# ASTM F1717 standard for the preclinical evaluation of posterior spinal fixators: Can we improve it?

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## Introduction

Preclinical evaluation of an orthopaedic device is a necessary step to assess its long-term mechanical reliability and to obtain the approval for clinical use. Some international organizations, like the American Society for Testing and Materials (ASTM) or the International Organization for Standardization (ISO), periodically publish and keep up-to-date standards and guidelines describing how to assess, evaluate and compare the mechanical performances of orthopaedic devices under controlled conditions.[1] In general, these standards implement only one, specific reference configuration which should replicate a physiological, pathological or worst-case configuration, that is, the most critical scenario which could take place in the lifetime of the device. In particular, ASTM originally published in 1996 the first version of the F1717 standard proposing

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a test method useful for the assessment of the mechanical properties of posterior spinal fixators.[2]

Spinal fixation with interpedicular screws and rods has proved to be useful in treating a great variety of disorders of the thoracolumbar spine.[3] In everyday life, these devices are subjected to cyclic load mainly due to walking[4] which could determine fatigue-related problems and complications (e.g. breakage of the device). Failure rates ranged from 7.7% to 27.4% in unstable thoracolumbar fractures, spondylolisthesis and pseudoarthrosis.[5–9] The highest incidence in the long term is related to screw breakage (from 1.7% to 52.6%), whereas rod failure is a minor issue.[5–10]

In order to investigate this problem in the preclinical evaluation phase, the ASTM F1717[2] is currently taken as a reference for the evaluation and comparison of posterior spinal fixation devices.[11–19] This standard, reapproved in recent years without significant changes, recommends simulating a vertebrectomy model using polyethylene (PE) blocks to mimic vertebral bodies (VBs). This configuration represents a worst-case scenario, since it assumes that the anterior column is totally compromised. In general, this is not the case, since posterior spinal fixation may be used when the integrity of the anterior column is significantly reduced (e.g. fracture, tumour or degenerative disc disease) but with a restoration of the anterior support (e.g. cage, bone graft). PE blocks are used to guarantee consistency in the fixation medium, overcoming problems related to the high variability of biological specimens, finally allowing for interlaboratory comparability of results. The description of the geometrical features of the entire experimental set-up was originally based on unpublished measurements taken on two-level constructs cited in a previous experimental work.[11] Even if many authors[20–53] reported a great amount of data describing the morphometric/anatomical features of the VBs (Table 1), only Chaynes et al.[35] investigated the geometrical relationship describing a complete functional spine unit (FSU) in relation to pedicle screw fixation. These parameters determine the final geometrical configuration of a spinal fixator and it would be very useful to determine the features of the experimental set-up closer to the clinical use, in order to build up a preclinical experimental set-up really representative of the clinical condition. Moreover, the importance of the specific values suggested within the standard in determining the outcome of the experimental test is not clear and never deeply investigated: small changes in these parameters may have a strong influence on the results.

Thus, the present study critically investigates the appropriateness of ASTM F1717[2] standard by means of a parametric finite element model (FEM). The aims of our study are as follows: (1) the comparison between the set of values suggested by the standard and their value within the physiological range in the thoracolumbar spine, (2) the comparison between the maximum stress level on the device according to standard suggestions and the one obtained varying each parameters over the physiological range and (3) the determination of the physiological worst case due to the superposition of all parameters.

## Materials and methods

In order to investigate the value of the parameters already considered within ASTM F1717[2] standard and investigate the possibility to include some other important ones, a total of 14 parameters were analysed. The majority of these variables are already included within the standard but their meaning and significance were never systematically investigated. The parameters were identified keeping the same definition used within ASTM F1717[2] standard as possible. They were classified into two groups as follows.

