator uncertainty (e.g. from repeat testing rather than the single-specimen point value currently used). Only one single specimen was tested because of the availability of the stent (specifically this size), which did not allow testing between different specimens.

5.3 Gap Between Validation Conditions and the in-silico thrombectomy procedure

The experimental validation performed in this work (flat-plate compression and three-point bending) characterises generic mechanical stiffness of the stent in isolation. The Context of Use simulations in Section 4.2, by contrast, concern the stent’s interaction with a delivery catheter and a vessel wall during crimping, deployment, and retraction – and, in the broader T-SIM application, would ultimately need to concern interaction with a thrombus as well. None of these

interaction-dominated loading conditions were part of the validation comparator set.

This is a meaningful gap. Radial and bending stiffness under idealised, loading (flat plates, supporting cylinders) are necessary but not sufficient descriptors of how the device will behave against a compliant vessel wall or a deformable thrombus, where friction, contact area, and local conforming behaviour all contribute to the force response in ways that a stiffness measurement alone does not capture. However the overall stiffness of the device for the deformation modes tested here is closely related to the real deformations during thrombectomy procedure, therefore there is some overlap between the validation and Context of Use. The Context of Use conclusions of Section 4.2.3 – that the braided wire is mechanically negligible in radial loading but measurably relevant in axial loading – were therefore obtained using a model that has been validated only against a mechanically simpler set of loading conditions than the one in which those conclusions were drawn. This does not necessarily undermine the qualitative conclusion (Section 5.7 discusses why the relative comparison is more robust than the absolute levels), but it should be stated plainly that the validation performed here characterises the building block, not the full intended application, and that this gap should be closed before the wire-influence conclusions can be considered validated in the ASME V&V-40 sense for the actual Context of Use. This could be done by doing the extra validations stated in the VVUQ plan that has been drafted beforehand.

5.4 Experimental Limitations

Several limitations of the experimental comparator data itself are independent of the accuracy of the computational model and should be considered separately from the modelling limitations discussed above.

Use of a previously deployed stent. Both experimental test campaigns were performed on a stent that had already been used in a real thrombectomy procedure, and which exhibited measurable permanent deformation and a residual bow along its length. This directly affects the three-point bending comparison in particular, where the bowed geometry caused the punch to make contact earlier than it would for a nominally straight stent, meaning the applied displacement in the physical test was not strictly equivalent to the nominal 3mm applied in the simulation. Also the flat-plate compression test was effected as the diameter of the stent was smaller than the diameter of the model, this is affecting the NRMSE for the test because of the offset the smaller diameter is creating. Testing an unused, as-manufactured specimen would remove this ambiguity.

Insufficiently constrained three-point bending setup. Because the stent was free to rotate and slide on the supporting cylinders, the second bending repetition exhibited a visible discontinuity corresponding to the stent rolling about its own axis. This is a test-fixture limitation rather than a device or model limitation, but it does mean that Test 1 was selected as the reference dataset partly by necessity rather than because it is unambiguously the more representative of the two repetitions. To solve this limitation, research could be done to use a known material (glue) to keep the stent in place while it is deformed. This material can then be later also be replicated in the simulation.

Insufficient number of tested samples. All comparator data, for both test types and all three stent sizes, were obtained from a single physical specimen per size, a limitation already reflected in the credibility matrix, where the rigor associated with the quantity of test samples was assessed as A. Without repeat specimens it is not possible to separate genuine device-to-device

manufacturing variability from the specific condition of the one tested stent, which limits the strength of any conclusion drawn from the validation exercise, and also removes the possibility of estimating a comparator uncertainty empirically – which, as noted in Section 5.2, is precisely what would be needed to perform a validation comparison that fully matches the assigned Risk Level 5 (minimum of 5 stents).

5.5 Uncertainty Quantification and Modelling Assumptions

A number of assumptions made in the uncertainty quantification and in the model inputs more broadly warrant closer scrutiny.

The Nitinol superelastic parameters were taken from a deterministic calibration to a single radial force curve for the same device (Wu et al., 2025), rather than from dedicated characterisation testing performed as part of this work. Because this calibration reports no associated experimental uncertainty, the uncertainty used throughout Sections 3.3–3.4 was instead estimated from the spread across independent literature sources (Table 3.1). Calibrating a full superelastic parameter set to a single force curve is subject to equifinality: different parameter combinations can reproduce a similar global response. The inter-source spread used here may therefore partly reflect this non-uniqueness rather than genuine physical variability in the material, which means the reported σ_{x_i} values for the Nitinol parameters may not have a strictly physical interpretation.

Relatedly, the first-order uncertainty propagation of Section 3.4 (Equation 3.3) assumes mutual independence between all input parameters. This assumption is questionable specifically for the Nitinol parameters, which were calibrated jointly from a single dataset and are therefore likely correlated. Neglecting such correlations in a root-sum-square combination can either over- or under-estimate the true propagated output uncertainty σ_k , depending on the sign and magnitude of the neglected covariances – a further reason why the point-value comparison discussed in Section 5.2 should not yet be treated as a fully rigorous Level-5 uncertainty-based validation. This could be solved by doing a tensile test on one strut for perfect calibration, or by doing a better uncertainty assessment with Monte carlos simulations.

The platinum–tungsten wire composition (Pt92/W8) was assumed based on a manufacturer datasheet rather than confirmed for the actual device modelled. Given the reported sensitivity of the wire’s elastic modulus to its degree of cold work and annealing state – itself partly responsible for the 138–230 GPa spread in Young’s modulus reported across sources (Table 3.1) – an incorrect compositional assumption represents an additional, unquantified source of epistemic uncertainty. This is particularly relevant given that the wire was found in Section 4.2 to have a measurable effect specifically on axial behaviour: if the assumed composition and resulting stiffness are inaccurate, the magnitude (though plausibly not the qualitative direction) of the reported 11.5% axial force difference could shift.

Finally, two verification activities were performed only on an earlier version of the model and were not repeated after subsequent revisions. The sensitivity analysis and first-order propagation (Section 3.4) were performed exclusively on Model Version 1, before the strut dimensions were revised for Model Version 2 (Section 3.6); the resulting sensitivity ranking and propagated uncertainty may therefore no longer be representative of the model actually used in the final validation and Context of Use simulations. It should be noted, however, that the revision between Model Version 1 and 2 changed only two scalar cross-sectional parameters (strut width and strut height), while the overall stent topology, unit-cell layout, and assembly procedure remained iden-

tical. Since the sensitivity analysis in Section 3.4 already identifies strut width and strut height as the dominant contributing parameters for both test cases, and since the relative influence of a given input on the model output is governed primarily by the underlying deformation mechanism (which remain unchanged) rather than by the specific value of the cross-section, the qualitative ranking of dominant parameters obtained for Model Version 1 is likely still representative of Model Version 2; the quantitative sensitivity coefficients S_i and the resulting propagated σ_k may shift somewhat, but a substantial re-ranking of which inputs matter most is not expected.

Likewise, the mesh convergence study for the beam-element model (Section 2.4.6, Figure 2.15) was performed using the original, smaller strut cross-section; since the optimal element size for a beam formulation can in principle depend on the cross-sectional dimensions relative to the element length, it is not guaranteed that the same 0.1 mm element size remains optimal for the revised geometry of Model Version 2. Here too, however, the change is expected to have limited practical impact: mesh convergence for this type of beam model is governed mainly by the element length relative to the length scale of local geometric features rather than by the absolute strut cross-section itself, and since these local features and the overall stent geometry are unchanged between the two model versions, the previously established convergence behaviour is likely to carry over sufficiently. Both analyses should nonetheless be repeated on the current model before its VVUQ package is considered complete, so that this expectation is confirmed quantitatively rather than assumed.

