Accelerating Medical Device Verification with Digital Twin Technology

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1. Introduction

The performance of a clip can be critical to ensuring reliable and consistent operation of a medical device. It is recognised that small variations in a clip's geometric parameters, as permitted by manufacturing tolerances, can influence its force-displacement characteristics, release timing, and overall functionality. As a result, it is required that the clip's behaviour is characterised across the upper and lower limits of the tolerance bands for each key geometric feature, to ensure that the device performs as intended under all permitted dimensional conditions.

In this study, an approach is presented, in which finite element analysis (FEA) and digital twin methods are used to characterise the clip's performance across its tolerance ranges. By developing and validating a digital twin model of the clip, the influence of key geometric variables on mechanical behaviour is assessed without the need for extensive physical prototyping. The approach is intended to reduce development time and cost, provide greater insight into the clip's response, and support risk-based verification of the medical device.

2. Design Space Analysis

To provide an initial understanding of the clip's mechanical response, hand calculations were conducted using classical beam theory. The clip was modelled as a simple cantilever beam under bending, allowing estimates of deflection and stiffness to be derived from geometric and material properties. This analytical approach offered a rapid method for assessing basic trends in performance during early-stage development.

$$F = \frac{\delta E b h^3}{4L^3}$$

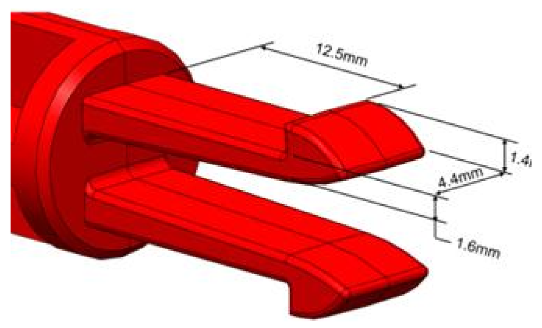


Figure 1: Classical beam bending hand calculation, where F= Force to deflect (N), δ= Deflection (1.4mm), E= Youngs Modulus (2400MPa) b= width of clip (4.4mm), h=thickness of clip (1.6mm), L=Length of clip (12.5mm).

The analysis revealed that clip thickness has the greatest impact on bending stiffness due to its cubic influence and small nominal size, while clip length, despite a similar cubic effect, has less impact because of its larger nominal dimension.

A Monte Carlo simulation with 5,000 samples was used to perform a statistical tolerance analysis, accounting for dimensional variability within specified tolerance ranges (assuming a normal distribution and Cp of 2). This approach provided a realistic prediction of force distribution, offering a more accurate view of performance variability during production, as shown in Figure 3.

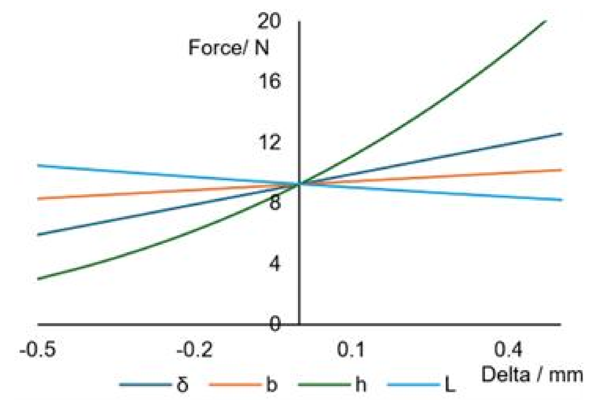


Figure 2: Illustration of variable sensitivity

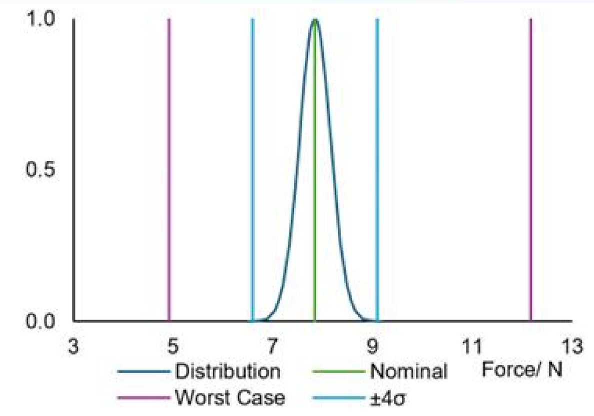


Figure 3 (Bottom): Illustration of tolerance analysis using Monte Carlo simulation