The *anatomical* parameters describe the biomechanics of the FSU, the orientation and the position of the pedicles with respect to the anatomical planes, assuming that the principal axes of the screw and the pedicle coincide (Figure 1(a)). The anatomical parameters are (Table 2) as follows:

*Block moment arm (BMA)*. It is the lever arm of the applied load according to the standard set-up. It represents the distance between screw insertion point (IP) in the pedicle and the follower-load (FL) line path, which models the overall contribution due to muscles and upper body weight. The FL line path can be assumed to pass through the centre of each VB.[54–57]

*Centre of fixation to rotation (CoFR)*. According to the standard set-up, it is the vertical distance between screw IP within the PE block and the centre of rotation of the cylindrical pin used to apply the load. It represents the distance between screw IP and the instantaneous centre of rotation (ICR) of the FSU, which is located close to the centre of the intervertebral disc (IVD) or slightly anterior in flexion.[57] This parameter can be applied to both the superior (CoFRsup) and the inferior (CoFRinf) vertebra of the standard set-up.

*Pedicular inclination with respect to the sagittal plane (PDIs)*. According to Panjabi's et al's.[28,29] definition.

*Interpedicular inclination with respect to the transverse plane (IPDIt)*. It is obtained as a difference between the pedicular inclinations of adjacent VBs with respect to the transverse plane (PDIt according to Panjabi's definition), compensating for EP (endplates) inclination.

*Half of the interpedicular distance (hIPD)*. It is the distance between the ideal IPs of the screws within the pedicles in the medio-lateral direction. This value was obtained summing the contributions of the interpedicular distance, and that one of the pedicular width projected on the frontal plane (both of these parameters were taken according to Panjabi's definition).

**Table 1.** Summary of the literature data reporting measurements for the investigated parameters.

| Reference | Population/ country | Considered spinal levels | Number of subjects (m = male, f = female) | Technique | PDIs | IPDIt | hIPD | hAL |
|---|---|---|---|---|---|---|---|---|
| Zindrick et al.[20] | United States | T1–L5 | n | CT | v | | | |
| Berry et al.[21] | United States (Caucasian) | T2, T7, T12, L1–L5 | 40 | Caliper, goniometer | v | | v | |
| Krag et al.[22,23] | United States | T9–L5 | 27 m, 14 ft | CT | v | | | |
| Marchesi et al.[24] | Switzerland | T6–L5 | 18 m, 15 ft | CT | v | | v | |
| Scoles et al.[25] | (16 m, 19 ft were Black) | T1, T3, T6, T9, T12, L1, L3, L5 | 25 m, 25 ft | Caliper, goniometer | v | | v | |
| Moran et al.[26] | United States (Caucasian) | T2, T7, T12, L1–L5 | 30 | Caliper, goniometer | v | | v | |
| Olsewski et al.[27] | United States | L1–L5 | 24 m, 25 ft | Caliper, protractor, CT | v | | | |
| Panjabi et al.[28] | United States | T1–T12 | 8 m, 4 ft | Morphometer | v | v | v | |
| Panjabi et al.[29] | United States | L1–L5 | 8 m, 4 ft | Morphometer | v | v | v | |
| Kim et al.[30] | Korea | T1–L5 | 42 m, 31 ft | Caliper, goniometer | v | | | |
| Cheung et al.[31] | Hong Kong (Asian) | L1–L5 | 100 | CT | v | | | |
| Vaccaro et al.[32] | 15 Central Asia, two North America | T4–T12 | 17 | Caliper, goniometer | v | | | |
| McCormack et al.[33] | United States | T1–T12 | 5 m, 6 ft | Caliper, goniometer | v | | v | |
| Cinotti et al.[34] | Rome | T4–T12 | 5 m, 6 ft | Caliper, goniometer | v | | | |
| Chaynes et al.[35] | France | T1–L5 | 10 | Caliper, goniometer | v | | v | v |
| Wolf et al.[36] | Israel | L1–L5 | 30 m, 25 ft | CT | v | | | |
| Tan et al.[37] | 10 Chinese, two Indian | L1–L5 | 12 m | 3D direct contact digitizer | v | | | |
| Mitra et al.[38] | Indian | L1–L5 | 18 m, 2 ft | Caliper, goniometer | v | | v | |
| Chadha et al.[39] | India | T9–S1 | 21 m, 10 ft | CT | v | | | |
| Balabaud et al.[40] | France | T1–T12 | 6 m | CT | | | v | |
| Kadioglu et al.[41] | Eastern Anatolian | L1–L5 | 15 m, 14 ft | Caliper, goniometer, CT | v | | v | |
| Datir and Mitra[42] | India | T1–T12 | 18 m | Caliper, goniometer, CT | v | | v | |
| Söyüncü et al.[43] | Turkey | L1–L5 | 10 | Electronic digital calipers (0.1 mm) | | | v | |
| Nojiri et al.[44] | Japan | T1–L5 | 56 m, 47 ft | Digital camera | v | | | |
| Liau et al.[45] | Malaysia | T1–T12 | 90 m, 90 ft | CT | v | | | |
| Lien et al.[46] | Taiwan | T1–L5 | 8 m, 7 ft | Caliper, goniometer | v | | | |
| Choi et al.[47] | Korea | T1–T8 | 18 m, 8 ft | CT | v | | | |
| Kim et al.[48] | Korea | T1–T12 | 57 m, 41 ft | CT | v | | | |
| Pai et al.[49] | India | T1–T12 | 15 | Caliper, goniometer, CT | v | | | |
| Mughir et al.[50] | Malaysia | L1–L5 | 36 m, 38 ft | CT | v | | | |
| Busscher et al.[51] | Netherlands | C3–L5 | 6 m | CT | v | | v | |
| Maaly et al.[52] | Egypt | L1–L5 | 45 m, 28 ft | Caliper, goniometer, CT | v | | | |
| Singh et al.[53] | India | T1–T12 | 81 m, 19 ft | Caliper, goniometer | v | | v | |