5.6 Numerical Aspects of the Context-of-Use Simulations

The irregular force fluctuations observed in the wireless configuration during catheter crimping were attributed to numerical damping associated with the mass scaling and alpha/beta damping used to stabilise the Abaqus/Explicit simulation, rather than to genuine physical behaviour. While this attribution is plausible, it has not been confirmed through, for example, a damping sensitivity study. The crimping simulation is one of only two loading cases (together with axial retraction) in which a measurable with/without-wire difference was reported, and both cases showed some level of solver-related noise. Since the wire-influence conclusions in Section 4.2.3 rest partly on distinguishing genuine differences between the two configurations from simulation noise, it would strengthen the Context of Use findings considerably to repeat at least the crimping simulation with reduced damping or with an implicit solver, to confirm that the observed divergence below 4 mm diameter is physical rather than an artefact of the explicit stabilisation scheme.

5.7 Applicability to the T-SIM Project

The work presented in this thesis contributes directly to Work Package 2 (In silico Thrombectomy) of the T-SIM project, which calls for a library of computationally efficient device models characterised against manufacturer and literature benchmarks – precisely the workflow followed in Chapter 2. Beyond the specific numerical results obtained for the Trevo XP ProVue 6×25, the reusable pipeline developed here – microscopy-based geometry acquisition, construction of a high-fidelity solid model, conversion to a corrected beam-element representation, mesh convergence analysis, and a structured ASME V&V-40 credibility assessment – is arguably the most directly

transferable contribution to the wider device library, since it can in principle be re-applied to other stent retrievers or aspiration devices as they are added to the platform.

It is useful to weigh the current state of the model against the concrete success criteria defined for WP2 of the T-SIM project. Of the three stated pillars of WP2, success, *compatibility/portability* is already satisfied: the models in this thesis were built and run using both Abaqus/Standard and Abaqus/Explicit, in line with the requirement that simulations remain compatible with these solvers (and, by extension, deployable on standard commercial cloud solutions). The *computational robustness and efficiency* criterion, however, has only been partially addressed. In the T-SIM project it is specified that a thrombectomy procedure should be simulable in under 12 hours on a regular high-performance workstation; the beam-element model was shown to reduce the number of elements and nodes by more than an order of magnitude relative to the solid-element model, which strongly suggests a substantial reduction in wall-clock time, but this reduction was never actually quantified in this work. Without this figure, it cannot yet be confirmed whether the corrected beam model meets the T-SIM efficiency target, only that it moves substantially in that direction. Finally, on *completeness*: this thesis delivers a single partially validated (with further suggestions to achieve full validation) device model, which represents one entry in the device library called for; the pipeline developed here is intended to make populating the remainder of that library more efficient, but the library’s completeness is a project-level, not thesis-level, deliverable.

The T-SIM project also explicitly identifies “*lack of data on original devices*” as an anticipated risk for the project, with the accepted mitigation being that individual device models can be calibrated within reasonable limits using external datasets. This is directly relevant to several of the assumptions criticised in Section 5.5 – the literature-derived Nitinol parameters and the assumed Pt92/W8 wire composition are both instances of exactly this anticipated, and accepted, project-level risk, rather than being unique shortcomings of this thesis. This does not remove the need to resolve them (Section 5.5 already outlines how), but it does mean they should be read as an expected data constraints, rather than as an unanticipated failure of this specific model.

More broadly, the ASME V&V-40 credibility assessment performed at the device-model level in this thesis (Section 2.2.3 and Appendix A.1) can be seen as a concrete, worked example that anticipates part of what will need to be defined at the level of the full T-SIM platform. In particular, the risk classification procedure (model influence $\times$ decision consequence, Section 2.2.3), the tiered rigor-of-comparison table (Table 2.1), and the credibility matrix (Table A.1) are all directly reusable templates. This thesis provides one partially validated model and a validation methodology, but the device-library completeness remain to be carried out.

Finally, the Context of Use conclusion that the braided wire is mechanically negligible under radial loading but measurably relevant under axial loading (Section 4.2.3) plausibly generalises to other thrombectomy devices that incorporate similar radiopaque braided-wire constructions, given that the underlying mechanism (a helically wound low-stiffness element resisting axial elongation while contributing little to radial expansion) is not obviously specific to the Trevo XP ProVue geometry. If confirmed across other devices as they are added to the T-SIM library, this could support a general simplification rule for the library: braided radiopacity wires may reasonably be omitted from device models intended primarily for radial-loading contexts of use (e.g. vessel-wall apposition, radial force studies), while being retained for contexts of use involving axial retraction, foreshortening, or catheter interaction forces. As emphasised throughout this chapter, however, this recommendation – like the specific numerical results obtained here – should

be treated as provisional until the model underlying it satisfies the acceptance criteria of its own assigned Risk Level 5.

Chapter 6

Conclusion

This thesis aimed to develop a computationally efficient finite element model of the Trevo XP ProVue stent retriever that remains sufficiently realistic and validated to represent the device’s mechanical behaviour in its intended in-silico thrombectomy application. Coupled to this central research question was the specific Question of Interest formulated in Section 2.1: what is the influence of the platinum–tungsten braided wires on the radial and axial mechanical behaviour of the stent? Based on the model development, verification, validation, and Context of Use simulations presented in the preceding chapters, the following conclusions can be drawn.

Model development and computational efficiency. Converting the high-fidelity solid-element model (C3D8I) into a beam-element representation (B31) initially produced substantial discrepancies with the solid model, most notably a 33% deviation in radial stiffness versus the initial beam results in. This discrepancy was traced to the single-node representation of the split between the connector element and the sinusoidal cell body in the beam model. Introducing an additional beam element at this location reduced the relative error for all four stiffness properties to within 1–4% of the solid-element reference, while reducing the number of elements and nodes by more than an order of magnitude relative to the solid model. The subsequent extended mesh convergence study confirmed that a coarser beam mesh size of 0.1 mm (ML-1) could be adopted without materially affecting the predicted stiffness values. Together, these results demonstrate that a corrected beam-element representation can reproduce the structural response of the high-resolution solid model with good accuracy at a fraction of the computational cost, directly addressing the efficiency requirement of the research question.

Validation against experimental data. Given the Risk Level 5 classification assigned to the model under the ASME V&V-40 risk framework, quantitative agreement between simulation and experiment within 10% was required for the model to be considered validated for its intended Context of Use. Model Version 1, incorporating the micro-CT-derived end features and braided wires, did not meet this criterion: comparison against the flat-plate compression and three-point bending in-vitro data yielded overall NRMSE values of 36.0% and 27.0%, respectively, with local stiffness errors as large as –75%. The sensitivity analysis identified strut width and strut height as the dominant contributing parameters to this discrepancy, motivating a repeated, more careful microscopy measurement and the construction of Model Version 2. Revalidation of this updated model showed a marked improvement, with overall NRMSE reduced to 16.8% and 22.1% for flat-plate compression and three point bending respectively and the loading-slope

error for flat-plate compression reduced to essentially zero -0.3% . Despite this improvement, neither test case met the required 10% acceptance criterion, so Model Version 2 cannot yet be considered formally validated for its intended Context of Use, notwithstanding the substantial progress made relative to Model Version 1.

Influence of the braided wires. The four Context of Use simulations comparing the stent with and without the platinum–tungsten braided wires provide a direct, though provisional, answer to the Question of Interest. For the radial mechanical response, the force-diameter curves during catheter crimping and the radial force exerted on the vessel wall during deployment and retraction were nearly identical with and without wires, indicating that the wires have little to no influence on radial behaviour. For the axial response, however, a consistent and measurable effect was found: the axial reaction force on the catheter during retraction showed a higher average force for the configuration with wires, and the change in stent length throughout the procedure confirmed that the wires slightly restrict axial elongation (foreshortening) toward the end of the procedure. Since these simulations were run using Model Version 2, which does not yet meet the 10% validation criterion, the absolute force levels underlying this comparison cannot be stated with full certainty. However, because both configurations were evaluated with the same underlying model and differ only in the presence of the wire, any remaining model discrepancy is expected to affect both curves in a similar way; the *relative* difference between the two configurations – and thus the qualitative conclusion itself – can therefore be argued to be considerably more robust than the absolute values. On this basis, it is concluded that the braided wires may reasonably be omitted from the model when only radial loading conditions are of interest, but should not be neglected when the axial behaviour of the device, such as during retraction, forms part of the intended Context of Use, a conclusion that should nonetheless be confirmed once a fully validated model becomes available.

