Doctoral Dissertation
PhD program in Bioengineering and Medical-Surgical Sciences (36th Cycle)

# Combined *in vitro – in silico* approaches to standardise the orthopaedic plate performance testing

## Summary


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# Summary


Fatigue behaviour is a crucial aspect of mandatory mechanical tests for regulatory purposes, designed to determine the load at which the plate withstands under a specific number of cycles, known as the *runout* condition. These mechanical tests are typically conducted according to the ASTM F382 standard, which employs a four-point bending test setup to evaluate the cyclic bending fatigue performance of the bone plate. These test campaigns require considerable financial outlay and have lengthy execution times. In addition, the determination of the minimum level of *in vivo* performance that the plate must fulfil remains an unresolved issue, often addressed by the direct comparison with predicate devices. However, no study has been conducted to support the experimental testing necessary for the certification of bone plates.

Thus, this doctoral dissertation focuses on the testing of bone plates, introducing a systematic framework that combines analytical, *in silico*, and *in vitro* approaches provide a comprehensive rationale for supporting bone plate testing and guiding the regulatory process to achieve CE marking.

The first part of this work seeks to establish a method for analytically calculating the maximum stress of any commercial bone plate. To achieve this, *in silico* Design of Experiments (DOEs) were implemented to create user-friendly surrogate polynomial models that extend the range of theoretical formulations for determining the stress concentration factor (SCF), accounting for the typical dimensions of commercial bone plates, including those not previously covered in existing literature. A custom MATLAB function, named *'polyKt'*, was developed to compute the SCF of a plate, given inputs for thickness, width, hole diameter, and optionally, the radius of curvature. If the latter is not provided, the function defaults to a custom SCF for a flat rectangular plate.

Eleven bone plates awaiting certification, each with unique cross-sections, were selected to test the surrogate models. A significant variation (up to 18%) in results

was observed between the model for flat rectangular plates and the one accounting for cross curvature, especially for smaller curvature radii, underscoring the necessity of considering curvature when calculating SCF.

The second part of this work presents an analytical framework for assessing the maximum bending moment of a bone plate within the ASTM F382 setup, providing guidance to speed-up the identification of the *runout* load for regulatory testing. A custom MATLAB function, named *'find_critical_section'*, was implemented to identify the section with the lowest flexural strength modulus of any plate, automatically extract the primary geometric characteristics. The analytical prediction of the maximum bending moment was derived starting from the ultimate strength and geometry of the plate.

To ensure the reliability of the analytical predictions, cross-checks and validations were conducted through *in silico* models and experimental tests in accordance with ASTM F382 standard. The eleven selected plates were subjected to a comprehensive testing campaign following the standard protocols to evaluate their static and fatigue bending properties. Therefore, the experimental force-displacement curves obtained were compared with those derived from the finite element (FE) analysis to validate the *in silico* models. The stress results obtained from the FE analysis were then used to verify the analytical outcomes for predicting the theoretical maximum bending moment within the critical section of the bone plate. Lastly, the predicted maximum bending moments were compared with those identified experimentally using the standard procedure to evaluate the potential time savings achievable by directly applying the analytical framework.

Results demonstrated promising predictive ability, with coefficients of determination above 0.95 in the *runout* condition. By applying the proposed methodology on the selected plates before the standard tests, it was estimated that 27 specimens and approximately 230 test hours could have been saved, contributing to a significant cost reduction for the manufacturer.

The third part of this work proposes a rationale that combines two different approaches, analytical and *in silico*, to establish the minimum performance criteria that the plate must satisfy under *in vivo* loads. Specifically, the femoral bone was considered the anatomical reference region. In the implanted condition, analytical results exhibited significant fluctuations when compared to the *in silico* analysis, highlighting their importance in complex loading scenarios. To address this issue, a digital platform called *'e-MPLATE'* was developed to automate the creation of FE models and the analysis of results, providing a streamlined approach to support the regulatory process for CE marking.