CT: computed tomography; PDIs: pedicular inclination with respect to the sagittal plane; IPDIt: interpedicular inclination with respect to the transverse plane; hIPD: half of the interpedicular distance; hAL: half of the active length; 3D: three dimensional.

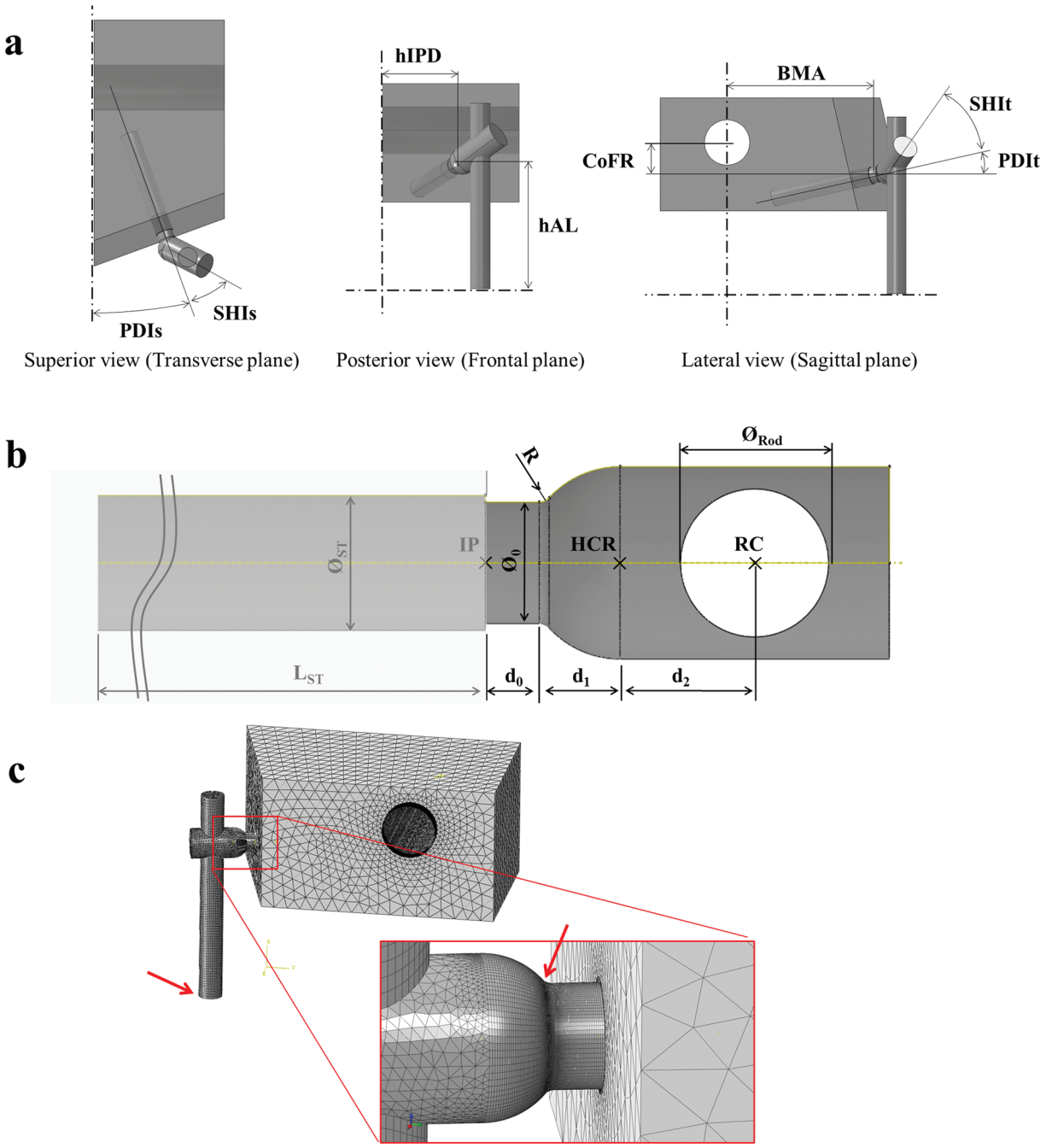


**Figure 1.** Definition of the parametric model describing (a) ASTM F1717[2] standard configuration and (b) pedicle screw design. (c) Overview of the meshed model simulating the reference configuration.
IP: screw insertion point in the ultra-high-molecular-weight polyethylene (UHMWPE) block; HCR: screw head centre of rotation; RC: rod centreline; PDIs: pedicular inclination with respect to the sagittal plane; SHIs: screw head inclination with respect to the sagittal plane; hIPD: half of the interpedicular distance; hAL: half of the active length; CoFR: centre of fixation to rotation; BMA: block moment arm; SHIt: screw head inclination with respect to the transverse plane; PDIt: pedicular inclinations of adjacent VBs with respect to the transverse plane.
The arrows indicate the region of interest where the von Mises stress values were considered.

*Half of the active length (hAL).* It is the distance between the ideal IPs of the pedicular screws belonging to a single FSU in the cranio-caudal direction. This distance can be taken parallel to the line which connects the centres of the VBs and approximates the curvature of the FSU.