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Chapter 7

Appendix

7.1 Credibility Matrix

Table 7.1: Credibility matrix summarising the achieved and target levels of rigor across all VVUQ activities (ASME V&V-40).

Activity	Credibility Factor	Level of Rigor		Credibility Level
		Achieved	Maximum	
Code Verification				
	Software Quality Assurance (SQA)	c	c	high
	Numerical Code Verification (NCV)	b	c	medium
Calculation Verification				
	Discretization Error	c	c	high
	Numerical Solver Error	b	c	medium
	Use Error	c	d	medium
Validation with Uncertainty Quantification				
Computational Model	Model Form	c	c	high
	Model Input – Quantification of Sensitivities	c	c	high
	Model Input – Quantification of Uncertainties	b	c	medium
Comparator	Test Samples – Quantity	a	c	medium
	Test Samples – Range of Characteristics	c	d	medium
	Test Samples – Measurements	c	c	high
	Test Samples – Uncertainty of Measurements	a	d	low
	Test Conditions – Quantity	b	c	medium
	Test Conditions – Range	d	d	high
	Test Conditions – Measurements	b	c	low–medium

Continued on next page

Table 7.1 – continued from previous page

Activity	Credibility Factor	Level of Rigor		Credibility Level
		<i>Achieved/Selected/Target</i>	<i>Maximum</i>	
	Test Conditions – Uncertainty of Measurements	a	d	low
Assessment	Equivalency of Input Parameters	c	c	high
	Output Comparison – Quantity	b	c	medium
	Output Comparison – Equivalence of Output Parameters	c	c	high
	Output Comparison – Rigor of Comparison	b	d	low–medium
	Output Comparison – Agreement of Comparison	a	c	low
Applicability of the Validation Activities to the COU				
	Relevance of the QOIs	b	c	medium
	Relevance of the Validation Activities to the COU	b	d	medium

7.2 Introduction

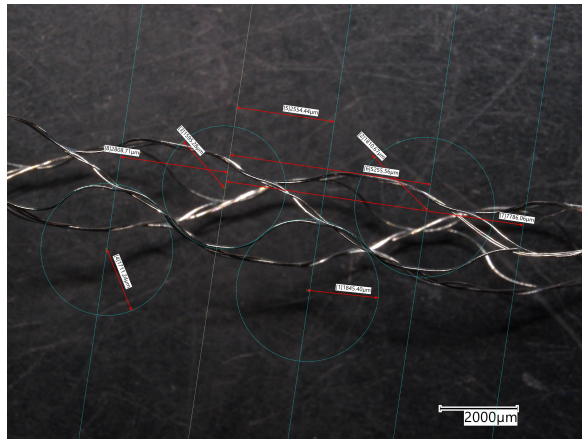
Table 7.2: Overview of commercially available stent retriever devices.

Device	Manufacturer	Material	Fabrication	Cell design	Diam. (mm)	Length (mm)
Merci Retriever	Concentric Medical	Nitinol	Memory-shaped wire	Helical spiral (no mesh)	1.1–2.8	–
Phenox (clot retriever)	Phenox GmbH	Nitinol	Wire	wire, no stent mesh	1–6	–
Catch+	Balt Medical	Nitinol	Braided	Self-expanding basket	3, 4, 6	15, 20, 30
Solitaire X	Medtronic	Nitinol	Laser cut sheet	Closed cell, peak-to-peak, overlapping	3, 4, 6	20, 24, 40
Trevo XP ProVue	Stryker	Nitinol	Laser cut tube	Closed cell, peak-to-peak, non-overlapping	3, 4, 6	20, 25, 30
Trevo NXT	Stryker	Nitinol	Laser cut tube	Closed cell, peak-to-peak, non-overlapping	4, 6	28, 37, 41
pRESET	Phenox GmbH	Nitinol	Laser cut	Closed cell; distal helical slit	4, 6	20, 30
EmboTrap III	Cerenovus (J&J MedTech)	Nitinol	Two-layered laser cut	Inner: closed cell / Outer: open cell	5, 6.5	22, 37, 45
Tigertriever	Rapid Medical	Nitinol (Ta core)	Braided	–	6	20.5, 22, 23, 32, 37, 45

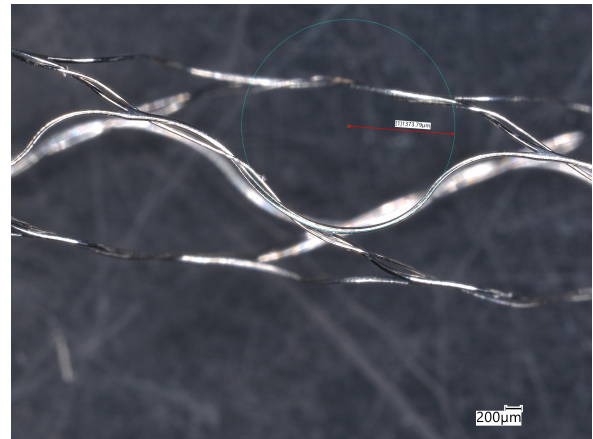
Table 7.2 – continued

Device	Manufacturer	Material	Fabrication	Cell design	Diam. (mm)	Length (mm)
3D Revasc. Device	Penumbra	Nitinol	Laser cut tube	Closed cell inner chambers; open cell outer	4.5	26
ERIC	MicroVention	Nitinol	Laser cut	Closed cell, inter- connected cages	3, 4, 6	20, 24, 44
Nimbus	Cerenovus	Nitinol	Laser cut	Proximal open cell; distal spiral	–	–
Revive SE	Codman (Micrus En- dovascular)	Nitinol	Proximal spiral; distal	–	4.5	22
MindFrame Capture LP	Medtronic	Nitinol	–	–	3	23
NeVa	Vesalio	Nitinol	Laser cut	Segmented de- sign, defined clot- engagement zones; tapered distal tip	4.0 ; 4–22	–
Dredger	Neurosafe	–	–	–	3, 4, 5, 6, 7	20, 24, 30, 40, 42
APERIO	Acandis	Nitinol	–	–	–	–
SuperNova	Gravity Medical Technology	–	–	–	4, 6	39, 43
Tron FX (II)	–	Nitinol	–	–	–	–