The analysis was confined to simplified bending of an idealized geometry, without accounting for localized geometric features or the dynamic evolution of contact forces during relatching. Accurate representation of the relatching force was not feasible, as both its direction and application point vary throughout the motion, introducing nonlinear interactions beyond the reach of analytical techniques. These limitations necessitated the implementation of a more advanced finite element–based digital twin modelling framework.

3. Physical Testing and Digital Twin Tuning

A simplified two-dimensional (2D) model of the clip was developed, in which one of the two identical clip arms was represented. This approach was selected to reduce computational complexity while capturing the key bending and latching behaviours of the component. The latching face of the model was fixed in position. The clip was displaced relative to this surface to simulate the engagement and relatching process during device operation.

The model was created in SolidWorks Premium FEA 2024, incorporating nonlinear contact and large displacement effects to simulate the clip-latch interaction. Boundary conditions and loading sequences replicated real-world clip engagement. To validate the simulation, physical clip samples were tested under matching displacement-controlled conditions using a tensile testing machine. Force-displacement curves from both tests were compared, and discrepancies were resolved by iteratively refining the material model. Although standard polymer properties were available, adjustments accounted for geometry-specific effects and moulding-induced anisotropy.

Figure 5 shows the calibrated model, which closely matches experimental data and serves as a validated baseline for further simulations.

