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Comparative analysis of international standards for the fatigue testing of posterior spinal fixation systems

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Abstract

BACKGROUND CONTEXT: Preclinical evaluation of the long-term reliability of devices for lumbar fixation is a mandatory activity before they are put into market. The experimental setups are described in two different standards edited by the International Organization for Standardization (ISO) and the American Society for Testing Materials (ASTM), but the evaluation of the suitability of such tests to simulate the actual loading with in vivo situations has never been performed.

PURPOSE: To calculate through finite element (FE) simulations the stress in the rods of the fixator when subjected to ASTM and ISO standards. To compare the calculated stresses arising in the same fixator once it has been virtually mounted in a physiological environment and loaded with physiological forces and moments.

STUDY DESIGN: FE simulations and validation experimental tests.

METHODS: FE models of the ISO and ASTM setups were created to conduct simulations of the tests prescribed by standards and calculate stresses in the rods. Validation of the simulations were performed through experimental tests; the same fixator was virtually mounted in an L2-L4 FE model of the lumbar spine and stresses in the rods were calculated when the spine was subjected to physiological forces and moments.

RESULTS: The comparison between FE simulations and experimental tests showed good agreement between results obtained using the two methodologies, thus confirming the suitability of the FE method to evaluate stresses in the device in different loading situations. The usage of a physiological load with ASTM standard is impossible due to the extreme severity of the ASTM configuration; in this circumstance, the presence of an anterior support is suggested. Also, ISO prescriptions, although the choice of the setup correctly simulates the mechanical contribution of the discs, seem to overstress the device as compared with a physiological loading condition. Some daily activities, other than walking, can induce a further state of stress in the device that should be taken into account in setting up new experimental procedures.

CONCLUSIONS: ISO standard loading prescriptions seems to be more severe than the expected physiological ones. The ASTM standard should be completed by including some anterior supporting device and declaring the value of the load to be imposed. Moreover, a further enhancement of standards would be simulating other movements representative of daily activities different from walking.

Keywords: Fatigue test; Spinal fixator; Finite element method; International standard; Validation

FDA device/drug status: Approved (Ti6Al4V spinal fixation system).

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Introduction

Preclinical evaluation of the long-term reliability of implantable devices has become a mandatory activity to assess the actual effectiveness and safety of the chosen therapy. In particular, devices used in orthopedic and spinal surgery normally undergo lengthy and expensive fatigue tests before they are put onto the market [1].

Identification of the correct experimental procedure for predictive mechanical behavior of the device once it is implanted in the patient is not a trivial activity. The experimental setup must also be sufficiently representative of the physiological environment in order to take into account all the contributions of the anatomical structures in the final state of stress in the device. At the same time, the experiment must be simple enough to ensure the repeatability of the procedure [2,3].

In the case of spinal fixators, fatigue issues are generally investigated in the laboratory following procedures established by international standards: the American Society for Testing Materials (ASTM) F 1717 (which was the first one published and has been recently revised in 2012) and International Organization for Standardization (ISO) 12189 (published in 2008) describe two different setups to run tests able to predict the long-time reliability of a posterior spinal fixation construct.

The ASTM standard prescribes an experimental model (Fig. 1) that mimics a segment composed of two functional spinal units, including a vertebrectomy in the center. Vertebrae are substituted with polyethylene (PE) blocks and the geometry, dimensions, and position of the screws in such blocks are precisely described in the standard. The ASTM standard for the fatigue test indicates the run-out number of cycles (5 Mcycles) but leaves the individuation of the load to be applied as the highest permitted to reach the run-out.

The experimental setup suggested by the ISO standard is similar to the ASTM one when related to a spinal segment made of three vertebrae (Fig. 1). But in this case, all the vertebrae are present and the intervertebral discs are simulated by interposition between each couple of PE blocks of three calibrated springs whose total stiffness should represent the stiffness of the disc. Moreover, the ISO standard indicates both the run-out (5 Mcycles) and the load to be applied (2,000 N for applications in the lumbar spine).

