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Technical Report

Comparative analysis of international standards for the fatigue testing of posterior spinal fixation systems: the importance of preload in ISO 12189

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Abstract

BACKGROUND CONTEXT: Preclinical evaluation of the mechanical reliability of fixation devices is a mandatory activity before their introduction into market. There are two standardized protocols for preclinical testing of spinal implants. The American Society for Testing Materials (ASTM) recommends the F1717 standard, which describes a vertebrectomy condition that is relatively simple to implement, whereas the International Organization for Standardization (ISO) suggests the 12189 standard, which describes a more complex physiological anterior support-based setup. Moreover, ASTM F1717 is nowadays well established, whereas ISO 12189 has received little attention: A few studies tried to accurately describe the ISO experimental procedure through numeric models, but these studies totally neglect the recommended precompression step.

PURPOSE: This study aimed to build up a reliable, validated numeric model capable of describing the stress on the rods of a spinal fixator assembled according to ISO 12189 standard procedure. Such a model would more adequately represent the *in vitro* testing condition.

STUDY DESIGN: This study used finite element (FE) simulations and experimental validation testing.

METHODS: An FE model of the ISO setup was built to calculate the stress on the rods. Simulation was validated by comparison with experimental strain gauges measurements. The same fixator has been previously 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 the FE predictions and experimental measurements is in good agreement, thus confirming the suitability of the FE method to evaluate the stresses in the device. The initial precompression induces a significant extension of the assembled construct. As the applied load increases, the initial extension is gradually compensated, so that at peak load the rods are bent in flexion: The final stress value predicted is thus reduced to about 50%, if compared with the previous model where the precompression was not considered.

CONCLUSIONS: Neglecting the initial preload due to the assembly of the overall construct according to ISO 12189 standard could lead to an overestimation of the stress on the rods up to 50%. To correctly describe the state of stress on the posterior spinal fixator, tested according to the ISO procedure, it is important to take into account the initial preload due to the assembly of the overall construct.

Keywords: ASTM F1717; Fatigue testing; Finite element; ISO 12189; Precompression; Preload; Standard; Strain gauge

Introduction

Despite the important steps forward made in the last decades in the field of computer simulation, experimental testing represents a fundamental step to assess the mechanical properties of any orthopedic implant and to obtain the approval for their introduction into clinical use [1].

Two test methods are currently available on posterior spinal fixators and stabilization devices. The American Society for

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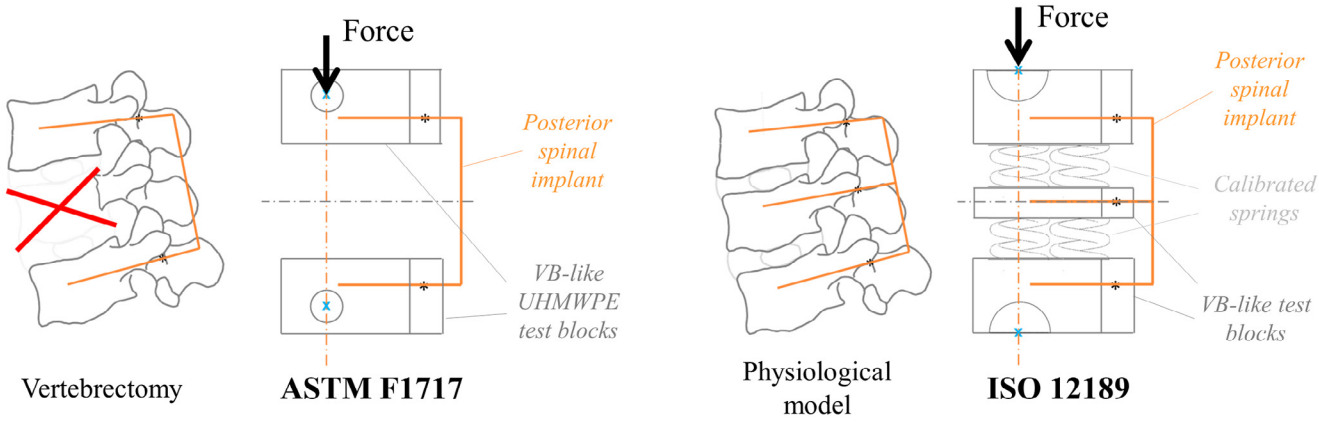

Fig. 1. Experimental setups according to the American Society for Testing Materials (ASTM F1717) standard (Left) and according to the International Organization for Standardization (ISO 12189) standard (Right).