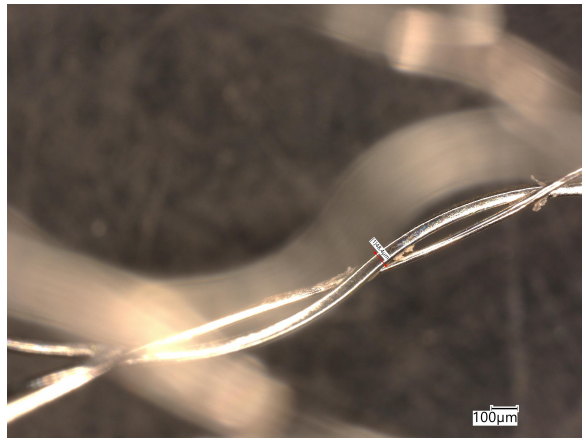
7.3 Development



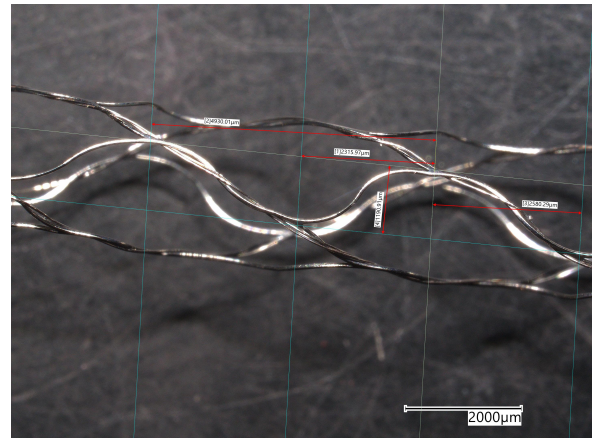
(a) Overall view



(b) Arcs



(c) Struts

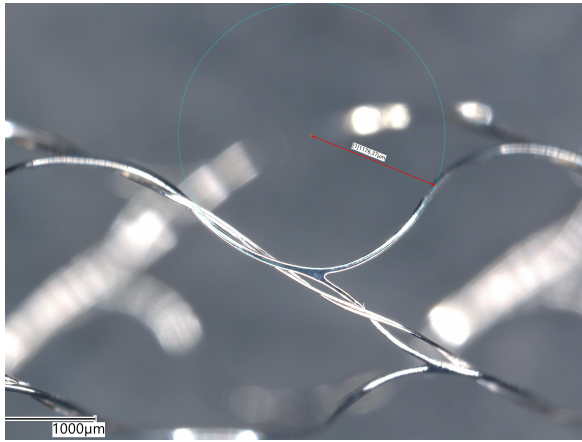


(d) Strut distance

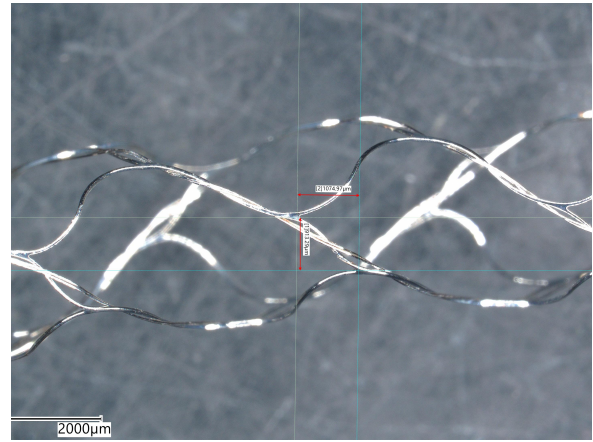
Figure 7.1: Microscopy measurements T3

Verification	Choice	Explanation	Comments
<u>Code Verification</u>			
Software Quality Assurance	A) very little or no SQA procedures were specified or followed B) SQA procedures were specified and documented C) SQA procedures were specified and documented; the software anomaly list and the software development environment were fully understood, and the impact on the COU was analyzed and documented; quality metrics were tracked	C	Analysing abaqus bug list and limitations regarding the used features. Checking own implemented python codes.
Numerical Code Verification	A) NCV was not performed. B) The numerical solution was compared to an accurate benchmark solution from another verified code. C) Discretization error was quantified by comparison to an exact solution, and a grid convergence study demonstrated that the numerical solution asymptotically approached the exact solution as the discretization was refined.	C	Material verification of beam (axial, bending), analytical solution vs numerical stiffnesses for different mesh size. Testing with different solvers, material model, element types etc.
<u>Calculation Verification</u>			
Discretization Error	A) No grid or time-step convergence analysis was performed to estimate the discretization error. B) Applicable grid or time-step convergence analyses were performed and their respective convergence behaviors were observed to be stable, but the discretization error was not estimated. C) Applicable grid or time-step convergence analyses were performed and discretization error was estimated.	C	Richardson extrapolation for axial, bending, torsional, radial stiffness of the full model was conducted to estimate the error
Numerical Solver Error	A) No solver parameter sensitivity was performed. B) No solver parameter sensitivity was performed. Solver parameters were established based on values from a previously verified computational model. C) Problem-specific sensitivity study was performed on solver parameters, confirming that changes in simulation results due to changes in the solver parameters were negligible relative to the model accuracy goal.	C	Parameters as stabilization factors (OTHER USED FUNCTIONS), were changed to look at the influence of those factors on the output
Use Error	A) Inputs and outputs were not verified. B) Key inputs and outputs were verified by the practitioner. C) Key inputs and outputs were verified by internal peer review. D) Key inputs and outputs were verified by reproducing	C/D	Outputs where verified by internal peer review
<u>Validation</u>			
<u>Computational Model</u>			
Model Form	A) Influence of model form assumptions was not explored. B) Influence of expected key model form assumptions was explored. C) Comprehensive evaluation of model form assumptions was conducted.	C	Beam model was compared to exact solid model. Coupling of referencepoint was researched
Model Inputs	Quantification of Sensitivities A) sensitivity analysis was not performed B) sensitivity analysis on expected key parameters was performed C) comprehensive sensitivity analysis was performed	C	Variation of geometry input, loading input, material properties was tested. Research on what inputs have high influence on outputs
	Quantification of Uncertainties A) uncertainties were not identified B) uncertainties on expected key inputs were identified and quantified, but were not propagated to quantitatively assess the effect on the simulation results C) uncertainties on all inputs were identified and quantified, and were propagated to quantitatively assess the effect on the simulation results	C	The uncertainties associated with inputs of high influence where quantified and tested for the uncertainty on the final questions of interest
<u>Comparator Flat Plate Compression/3 Point Bending/Comparator Axial Elongation/Comparator Axial Elongation/Radial compression</u>			
Test Samples	Quantity of Test Samples A) a single sample was used B) multiple samples were used, but not enough to be statistically relevant C) a statistically relevant number of samples were used	B/C	5 Samples where used for testing and measurements
	Range of Characteristics of Test Samples A) one or more samples with a single set of characteristics were included B) samples representing a range of characteristics near nominal were included C) samples representing the expected extreme values of the parameters were included D) samples representing the entire range of parameters were included	C/D	All the sizes of the stent design where included
	Measurements of Test Samples A) test samples were not measured and/or characterized B) one or more key characteristics of the test samples were measured C) all key characteristics of the test samples were measured	C	CT scan of stent was conducted for al geometry
	Uncertainty of Test Sample Measurements A) samples were not characterized or were characterized with gross observations, and measurement uncertainty was not addressed B) uncertainty analysis incorporated instrument accuracy only C) uncertainty analysis incorporated instrument accuracy and repeatability (i.e. statistical treatment of repeated measurements) D) uncertainty analysis incorporated a comprehensive uncertainty quantification, which included instrument accuracy, repeatability, and other conditions affecting the measurements	D	Test of CT, Tensile repeating 5 times, information about uncertainty of equipment
	Quantity of Test Conditions A) a single test condition was examined B) multiple (two to four) test conditions were examined C) more than four test conditions were examined	B/C	Flat plate compression test was conducted, to determine radial stiffness
	Range of Test Conditions A) a single test condition was examined B) test conditions representing a range of conditions near nominal were examined C) test conditions representing the expected extreme conditions were examined D) test conditions representing the entire range of conditions were examined	D	Compression force and displacement where tested continuously from compressing 100->50 percent of diameter
Measurements of Test Conditions			