In order to determine the physiological range values for each anatomical parameter in the thoracolumbar spine, a literature review (Table 1) was performed, and morphometric-anatomical data belonging to different ethnicities were compared to the specific values set by the standard.

**Table 2.** Anatomical parameters: value suggested by ASTM F1717,[2] physiologic range value, maximum increase in von Mises stress value on the screw (or rod) normalized with respect to the reference configuration (0% corresponds to the reference configuration) and correlation coefficient ($R^2$) for the relationship between the parameters and the stress on the screw.

| Anatomical parameters | | | | | |
|---|---|---|---|---|---|
| Parameter | Suggested value[a] | Physiologic range | Maximum increase in $\sigma_{VM}$ (%) | | $R^2$ |
| | | | Screw | Rod | |
| BMA (mm) | 40 | 17.1 to 43.0 (Figure 2) | 7.0 | 6.1 | 1.00 |
| CoFR (mm) | 12 | 4.4 to 25.9 (Figure 3) | 2.7 | 1.8 | 1.00 |
| PDIs (°) | 15 | −9.0 to 50.9 (Figure 4) | 2.2 | 0.8 | 0.99 |
| IPDIt (°) | 0 | −25.3 to 22.5 (Figure 5(a)) | 0.7 | 0.0 | – |
| hIPD (mm) | 20 | 8.5 to 25.3 (Figure 5(b)) | 0.1 | 0.1 | – |
| hAL (mm) | 38 | 13.7 to 38.4 (Figure 5(c)) | 0.1 | 0.1 | – |

BMA: block moment arm; hAL: half of the active length; CoFR: centre of fixation to rotation; PDIs: pedicular inclination with respect to the sagittal plane; IPDIt: interpedicular inclination with respect to the transverse plane; hIPD: half of the interpedicular distance.
[a]Set of parameters reported in this column was assumed in the reference configuration.