Testing Materials (ASTM) F1717 standard [2] recommends the use of ultra-high-molecular-weight polyethylene (UHMWPE) vertebral body-like test blocks, which makes possible spinal implant constructs that reproduce a *worst-case* vertebrectomy model (Fig. 1A). The International Organization for Standardization (ISO) 12189 standard [3] prescribes to replicate a physiological anterior support model using three calibrated springs to reproduce the compressive behavior of the lumbar intervertebral disc (Fig. 1B). Although the implemented vertebrectomy scenario of ASTM F1717 guarantees a high safety coefficient for the tested implant, the ISO 12189 anterior support model can offer some important advantages. In fact, such a configuration is more representative of the effective clinical use of rigid stabilization devices, which are usually combined with an anterior support (eg, intervertebral cages, bone grafts) to achieve fusion of a specific spine segment. Moreover, the ISO anterior support model also allows for testing of flexible and dynamic stabilization devices, which are designed to permit more physiological load sharing with the anterior column and which could not be tested in a vertebrectomy scenario due to an excessive deflection.

Because experimental tests are very expensive in terms of time and costs, numeric models can be very useful. In particular, finite element (FE) represents a very effective method in investigating the complete stress (or strain) field arising on the implant when loaded in a specific framework. Validation, that is, the comparison between the values of a specific parameter predicted with the FE method and the corresponding experimental measurements, is a key step in ensuring the accuracy and reliability of the numeric results. Moreover, a validated numeric model describing the standard setup may represent a reliable tool to speed up the design process of any new device directly in a framework representative of the final test conditions.

For this purpose it is important to describe the standard setup conditions in the most proper way. Only a few studies have tried to describe the international standards currently available for the preclinical evaluation of posterior spinal fixators. In an earlier study, Mosnier used a very simple description of the implant using beam elements [4]; however no experimental validation was performed. More recently, Villa and colleagues [5] compared the setups proposed by ASTM F1717 [2] and ISO 12189 [3] standards with a more realistic loading and boundary condition represented by an L2–L4 spine segment; although they used an accurate representation of the implant with solid elements, some limitations were highlighted, which dealt particularly with the initial preload arising on the fixator due to the assembly of the ISO 12189 construct [3]. Thus, the aims of the present work are (1) to build up a validated FE model capable of describing the stress on the rods of a spinal fixator assembled according to ISO 12189 standard; (2) to compare it with a previous model of the ISO setup (where the preload effect was not taken into account); and (3) to comment on the ISO testing condition, considering a physiological L2–L4 spinal numeric model loaded under more realistic loading conditions. The ASTM and ISO models were already described by Villa and colleagues in an earlier study [5].

Materials and methods

FE model of the experimental setup

To simulate the initial precompression step according to ISO suggestions [3], the FE model of ISO 12189 experimental setup described by Villa and colleagues [5] was modified, so that the distance between polyethylene blocks was 24 mm, whereas the initial length of the spring was kept to be equal to 25 mm (Fig. 2A). The model will be called ISP herein (ISO FE model which takes into account for the effect of Precompression). The simulations were run in ABAQUS/Standard 6.10 (Dassault Systèmes Simulia Corp., Waltham, MA, USA), assuming geometric non-linearity and considering the following steps:

- *Precompression*: A plane was used to compress the springs down 1 mm to allow them fit among the tests blocks (Fig. 2B). Contacts were defined between the springs and the central test block.