In the literature, there is no consensus on how the procedure for the fatigue test, run according to ASTM configuration, must be completed. When choosing the different parameters, in terms of the load to be applied, different values have been proposed ranging from 163 N [4] to 700 N [5] (generally the ratio between minimum and maximum applied load is equal to 0.1). Considerations of the

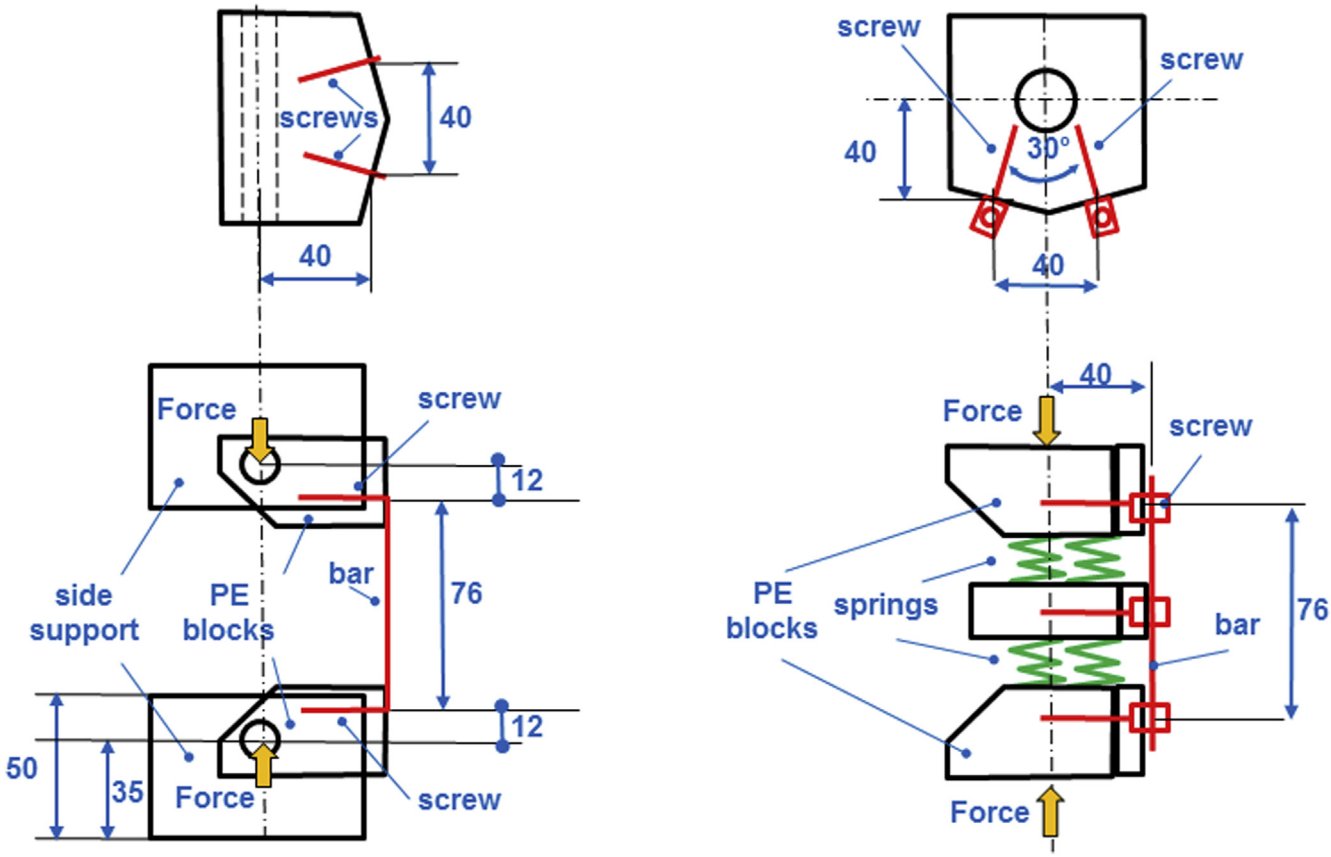

Fig. 1. Experimental setup according to American Society for Testing Materials (ASTM) standard (Left) and according to International Organization for Standardization (ISO) standard (Right).