**Table 3.** Mechanical parameters: value recommended by ASTM F1717,[2] investigated range value, maximum increase in von Mises stress value on the screw (or rod) normalized with respect to the reference configuration (0% corresponds to the reference configuration).

| Mechanical parameters | | | | |
|---|---|---|---|---|
| Parameter | Reference value[a] | Investigated range | Maximum increase in $\sigma_{VM}$ (%) | |
| | | | Screw | Rod |
| SHIt (°) | 0 | −45 to 45 | 6.1 | 0.0 |
| $d_0$ (mm) | 2[b] | 1 to 3 | 3.5 | 2.1 |
| SHIs (°) | 0 | −45 to 45 | 0.8 | 0.4 |
| Curv (mm) | ∞ | −250 to 250 | 0.0 | 4.9 |
| $\emptyset_0$ (mm) | 4.5 | 4 to 5 | 38.8 | 0.2 |
| $d_2$ (mm) | 5 | 4 to 6 | 1.0 | 2.0 |
| $\emptyset_{ST}$ (mm) | 5 | 4.5 to 5.5 | 0.7 | 0.0 |
| $\emptyset_{Rod}$ (mm) | 5.5 | 5 to 6 | 0.4 | 35.1 |
| $L_{ST}$ (mm) | 30 | – | – | – |
| $d_1$ (mm) | 3 | – | – | – |
| R (mm) | 0.5 | – | – | – |

SHIt: screw head inclination with respect to the transverse plane; SHIs: screw head inclination with respect to the sagittal plane.
[a]Set of parameters reported in this column was assumed in the reference configuration.
[b]The current version of ASTM F1717 assumes a $d_0$ values equal to 0 mm.

The *mechanical* parameters describe the *test set-up* configuration and are not explicitly considered in the current standard (Table 3):

*Screw head inclination with respect to the transverse plane (SHIt) and screw head inclination with respect to the sagittal plane (SHIs)*. These parameters allow for describing polyaxial screws having a tilted head with respect to the main screw axis (Figure 1(a)). A cranial angulation was assumed to be positive for SHIt, while a lateral angulation was considered positive for SHIs (if the head is aligned with the main axis of the screw, 0° is assumed in both cases). We assumed an overall maximal excursion of 90°, according to the maximum range found for commercially available polyaxial screws.
*Unsupported screw length ($d_0$)*. It is the portion of the screw which is left outside the block (Figure 1(b)). This allows the polyaxial screw head free to rotate following rod curvature. Moreover, this parameter could play a significant role in determining the outcome of fatigue testing. For this reason, we assumed this parameter equal to 2 mm in the reference configuration, as suggested in ASTM F2706.[58]
*Rod curvature radius (Curv)*. The standard prescribes to use straight rods (rod curvature radius is infinite), but we assumed a minimum value of 250 mm, according to the maximum range found for prebent commercially available rods (lordotic and kyphotic rod have a positive and negative value, respectively).

Other parameters describing the specific *design* of the spinal fixator were considered (Figure 1(b)):

Screw diameter beneath the head ($Ø_0$) – the diameter of the portion of the screw left outside the PE block;
Distance ($d_2$) between screw head centre of rotation (HCR) and rod centreline (RC);