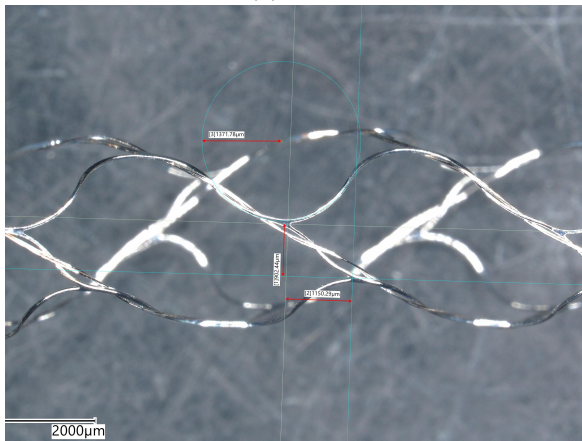
Test Conditions	A) test conditions were qualitatively measured and/or characterized B) one or more key characteristics of the test conditions were measured C) all key characteristics of the test conditions were measured	B/C	Temperature was measured, axial elongation was measured, compression force measured and plate displacement was measured
	Uncertainty of Test Condition Measurements A) test conditions were not characterized or were characterized with gross observations, measurement uncertainty was not addressed B) uncertainty analysis incorporated instrument accuracy only C) uncertainty analysis incorporated instrument accuracy and repeatability (i.e. statistical treatment of repeated measurements) D) uncertainty analysis incorporated a comprehensive uncertainty quantification, which included instrument accuracy, repeatability, and other conditions affecting the measurements	D	Compression repeating 5 times, information about uncertainty of equipment
Assesment			
Equivalency of Input Parameters	A) the types of some inputs were dissimilar B) the types of all inputs were similar, but the ranges were not equivalent C) the types and ranges of all inputs were equivalent	C	Exact inputs where given in the model as in the testing
Output Comparison	Quantity A) a single output was compared B) multiple outputs were compared	B	Width was measured while axial elongation. Length was measured while compression test. Angle was measured during bending
	Equivalence of Output Parameters A) types of outputs were dissimilar B) types of outputs were similar C) types of outputs were equivalent	C	Outputs the same
	Rigor of Output Comparison A) visual comparison was performed B) comparison was performed by determining the arithmetic difference between computational results and experimental results C) uncertainty in the output of the computational model or the comparator was used the output comparison D) uncertainties in the output of the computational model and the comparator were used in the output comparison	D	Same Questions of interest. Both uncertainty computational and experimental used for output comparison
	Agreement of Output Comparison A) the level of agreement of the output comparison was not satisfactory for key comparisons B) the level of agreement of the output comparison was satisfactory for key comparisons, but not all comparisons C) the level of agreement of the output comparison was satisfactory for all comparisons	C	All outputs were below 10% disagreement. Therefore al ouput comparison was satisfactory



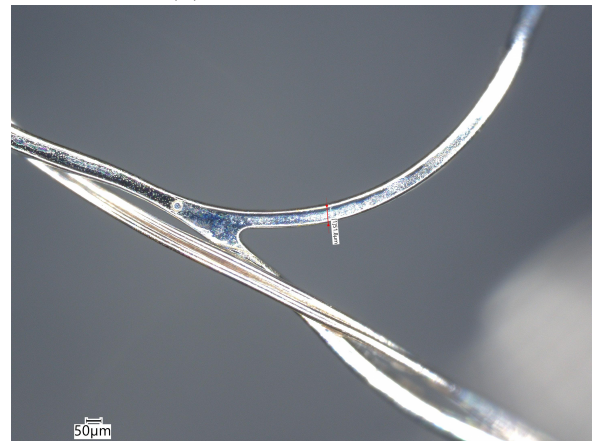
(a) Arcs



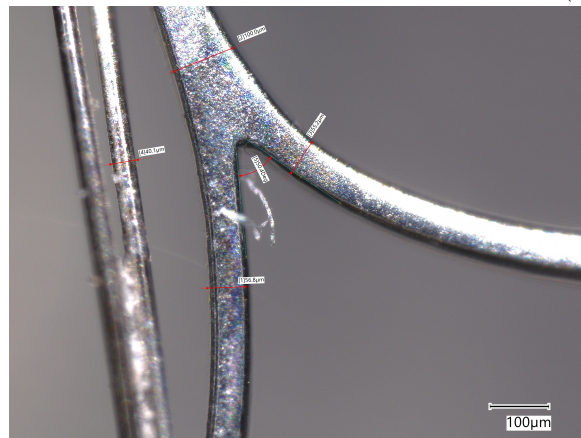
(b) Connector distance



(c) Radius/distance sections

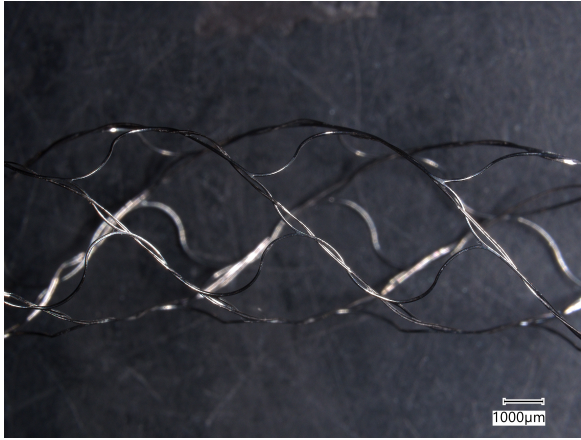


(d) Strut

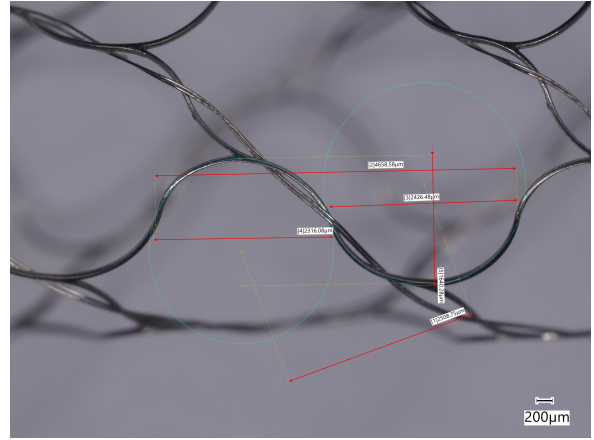


(e) Wire radius

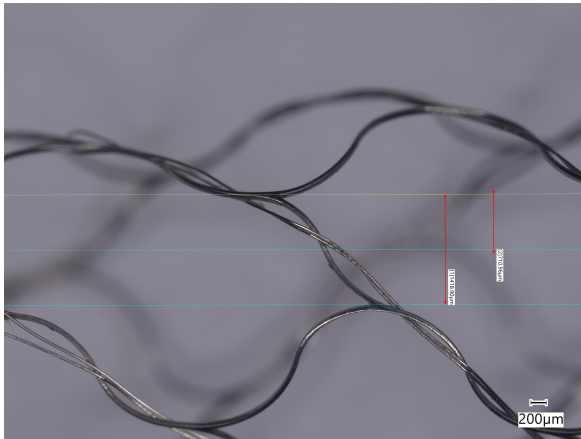
Figure 7.2: Microscopy measurements T4



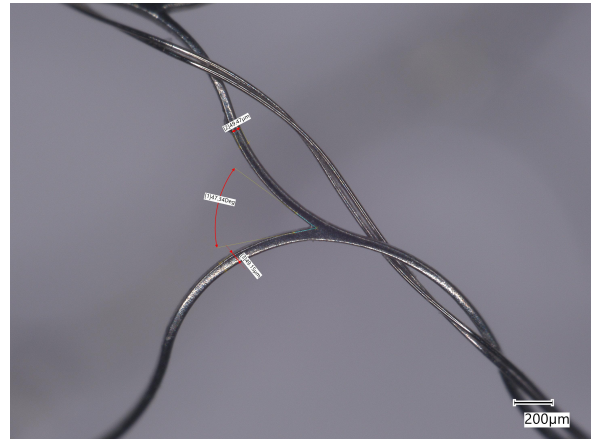
(a) Overall



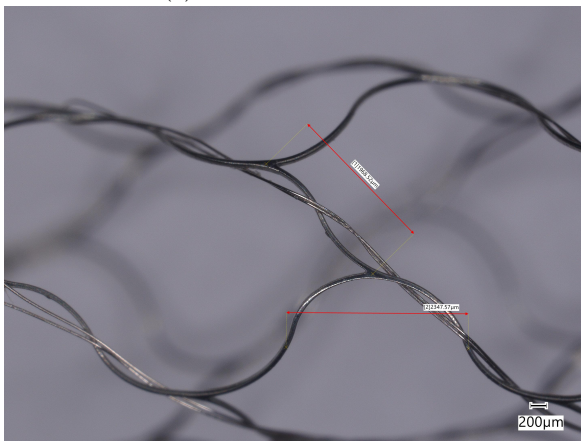
(b) Arcs



(c) Connector distance



(d) Strut



(e) Connector strut



(f) Wire loop

Figure 7.3: Microscopy measurements T6

7.4 Validation

Table 7.3: Nitinol material parameter values reported across the independent sources used to establish the applied uncertainty range in Table 3.1: generic literature values [Finotello et al. \(2017\)](#), a calibration performed for a different commercial stent (Solitaire FR), the calibration performed for the specific stent considered in this work (Trevor XP ProVue, used as baseline) [Wu et al. \(2025\)](#), and three additional independent datasets from 4RealSim.

