ANALYTICAL MODEL FOR THE MECHANICAL PERFORMANCE PREDICTION OF A BONE-PLATE IMPLANT.

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Introduction

Every osteosynthesis device needs to guarantee the mechanical success of the implant: ASTM F382 is the latest and most widely used test standard for metallic bone plates [1]. ASTM standards establish a test methodology and define the setup condition, but insufficient knowledge is available to predict the success or failure of fixation devices in the first few days after surgery. The main purpose of this work is to develop an analytical procedure to determine the minimum level of performance of a generic bone plate and simplify the experimental tests campaign for regulatory purposes.

Methods

Quasi-static and dynamic four-point bending tests were performed as reported in the ASTM standard to determine the plate fatigue life and the related maximum bending moment. The maximum von Mises stress in the ASTM setup was calculated, and then validated through a Finite Element (FE) model, with a first analytical model (Figure 1a), informed by a parametric FE model (FEM-SCF) able to determine the stress concentration factor (SCF) induced by the hole plate longitudinal curvature. A second analytical model of the implanted plate was created starting from the experimental failure section of the plate (second-order tetrahedral mesh with a size of 1 mm). The femur was modelled with cortical bone only, considered as a rigid body, while the fractured bone was inserted in correspondence with the free length of the plate through a linear spring (stiffness equivalent to 5 % of the axial stiffness of femur cortical bone). Loads measured during normal walking were applied to the femur, according to Bergmann et al., 2001 [2]. The analytical model was finally validated with a FE model of the plate-femur assembly (Figure 1b).

Results

The runout load obtained through the experimental tests was equal to 22800 Nmm. In the ASTM setup, the analytical model of the plate determined maximum equivalent stress equal to 1029 MPa (the standard SCF [3] was increased by 2.25 times because of the curvature, as obtained from FEM-SCF results), while the FE model showed a peak of 1025 MPa in the same zone where the failed specimens exhibited fracture (Figure 1a). The maximum analytical stress calculated on the critical section of the implanted plate was reported in Figure 1b and it was equal to 780 MPa (error with respect to FE model < 5 %).

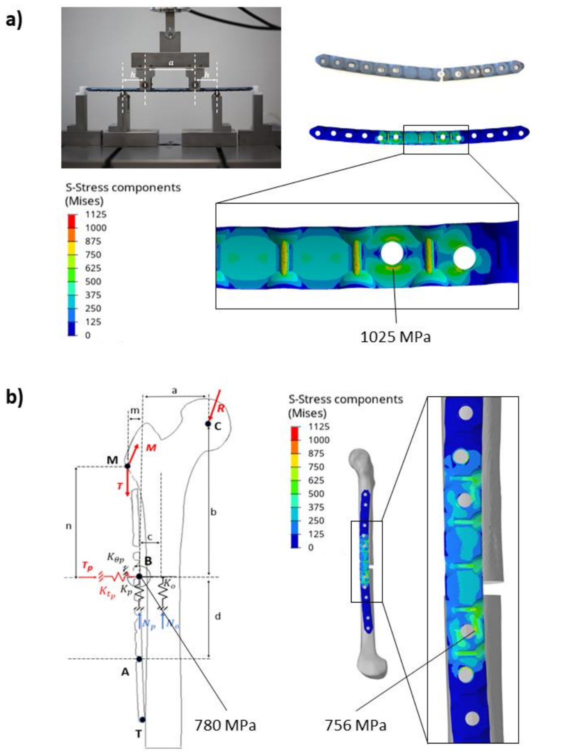

Figure 1: a) Four-point bending setup, fractured zone of a failed specimen, and related FE model results of tested area for model validation; b) analytical model of the femur-plate construct and equivalent stress distribution on the implanted plate.

Discussion

The proposed procedure allows to avoid comparison with a predicate device and reduce the times involved in the experimental tests for regulatory purposes. In addition, the parametrical study for the SCF determination of a curved plate could be extended in order to identify the minimum performance of a wide range of fixation devices.

References

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