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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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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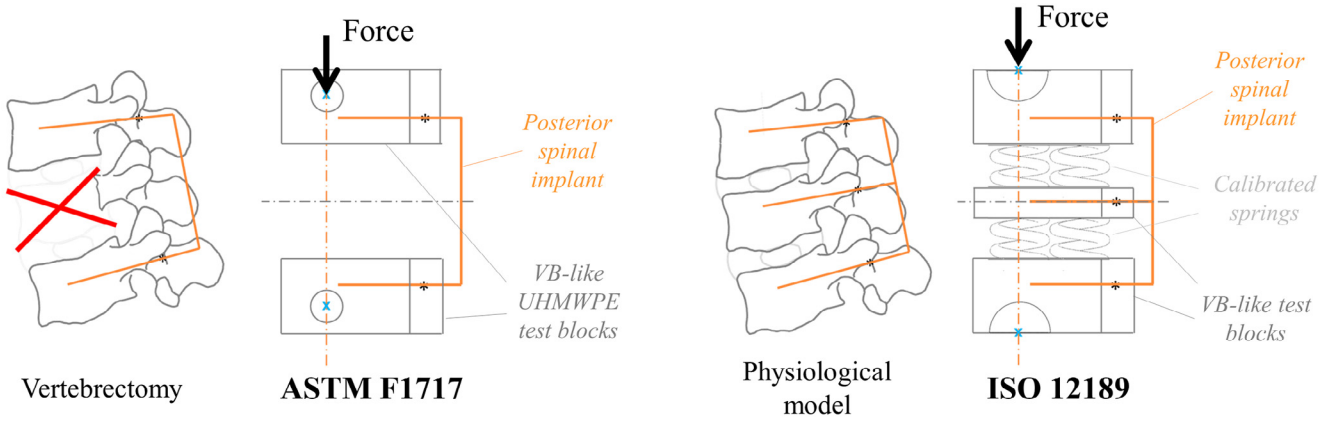

Fig. 1. Experimental setups according to the American Society for Testing Materials (ASTM F1717) standard (Left) and according to the International Organization for Standardization (ISO 12189) standard (Right).

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.