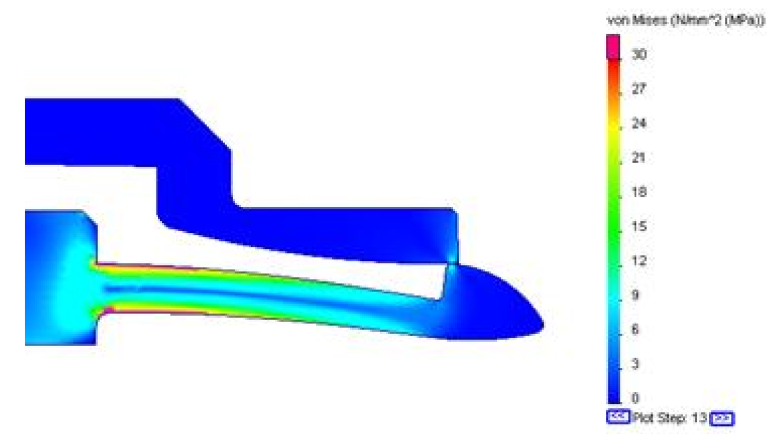


Figure 4: Simulation result showing von Mises Stress

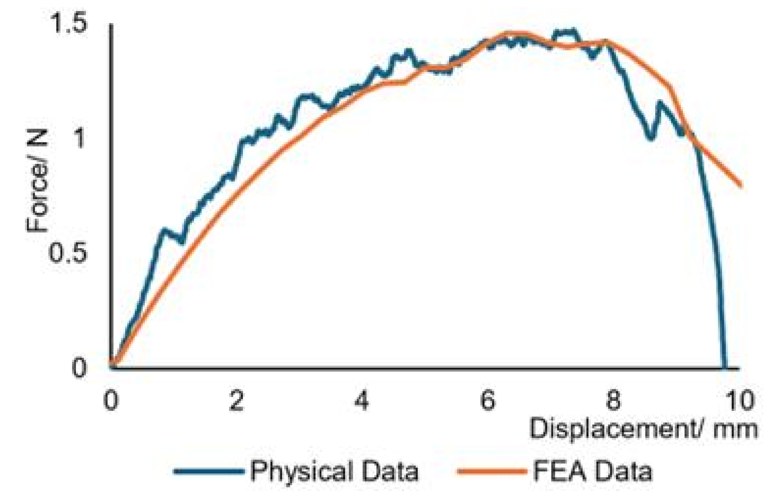
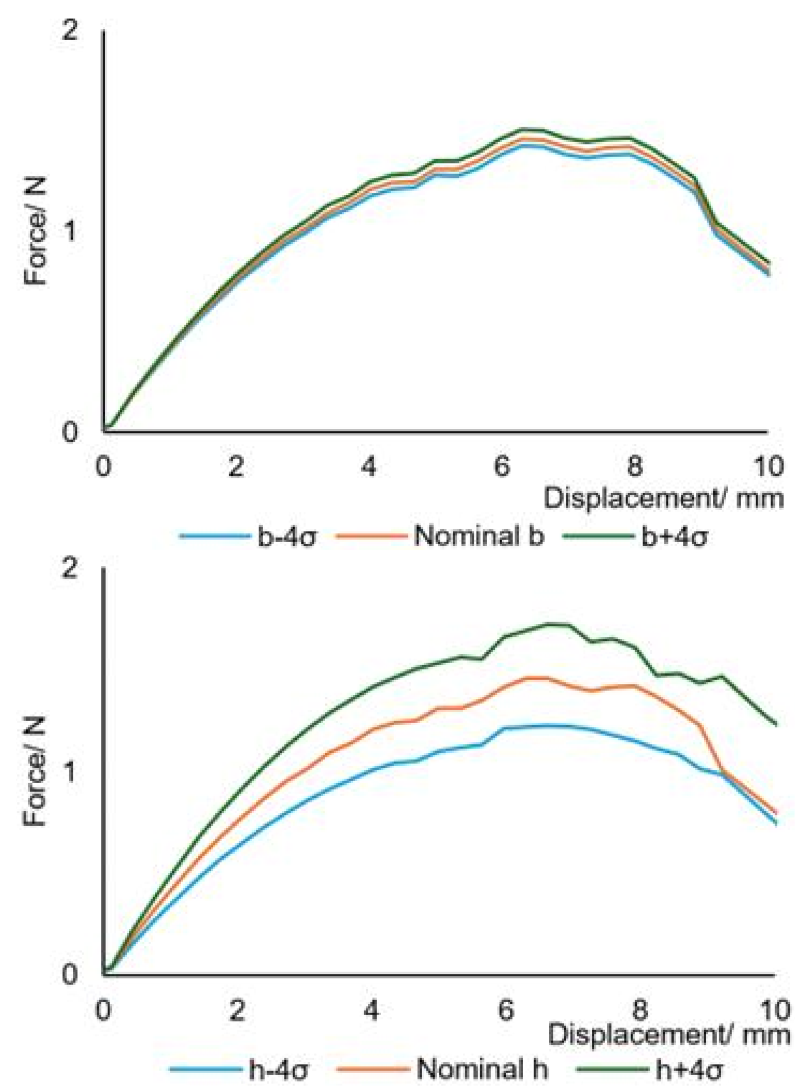


Figure 5: Physical test data and tuned FEA data

4. Results

The validated finite element analysis (FEA) model was used to conduct a series of virtual experiments in which the five key geometric parameters were varied individually to their upper and lower tolerance limits. For each variation, force-displacement curves were generated to assess the clip's bending stiffness, maximum force required for deflection, and the force profile during relatching.



Figures 6 and 7: Results for width (b) and thickness (h) at upper and lower statistical limits