Parameter	Auricchio (generic)	Solitaire FR	Trevo (baseline)	Source 1	Source 2	Source 3
Austenite E [MPa]	51,700	60,000	56,000	68,212	56,000	67,196.6
Austenite ν [-]	0.30	0.30	0.30	0.33	0.33	0.33
Martensite E [MPa]	47,800	47,800	23,700	24,285	31,000	23,804.1
Martensite ν [-]	0.30	0.30	0.30	0.33	0.33	0.33
Transformation strain [-]	0.063	0.063	0.063	0.0421	0.0465	0.0434
Loading start of transformation stress σ_L^S [MPa]	600	600	635	539	470	463.04
Loading end of transformation stress σ_L^E [MPa]	670	670	677	620	500	498.54
Unloading start of transformation stress σ_U^S [MPa]	288	288	288	380	270	274.80
Unloading end of transformation stress σ_U^E [MPa]	254	254	254	343	225	221.96
Compressive transformation stress (start) [MPa]	900	—	952.5	808	590	—
Stress/temperature slope, loading [MPa/°C]	6.5	—	6.5	6.00	6.00	—
Stress/temperature slope, unloading [MPa/°C]	6.5	—	6.5	6.00	6.00	—

Table 7.4: Full sensitivity analysis run data for the flat-plate compression test case. $k = RF_2/u_2$ is the stiffness (Eq. (3.1)), Δk (%) and Δk (abs) are the relative and absolute change with respect to the baseline, and S_i is the sensitivity coefficient computed directly from each run pair via Eq. (3.2).

Variation	Max RF_2 [N]	u_2 [mm]	k [N/mm]	Δk (%)	S_i
<i>Strut width</i>					
-10%	0.0972	3.0	0.0324	-18.59	1.480
-5%	0.1083	3.0	0.036158	-9.15	1.457
Baseline	0.1194	3.0	0.0398	0.00	—
+5%	0.1328	3.0	0.044137	10.90	1.735
+10%	0.1441	3.0	0.047928	20.42	1.626
<i>Strut height</i>					
-10%	0.1044	3.0	0.034856	-12.42	0.989
-5%	0.1109	3.0	0.036881	-7.34	1.168
Baseline	0.1194	3.0	0.0398	0.00	—
+5%	0.1276	3.0	0.042412	6.56	1.045
+10%	0.1360	3.0	0.045228	13.64	1.086
<i>Strut width & height combined</i>					
-10%	0.0843	3.0	0.028145	-29.28	24.537
-5%	0.1026	3.0	0.034102	-14.32	23.375
Baseline	0.1194	3.0	0.0398	0.00	—
+5%	0.1419	3.0	0.047165	18.50	28.741
+10%	0.1666	3.0	0.055408	39.22	29.729
<i>Friction wire-plate</i>					
$\mu = 0.05$	0.1179	3.0	0.039324	-1.20	0.00953
$\mu = 0.10$ (Baseline)	0.1194	3.0	0.0398	0.00	—
$\mu = 0.20$	0.1205	3.0	0.040167	0.92	0.00367

Table 7.4 – continued

Variation	Max RF_2 [N]	u_2 [mm]	k [N/mm]	Δk (%)	S_i
$\mu = 0.40$	0.1222	3.0	0.040733	2.35	0.00311
$\mu = 0.80$	0.1235	3.0	0.041167	3.43	0.00195
<i>Friction stent-plate</i>					
$\mu = 0.05$	0.1184	3.0	0.039467	−0.84	0.00667
$\mu = 0.10$ (Baseline)	0.1194	3.0	0.0398	0.00	–
$\mu = 0.20$	0.1211	3.0	0.040367	1.42	0.00567
$\mu = 0.40$	0.1217	3.0	0.040567	1.93	0.00256
$\mu = 0.80$	0.1231	3.0	0.041058	3.16	0.00180
<i>Friction stent-plate & wire-plate combined</i>					
$\mu = 0.05$	0.1174	3.0	0.039133	−1.68	0.01333
$\mu = 0.10$ (Baseline)	0.1194	3.0	0.0398	0.00	–
$\mu = 0.20$	0.1227	3.0	0.0409	2.76	0.01100
$\mu = 0.40$	0.1232	3.0	0.041067	3.18	0.00422
$\mu = 0.80$	0.1258	3.0	0.041959	5.42	0.00308
<i>Friction wire-wire</i>					
Baseline	0.1194	3.0	0.0398	0.00	–
$\mu = 0.05$	0.1192	3.0	0.039733	−0.17	−0.00133
$\mu = 0.10$	0.1195	3.0	0.039833	0.08	0.00033
$\mu = 0.20$	0.1200	3.0	0.0400	0.50	0.00100
$\mu = 0.40$	0.1202	3.0	0.040067	0.67	0.00067
$\mu = 0.80$	0.1204	3.0	0.040133	0.84	0.00042
<i>Friction stent-wire</i>					
Baseline	0.1194	3.0	0.0398	0.00	–
$\mu = 0.05$	0.1203	3.0	0.0401	0.75	0.00600
$\mu = 0.10$	0.1199	3.0	0.03995	0.38	0.00150
$\mu = 0.20$	0.1206	3.0	0.040224	1.07	0.00212
$\mu = 0.40$	0.1211	3.0	0.040391	1.48	0.00148
$\mu = 0.80$	0.1232	3.0	0.040945	2.88	0.00143
<i>Nitinol loading (transformation stress)</i>					
−20%	0.1199	3.0	0.039852	0.13	−4.13E-07
Baseline	0.1194	3.0	0.0398	0.00	–
+20%	0.1213	3.0	0.040318	1.30	4.08E-06
<i>Nitinol unloading (transformation stress)</i>					
−20%	0.1205	3.0	0.040052	0.63	−4.37E-06
Baseline	0.1194	3.0	0.0398	0.00	–
+20%	0.1205	3.0	0.040052	0.63	4.37E-06
<i>Martensite Young's modulus</i>					
−10%	0.1201	3.0	0.040033	0.59	−4.17E-08
−5%	0.1200	3.0	0.0400	0.50	−7.14E-08
Baseline	0.1194	3.0	0.0398	0.00	–
+5%	0.1199	3.0	0.039967	0.42	5.95E-08
+10%	0.1200	3.0	0.0400	0.50	3.57E-08