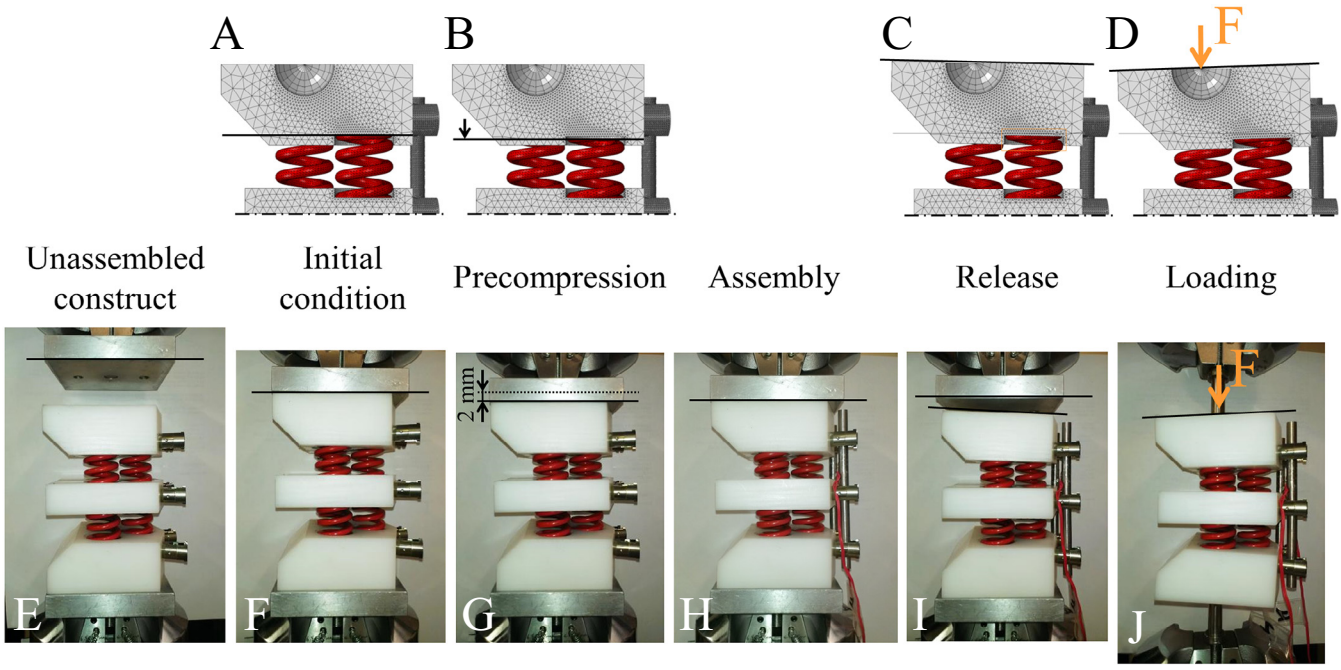

Fig. 2. Steps simulated with the numeric model (Top): initial condition (A), 1 mm springs' precompression using a plate (B), springs' release (C) and loading up to 2000 N (D). Steps followed in the experimental tests (Bottom): unassembled construct (E), initial condition (F), 2 mm precompression between two plates (G), tightening of the interconnection mechanisms (H), release of the assembled construct (I), loading up to 2000 N (J).

- *Release*: The rigid plane surface was moved upward so that the superior part of the springs was allowed to gradually come into contact with the inferior surface of the upper polyethylene block (Fig. 2C).
- *Loading:* Vertical forces of 600 and 2000 N were applied using a spherical rigid surface, which simulates the spherical pin used to experimentally apply the vertical load (Fig. 1D).

The maximum von Mises stress value (σ_{VM}) on the rods was calculated and its location with respect to the anatomical axis was determined according to the definitions reported by Villa and colleagues [5].

Moreover, these results have been compared and discussed with a previous model of the ISO setup (IS according to Reference 5), in which the preload effect was not taken into account, and that of a physiological L2–L4 spinal numeric model (MO1 according to Reference 5) loaded under more realistic conditions.

Experimental validation

By assembling an STL spinal fixator provided by the manufacturer (2B1 srl, Milan, Italy), the experimental validation of the FE model was performed according to ISO standard [3].

Two uniaxial linear strain gages (KGF-02–120-C1-11; Kyowa Electronic Instruments Co. Ltd, Tokyo, Japan) were glued to the rods, with their long axis aligned with the longitudinal axis of the rods. The first one was positioned posteriorly (P) on the left rod, whereas the second one was positioned anteriorly (A) on the right rod. Both strain gauges (SGs) were placed on the portions of the rods just between the superior and the central test blocks. SGs were connected in half-bridge Wheatstone configuration and connected to an HBM Spider 8 (HBM, Darmstadt, Germany) amplifier system, as already described [5].

The whole construct was mounted on a servohydraulic MTS 858 (MTS Systems, Minneapolis, MN, USA) testing machine equipped with a 15-kN load cell, as per the following steps:

- Zeroing of the signal measured by the SGs glued on the unloaded rods;
- *Precompression*: The unassembled construct (Fig. 2E) was loaded between two parallel plates until an overall vertical displacement of 2 mm was reached (Fig. 2F and G), according to ISO 12189 indications [3];
- Engaging of the rods on screw head and tightening of the nuts (Fig. 2H);
- *Release* of the assembled construct: The *release strain* values on the rods were measured at this time (Fig. 2I);
- *Loading*: The assembled construct was subjected to a cyclical compressive force, loading and unloading between 600 and 2000 N until repeatability of the measurement was attained (Fig. 2J). The strain values coming from the transducer during the test were sampled at a frequency of 20 Hz; the mean value and standard deviation of the strains measured during the last five cycles of the tests were calculated upon release, at 600 and 2000 N. To take into account the repeatability of

assemblage procedure, these steps were repeated three times, keeping always the same tightening sequence.

The strain values predicted by the FE model were validated by comparison with experimental measurements in the same regions where the SGs were applied.

Results

The results of the experimental measurements, as well as the numeric predictions, both in terms of overall stiffness of the construct and strain values on the rods, are collected in the Table. Of concern, the FE model underestimates the stiffness value (K) of the assembled construct as measured experimentally with a percentage difference of about 7% (Table).