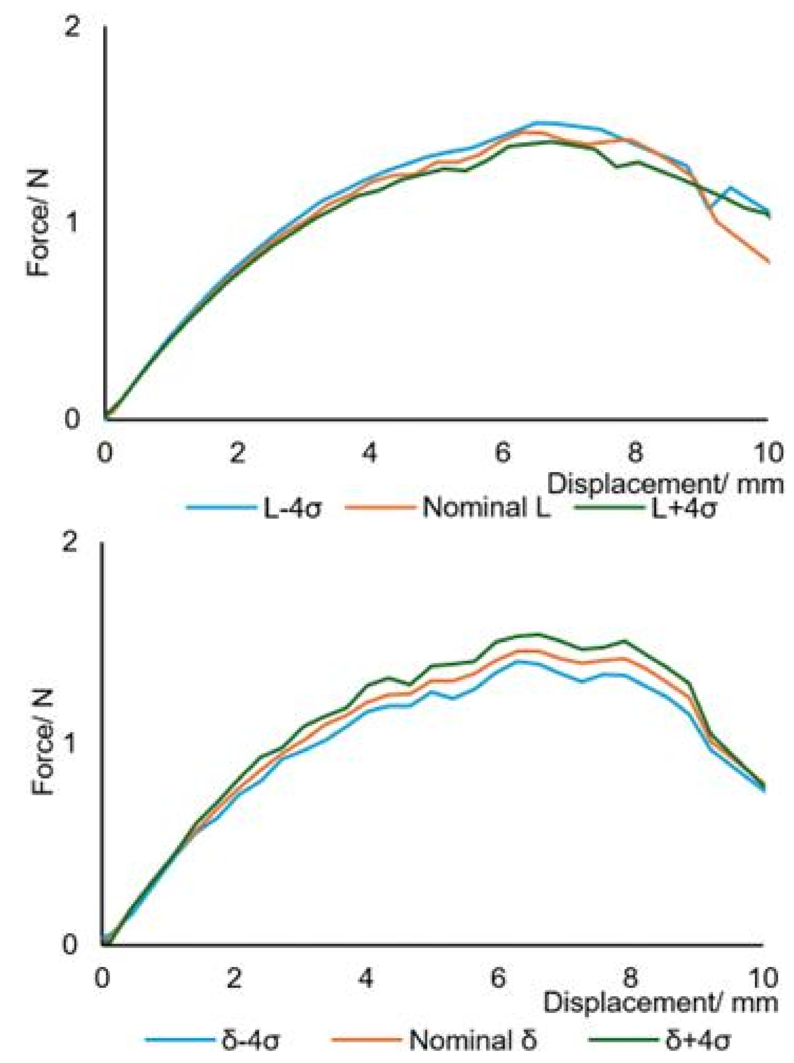


Figure 8 and 9: Results for length (L) and deflection (δ) at upper and lower statistical limits

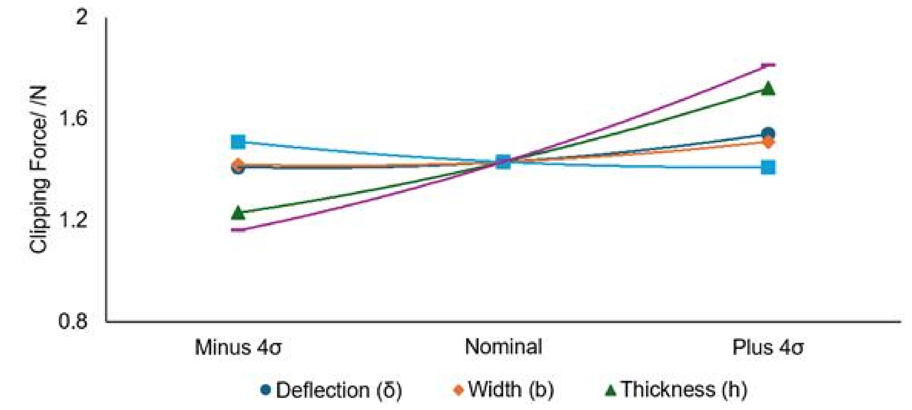


Figure 10: Summary of simulation results at ±4σ tolerance limits

5. Discussion & Conclusion

The study shows how clip performance is highly sensitive to specific geometric parameters, particularly thickness, which showed the greatest variation in peak force and stiffness. While clip length also affects stiffness significantly, its larger nominal value makes it less sensitive to tolerance changes. Parameters like deflection and width had moderate impact.

Using simulation rather than physical prototyping offers major benefits: it allows extensive testing of dimensional variations without costly tooling, enabling faster design exploration and reducing waste. By identifying which parameters most affect performance, designers can focus on refining critical features, speeding up development and lowering costs.

However, the study notes that simulation has limitations. While effective for the simplified 2D model used here, more complex parts may still require physical testing to ensure accuracy. Thus, simulation-based methods should be applied with consideration of their ability to realistically capture actual behaviour.

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