Table 7.4 – continued

Variation	Max RF_2 [N]	u_2 [mm]	k [N/mm]	Δk (%)	S_i
<i>Austenite Young's modulus</i>					
–5%	0.1142	3.0	0.038067	–4.36	6.19E-07
Baseline	0.1194	3.0	0.0398	0.00	–
+5%	0.1256	3.0	0.041867	5.19	7.38E-07
<i>Compressive transformation stress limit</i>					
–5%	0.1196	3.0	0.039867	0.17	–1.40E-06
Baseline	0.1194	3.0	0.0398	0.00	–
+5%	0.1200	3.0	0.0400	0.50	4.20E-06
<i>Martensite Poisson's ratio</i>					
–5%	0.1198	3.0	0.039933	0.34	–0.00889
Baseline	0.1194	3.0	0.0398	0.00	–
+5%	0.1198	3.0	0.039933	0.34	0.00889
<i>Austenite Poisson's ratio</i>					
–5%	0.1199	3.0	0.039967	0.42	–0.01010
Baseline	0.1194	3.0	0.0398	0.00	–
+5%	0.1190	3.0	0.039667	–0.34	–0.00808
<i>Stress/temperature slope, loading</i>					
–5%	0.1199	3.0	0.039967	0.42	–0.000513
Baseline	0.1194	3.0	0.0398	0.00	–
+5%	0.1200	3.0	0.0400	0.50	0.000615
<i>Stress/temperature slope, unloading</i>					
–5%	0.1194	3.0	0.0398	0.00	0
Baseline	0.1194	3.0	0.0398	0.00	–
+5%	0.1194	3.0	0.0398	0.00	0
<i>Transformation strain</i>					
–5%	0.1201	3.0	0.040033	0.59	–0.0741
Baseline	0.1194	3.0	0.0398	0.00	–
+5%	0.1203	3.0	0.0401	0.75	0.0952
<i>Test temperature</i>					
–5%	0.1193	3.0	0.039767	–0.08	3.25E-05
Baseline	0.1194	3.0	0.0398	0.00	–
+5%	0.1201	3.0	0.040033	0.59	2.28E-04
<i>Pt–W Young's modulus</i>					
–5%	0.1192	3.0	0.039733	–0.17	9.66E-09
Baseline	0.1194	3.0	0.0398	0.00	–
+5%	0.1202	3.0	0.040067	0.67	3.86E-08
<i>Pt–W Poisson's ratio</i>					
–5%	0.1194	3.0	0.0398	0.00	0
Baseline	0.1194	3.0	0.0398	0.00	–
+5%	0.1196	3.0	0.039867	0.17	0.00444
<i>Wire radius</i>					
–5%	0.1160	3.0	0.038667	–2.85	1.133

Table 7.4 – continued

Variation	Max RF_2 [N]	u_2 [mm]	k [N/mm]	Δk (%)	S_i
Baseline	0.1194	3.0	0.0398	0.00	–
+5%	0.1218	3.0	0.040785	2.47	0.985

Table 7.5: Full sensitivity analysis run data for the three-point bending test case. $k = RF_2/u_2$ is the stiffness (Eq. (3.1)), Δk (%) and Δk (abs) are the relative and absolute change with respect to the baseline.

Variation	Max RF_2 [N]	u_2 [mm]	k [N/mm]	Δk (%)
<i>Strut width</i>				
–10%	0.0195	3.0	0.0065	–11.0
–5%	0.0207	3.0	0.0069	–5.5
Baseline	0.0219	3.0	0.0073	0.0
+5%	0.0231	3.0	0.0077	5.5
+10%	0.0243	3.0	0.0081	11.0
<i>Strut height</i>				
–10%	0.0169	3.0	0.005633	–22.8
–5%	0.0193	3.0	0.006433	–11.9
Baseline	0.0219	3.0	0.0073	0.0
+5%	0.0248	3.0	0.008267	13.2
+10%	0.0279	3.0	0.0093	27.4
<i>Strut width & height combined</i>				
–10%	0.0151	3.0	0.005033	–31.1
–5%	0.0182	3.0	0.006067	–16.9
Baseline	0.0219	3.0	0.0073	0.0
+5%	0.0262	3.0	0.008733	19.6
+10%	0.0311	3.0	0.010367	42.0
<i>Friction stent–wire (sw)</i>				
$\mu = 0.05$	0.0219	3.0	0.0073	0.0
$\mu = 0.10$ (Baseline)	0.0220	3.0	0.007333	0.5
$\mu = 0.20$	0.0220	3.0	0.007333	0.5
$\mu = 0.40$	0.0221	3.0	0.007367	0.9
$\mu = 0.80$	0.0222	3.0	0.0074	1.4
<i>Friction wire–wire (ww)</i>				
$\mu = 0.05$	0.0219	3.0	0.0073	0.0
$\mu = 0.10$	0.0219	3.0	0.0073	0.0
$\mu = 0.20$	0.0219	3.0	0.0073	0.0
$\mu = 0.40$	0.0219	3.0	0.0073	0.0
$\mu = 0.80$	0.0219	3.0	0.0073	0.0
Baseline	0.0219	3.0	0.0073	0.0
<i>Nitinol loading (transformation stress)</i>				
–20%	0.0219	3.0	0.0073	0.0

Table 7.5 – continued

Variation	Max RF_2 [N]	u_2 [mm]	k [N/mm]	Δk (%)
Baseline	0.0219	3.0	0.0073	0.0
+20%	0.0219	3.0	0.0073	0.0
<i>Nitinol unloading (transformation stress)</i>				
−20%	0.0219	3.0	0.0073	0.0
Baseline	0.0219	3.0	0.0073	0.0
+20%	0.0219	3.0	0.0073	0.0
<i>Martensite Young's modulus</i>				
−10%	0.0219	3.0	0.0073	0.0
−5%	0.0219	3.0	0.0073	0.0
Baseline	0.0219	3.0	0.0073	0.0
+5%	0.0219	3.0	0.0073	0.0
+10%	0.0219	3.0	0.0073	0.0
<i>Compressive transformation stress limit</i>				
−5%	0.0219	3.0	0.0073	0.0
Baseline	0.0219	3.0	0.0073	0.0
+5%	0.0219	3.0	0.0073	0.0
<i>Martensite Poisson's ratio</i>				
−5%	0.0219	3.0	0.0073	0.0
Baseline	0.0219	3.0	0.0073	0.0
+5%	0.0219	3.0	0.0073	0.0
<i>Austenite Poisson's ratio</i>				
−5%	0.0219	3.0	0.0073	0.0
Baseline	0.0219	3.0	0.0073	0.0
+5%	0.0219	3.0	0.0073	0.0
<i>Stress/temperature slope, loading</i>				
−5%	0.0219	3.0	0.0073	0.0
Baseline	0.0219	3.0	0.0073	0.0
+5%	0.0219	3.0	0.0073	0.0
<i>Stress/temperature slope, unloading</i>				
−5%	0.0219	3.0	0.0073	0.0
Baseline	0.0219	3.0	0.0073	0.0
+5%	0.0219	3.0	0.0073	0.0
<i>Transformation strain</i>				
−5%	0.0219	3.0	0.0073	0.0
Baseline	0.0219	3.0	0.0073	0.0
+5%	0.0219	3.0	0.0073	0.0
<i>Test temperature</i>				
−5%	0.0219	3.0	0.0073	0.0
Baseline	0.0219	3.0	0.0073	0.0
+5%	0.0219	3.0	0.0073	0.0
<i>Pt–W Young's modulus</i>				
−5%	0.0218	3.0	0.007267	−0.5

Table 7.5 – continued

Variation	Max RF_2 [N]	u_2 [mm]	k [N/mm]	Δk (%)
Baseline	0.0219	3.0	0.0073	0.0
+5%	0.0220	3.0	0.007333	0.5
<i>Pt–W Poisson’s ratio</i>				
–5%	0.0219	3.0	0.0073	0.0
Baseline	0.0219	3.0	0.0073	0.0
+5%	0.0219	3.0	0.0073	0.0
<i>Austenite Young’s modulus</i>				
–5%	0.0209	3.0	0.006967	–4.6
Baseline	0.0219	3.0	0.0073	0.0
+5%	0.0229	3.0	0.007633	4.6
<i>Wire radius</i>				
–5%	0.0215	3.0	0.007167	–1.8
Baseline	0.0219	3.0	0.0073	0.0
+5%	0.0224	3.0	0.007467	2.3

Table 7.6: Sensitivity analysis and first-order uncertainty propagation for the three-point bending test case. Baseline stiffness $k_0 = 0.0073$. S_i computed via Eq. (3.2), σ_{x_i} from Table 3.1, contribution $S_i^2 \sigma_{x_i}^2$ and C_i via Eq. (3.4). Friction coefficients are excluded from the propagation (marked n/a) per Section 3.3. Parameters for which the model output showed no measurable change relative to baseline are reported with $S_i = 0$.