In regard to the repeatability of the strain measurements on the spinal rods, the experimental values show a relatively high standard deviation (Table). The percentage deviation of the measurements from the average measured value is about 16.3% posteriorly and 35.1% anteriorly upon release, whereas at 2000 N it is 13.3% posteriorly and 6.5% anteriorly.

Given these observations, the predicted and measured strains demonstrate some differences, especially for the posterior part of the rod; the predicted value overestimates the experimental range of values of 11.7% after release and 17.1% at peak load. Differences on the anterior portion of the spinal rod demonstrate an overestimation of 64.8% after release and only a slight underestimation of 5.5% at 2000 N.

Despite these quantitative differences, both methods allow for highlighting some key points.

The precompression significantly influences the von Mises stress value on the spinal implant and the springs release induces an initial extension on the rods; the anterior and posterior areas of the rod undergo a tractional and compressive stress, respectively (Table). Increasing the applied vertical load, the resultant bending moment in the rods increases and gradually compensates for the extension due to precompression. At 2000 N the rods are bent in flexion, and the anterior and posterior areas of the rod undergo a compressive and tensional stress, respectively (Table). The final stress value predicted with the ISP model under compression is thus reduced to about 50%, if compared with the IS model where the preload effect was not taken into account (Fig. 3).

Discussion

To correctly describe the experimental test setup according to ISO 12189 [3], we took into account the initial precompression step. However, it is not so clear why this step has been introduced in the standard procedure. On the one hand, it may guarantee the stability of the overall construct, avoiding any movements of the springs within their housing on the UHMWPE blocks. On the other hand, it may be necessary not to completely unload the rods while decreasing the applied load from 2000 N to 600 N.

However, this initial precompression has a very significant effect on the stress applied on the rods at 2000 N. Our results demonstrate that neglecting this step could lead to a significant overestimation of the stress on the device. In fact, the 2-mm precompression of the whole construct before tightening the nuts of the interconnection mechanisms reduces the von Mises stress value to about 50% if compared with the model (IS) where the preload effect was neglected (Fig. 3). Moreover, this result is also confirmed by experiments; in fact, when comparing our measurement for the posterior SG at 2000 N (1.146,9±152,3 μstrain) with the corresponding value (2.088,7 μstrain) reported for ISO standard in a previous publication [5], a percentage difference of −44.8% can be obtained. Discrepancies between experimental and numeric results may probably be due to the intrinsic inaccuracies of the SG technique (eg, difficulties in maintaining the rods exactly in the same position during consecutive tests after disassembling and reassembling the construct each time) or to simplification of the FE model (eg, simplified spinal fixator design, simplified loading condition). Despite these differences, the results coming from both approaches support our idea that precompression plays an important and non-negligible effect on the stress on the spinal rod. Additionally, considering the comparative purpose of our study, the FE model described here is able to predict such an effect.

This finding allows for a better comparison between the state of stress arising in the rods of a posterior spinal fixation system caused by different experimental setups [2,3] and a more physiological environment that also takes into account the contribution of surrounding tissues (bone, discs, and ligaments). This comparison, already started in a previous study [5], is further discussed here.

Table
Comparison between FE predictions (FEM) and experimental measures (Exp) expressed as mean value±standard deviation, either in terms of strains (ε) on the rods and overall axial stiffness (K).

		ε_{FEM} (μstrain)		ε_{Exp} (μstrain)			
Model	Strain gauge	Release	2000 N	Release	2000 N	K_{FEM} (N/mm)	K_{Exp} (N/mm)
ISP	P (left)	−1107.8	1521.0	−852.6±138.8	1146.9±152.3	431.0	465.5±1.3
	A (right)	1179.2	−1493.7	529.5±185.7	−1691.0±109.8		

ε_{FEM}, calculated strains; ε_{Exp}, measured strains; K_{FEM}, calculated stiffness; K_{Exp}, measured stiffness; ISP, ISO model with Precompression.

