PREDICTING BONE PLATES RUNOUT USING TENSILE STRENGTH AND GEOMETRIC PROPERTIES TO REDUCE REGULATORY TESTING

Federico Bologna (1,2), Alberto Audenino (1,2), Mara Terzini (1,2)

1. Department of Mechanical and Aerospace Engineering, Politecnico di Torino, Turin, Italy
2. Polito^{BIO}Med Lab, Politecnico di Torino, Turin, Italy

Introduction

Mechanical tests on bone plates are mandatory for regulatory purposes and, typically, the ASTM F382 standard [1] is used, which involves a four-point bending test setup to evaluate the bending stiffness, structural stiffness, bending strength, and cyclic bending fatigue performance of the bone plate. These test campaigns require a considerable financial outlay and long execution times; therefore, an accurate prediction of experimental outcomes can reduce test runtime with beneficial costs cut for manufacturers [2].
Hence, an analytical framework is here proposed for the direct estimation of the maximum bending moment of a bone plate under fatigue loading, to guide the identification of the runout load for regulatory testing.

Methods

A complete test campaign was carried out according to ASTM F382 to evaluate the static and fatigue bending properties of eleven bone plates pending certification. The bone plates involved in the study were designed for different anatomical regions and manufactured from steel and titanium alloys. An analytical prediction of the maximum bending moment was then implemented starting from the ultimate tensile strength (σ_{UTS}) specified in the raw material certification and the plate geometry. The section of each plate with the minimum moment of inertia in the bending direction was detected with an automatic procedure. In this section, the width and thickness of the plates, as well as the diameter of the screw hole were automatically extrapolated. Through these dimensions, Peterson's stress concentration factors [3] were determined to account for the presence of the screw hole. A fatigue limit equal to $0.5\sigma_{UTS}$ [4] was applied for all bone plates. The Goodman and Gerber failure criteria [5] were implemented to calculate the mean stress effect due to an *R-ratio* equal to 0.1 (the minimum of the sinusoidal waveform was computed as 10% of the maximum stress), as required by the standard for the testing condition. The maximum bending moment was calculated for each bone plate using both failure criteria, defining the range of the runout moment prediction. Stress-life (S-N) diagrams were therefore estimated to additionally compare the experimental loads above the runout with the analytical prediction; Basquin's equation [5] was applied to calculate the alternating stress from the experimental number of cycles. The resulting moments were finally categorized into three intervals: (a) plastic range, (b) elastic range, and (c) runout condition in order to verify the prediction accuracy of the analytical approach.

Results

In the runout condition, most experimental values fall within the predicted range outlined by the Goodman and Gerber criteria (Figure 1). Maximum bending moments calculated with the Goodman approach were considered as the lower limit of the range prediction: eight out of eleven plates met this expectation. On the other hand, all tested bone plates showed a maximum bending moment below the limit estimated with the Gerber criterion.

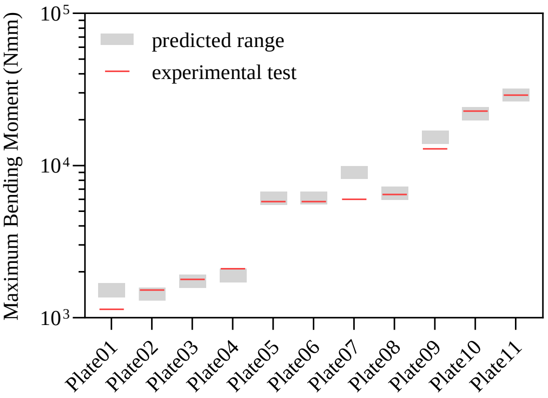

Figure 1: Experimental (red lines) and predicted (grey boxes) maximum bending moments for each bone plate.

Lastly, the predicted values were compared with experimental results (Table 1): while the predictive ability drastically decreased, as expected, when the yield strength of the material was exceeded, in the elastic range, as well as in the runout condition, the prediction performance has shown a significant improvement.

R^2	Plastic	Elastic	Runout
Goodman	0.4089	0.9604	0.9694
Gerber	0.6183	0.9716	0.9549

Table 1: R^2 coefficients in plastic, elastic, and runout conditions for the Goodman and Gerber criteria.

Discussion

The developed analytical framework exhibited a promising predictive ability, with potential impact in reducing the experimental tests needed for the CE marking of bone plates and could represent a guideline to avoid the underestimation of the runout load.

References

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