Category	Parameter	Baseline	Tested values	Resulting k	S_i	σ_{x_i}	$S_i^2 \sigma_{x_i}^2$	C_i (%)
Geometry	Strut width	0.05 mm	0.0525	0.0077	0.160	0.00575	8.464E-07	4.002
	Strut height	0.05 mm	0.0525	0.008267	0.387	0.01155	1.996E-05	94.35
	Wire radius	0.02 mm	0.021	0.007467	0.167	0.00058	9.383E-09	0.044
Contact / friction	Friction stent–wire	0.0	0.05, 0.10, 0.20, 0.40, 0.80	0.0073;0.007333;0.007333;0.007367;0.0074	n/a	n/a	n/a	n/a (SA only)
	Friction wire–wire	0.0	0.05, 0.10, 0.20, 0.40, 0.80	0.0073;0.0073;0.0073;0.0073;0.0073	n/a	n/a	n/a	n/a (SA only)
	Test temperature	20.5	21.525	0.0073	0	0.592	0	0.000
Nitinol material model	Austenite E	56,000	58,800	0.007633	1.190E-07	4.767	3.217E-07	1.521
	Austenite ν	0.30	0.315	0.0073	0	0.0087	0	0.000
	Martensite E	23,700	24,885	0.0073	0	6.958	0	0.000
	Martensite ν	0.30	0.315	0.0073	0	0.0087	0	0.000
	Transformation strain	0.063	0.0662	0.0073	0	0.0060	0	0.000
	σ_{LS}	635	667	0.0073	0	49.64	0	0.000
	σ_{LE}	677	711	0.0073	0	51.52	0	0.000
	σ_{US}	288	302	0.0073	0	31.75	0	0.000
	σ_{UE}	254	267	0.0073	0	34.94	0	0.000
Pt–W wire	Young’s modulus	138,000	144,900	0.007333	4.831E-09	26,560	1.647E-08	0.078
	Poisson’s ratio	0.30	0.315	0.0073	0	0.0289	0	0.000
Total propagated uncertainty $\sigma_k = \sqrt{\sigma_k^2}$							0.004599	

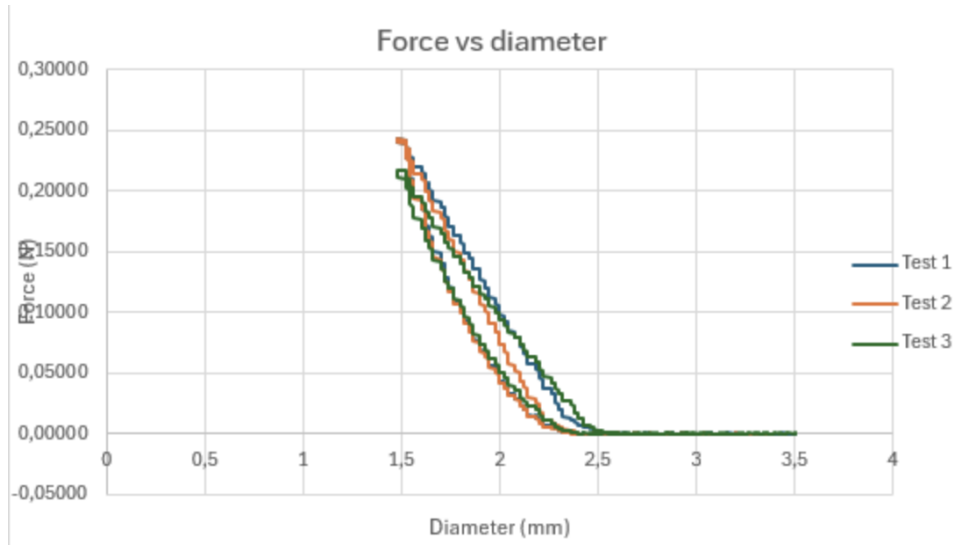


Figure 7.4: Vitro test data flat-plate compression T3

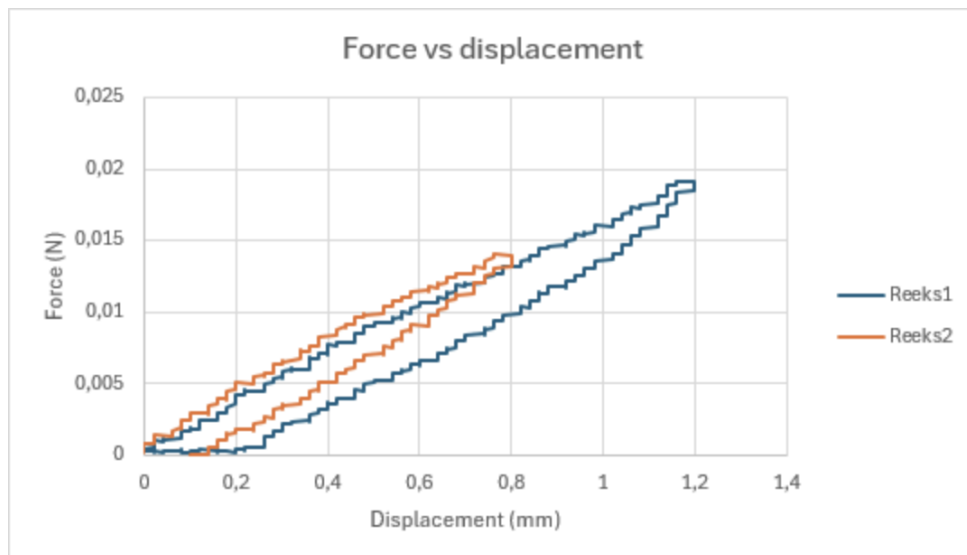


Figure 7.5: Vitro test data three-point bending compression T3

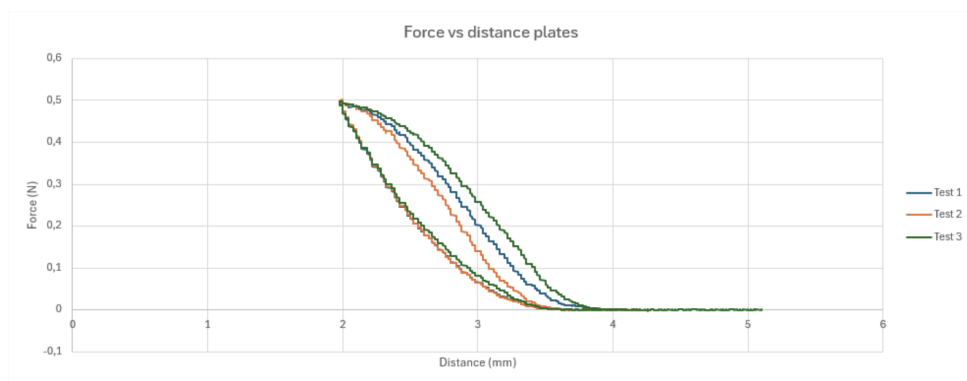


Figure 7.6: Vitro test data flat-plate compression T4

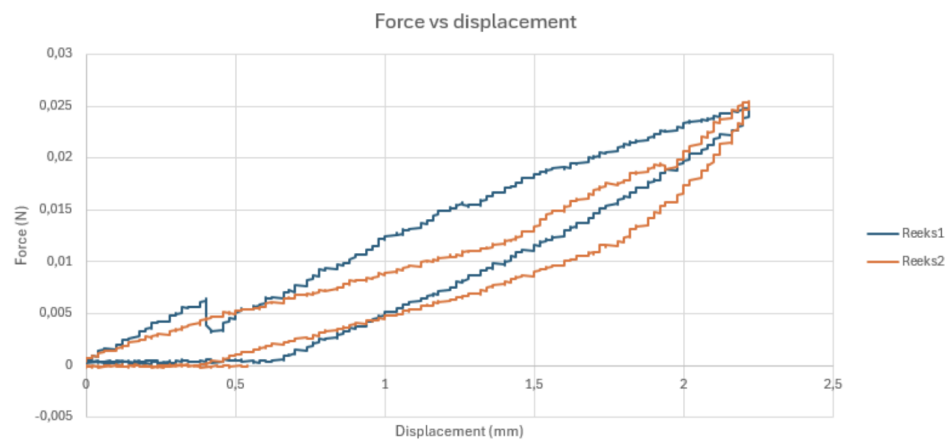


Figure 7.7: Vitro test data three-point bending compression T4