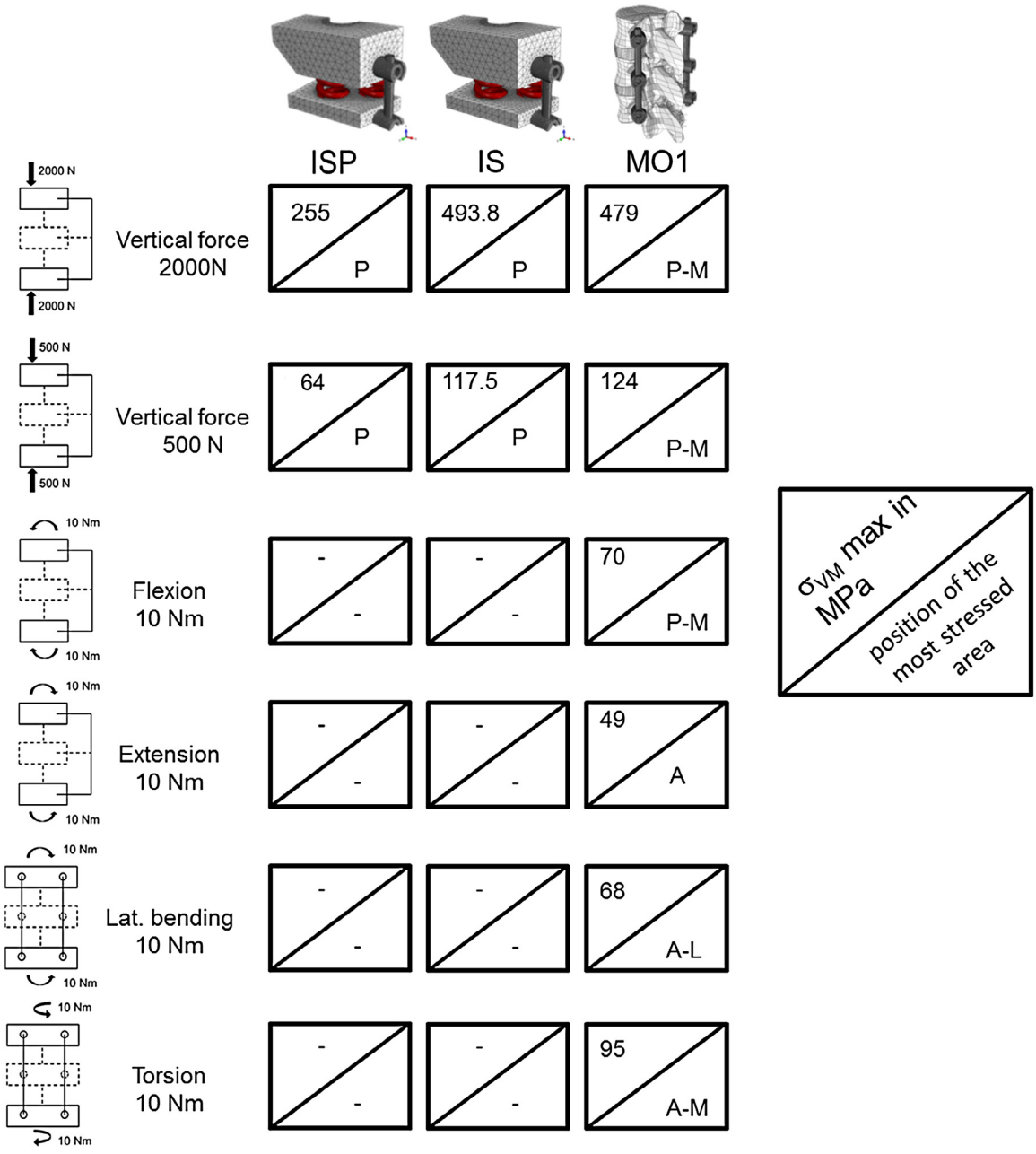

Fig. 3. Results. Data for IS and MO1 models previously reported by Villa and colleagues [5].

At first, both the configuration and the load value (2 kN) prescribed by ISO standard tend to overstress the rods if compared with a more physiological load of 500 N [6] applied to a bisegmental stabilization model (ISP: 255 MPa vs. MO1: 124 MPa). This scenario guarantees a safety coefficient of about 2. Moreover, when the contribution due to flexion is also considered, which is coupled to axial compression during walking [7], the safety coefficient would reduce to 1.3 (ISP: 255 MPa vs. MO1: 124+70 MPa).

Considering a 2-kN load, representative of the load value at the lumbar level [8], the safety coefficient decreases to 0.53 (ISP: 255 MPa vs. MO1: 479 MPa), and when the contribution due to flexion is also added, the value decreases to 0.46 (ISP: 255 MP vs. MO1: 479+70 MPa). On the one hand, these findings suggest that the resultant stiffness of the calibrated springs proposed by ISO 12189 (roughly estimated to represent the effective stiffness in compression of physiological lumbar intervertebral discs) could be too high. Reducing the stiffness of the synthetic disc (made up with three springs) could lead to a higher load sharing ratio (ie, the rods would be more stressed) and a result closer to the physiological bisegmental stabilization model (MO1) could be achieved. On the other hand, Villa and colleagues [5] considered the physiological FE model of only one patient, so that his

peculiar geometry (eg, anatomy) may influence the comparison with the ISP model.

Another important aspect is that the loading and boundary conditions that are applied on a spinal fixator in an *in vivo* environment are unknown and may differ significantly from the testing conditions described in ISO 12189 standard [3]. The ISO standard suggests applying a vertical load, which seems to mimic the loading condition expected *in vivo* for walking, which is the most frequent activity in a patient's everyday life, and thus leading to high risk of mechanical fatigue [7]. Rohlmann and colleagues investigated a wide range of loading conditions to describe different activities, such as standing [9] or upper body bending [10], using a numeric model. Although not directly considered, we may assume that walking could be described as a slight flexion or extension starting from an initial standing condition. This condition should have been simulated by applying a follower load with superimposed moments in flexion and extension. We did not consider this loading condition for the ISP model, and we applied only a vertical force. Because the lever arm is different between the ISP and MO1 models (in antero-posterior direction ISP: 47.4 mm vs. MO1: 41.4 mm, 42.5 mm, and 44.5 mm in average for L2, L3, and L4, respectively), a bending moment on the rods occurs, which is almost constant in the ISP model, whereas it increases linearly from L2 to L4 in MO1. The comparison becomes even more difficult, considering that the L2–L4 segments bend anteriorly, increasing the lever arm of the applied load, and that the constraint conditions at the distal part of the L2–L4 segments are quite different if compared with the degrees of freedom left free in the ISP model.

Rohlmann and Wilke also performed some *in vitro* tests on lumbar segments stabilized with an instrumented internal fixator by applying a compressive central load to compare it with *in vivo* measurements during standing [11], and an eccentric load [11] or pure moments [12] to compare it with *in vivo* measurements during flexion and extension movements. Even if the applied loads, the lever arms, and the spinal fixator's design are different, the effect of loads on the deformation of the rods calculated by our numeric model seems in reasonable agreement with Rohlmann's and Wilke's findings. However, this comparison will need a further investigation to better clarify the contribution of each parameter.

Because Villa and colleagues [5] used the results of ISO 12189 to define a load level to be applied on the vertebrectomy model implemented in ASTM F1717 standard, it is important to recall here some concepts and correct the findings already reported by Villa and colleagues [5].

Although it has been claimed that ASTM F1717 does not prescribe any performance criteria and does not specify any load to be applied to the vertebrectomy construct [13], other authors have suggested that indicating a load is a key factor for ensuring the significance of the testing method with respect to clinical application [14]. In this light, a reasonable criteria, which also allows for the comparison of the results of experimental fatigue tests performed according to ASTM F1717 and ISO 12189 setups, would be to determine the value of the vertical load to apply to ASTM model (AS according to Reference 5) to obtain the same maximum stress as in ISP; this value is approximately 215 N. It should be kept in mind that this force level cannot be generalized to devices having a rod diameter and material other than the one we used in this work, because the load shared by the posterior implant is expected to vary depending on its stiffness characteristics.

Conclusions

Taking into account the initial preload due to the assembly of the overall construct is important to correctly describe the state of stress on the posterior spinal fixator; neglecting this phase could lead to an overestimation of the stress on the rods up to 50%.

In addition, it should be interesting to investigate further the assemblage phase to take into account the influence of tightening sequence on the strains on the rods. Considering also the high tolerance (10%) of the commercial springs compliant to ISO 10243 [15], this aspect may be crucial in determining the effective stress level applied on a specific device tested according to ISO 12189 test procedure [3].

Moreover, it should be interesting to validate experimentally the strains values predicted on the rods using a more accurate choice of SG type and distribution. In this way, the internal loads (ie, axial load, bending and torsional moments) on the rods could also be compared and the numeric models would be more reliable.

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