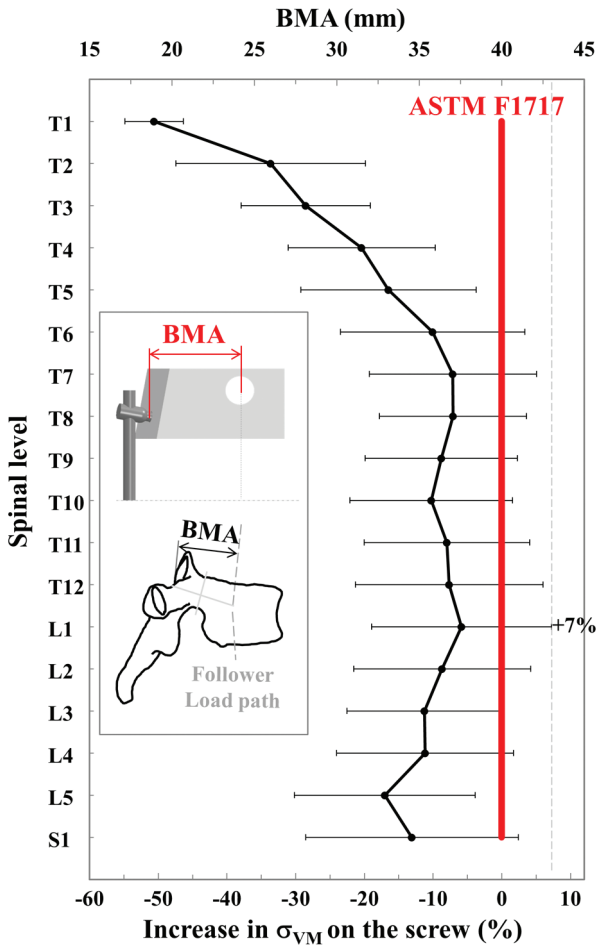


**Figure 2.** Block moment arm (BMA) as a function of the spinal level: comparison between the value settled by ASTM F1717[2] and data from our patients' database (average value ± standard deviation). The lower horizontal axis shows the corresponding percentage increase in the von Mises stress on the screw compared to the reference configuration.
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Diameter of the threaded part of the screw ($Ø_{ST}$);
Rod diameter ($Ø_{Rod}$).

Moreover, we assumed that the length of the threaded part of the screw ($L_{ST}$) within the PE block is equal to 30 mm, while the tip radius (R) between the screw head and the shaft is equal to 0.5 mm, in order to avoid a sharp notch transition beneath screw head. Finally, the remaining variable ($d_1$) was chosen so that, summed to $d_2$, a distance of 8 mm would be obtained.[59]

The morphometric and anatomical characteristic of the pedicles are deeply reported in the literature,[20–53] but only one article[35] analysed the relative position/angles between adjacent vertebrae measuring hAL (Table 1).

In order to compensate the lack of data describing BMA and CoFR, a total of 13 patients, six males (average age: 70 years, range: 59–81 years) and seven females (average age: 66 years, range: 48–74 years), were collected from the database of Neurosurgery Department. All the patients selected signed the consent for the processing of their personal data and received during their hospitalization a standing position X-ray performed with EOS System (EOS imaging, Paris, France) for clinical reasons. The biplanar X-ray images were then used to manually to measure BMA, CoFRinf, CoFRsup and hAL according to the definition already explained (intraobserver maximum difference = 1.2 mm, interobserver maximum difference = 2.4 mm). The measurements were expressed as a mean value ± standard deviation for each spinal level within the thoracolumbar spine and then compared to the value suggested within ASTM standard.

A parametric FEM of one-quarter of the ASTM F1717 set-up was considered, assuming its symmetry in terms of geometry, boundary and loading conditions with respect to the anatomical planes (Figure 1(a)). The geometry of the polyaxial screw was simplified with respect to a real one, so that either the thread or the head was assumed to be cylindrical. A fillet radius between this two parts was assumed, in order to describe the stress intensification effect occurring beneath the screw head, where crack initiation and propagation occur.[5–10] The model was then discretized assuming linear elastic material properties either for the spinal fixator (Titanium alloy, E = 110 GPa, $\nu = 0.3$) or the PE block (E = 1.05 GPa, $\nu = 0.4$). The rod was discretized using eight-node hexahedral elements, and the screw head and body were meshed using a hybrid four-node tetrahedral and eight-node hexahedral mesh, respectively (Figure 1(c)). Tie constraints were assumed at screw–rod and screw–block interfaces.[59,60]

During simulations, a vertical load of 150 N was applied (300 N considering the complete assembly) using a analytically rigid surface inserted within the horizontal hole of the PE block and assuming a frictionless contact. Simulations were run in ABAQUS/Standard 6.10 (Dassault Systèmes Ri. Simulia, Waltham, MA, USA), assuming geometrical nonlinearity and using a systematic approach, so that each parameter was set to its minimum or maximum value maintaining all the other parameters fixed according to the *reference condition*: the set of values assumed for each parameter in this condition is reported in the second column of Tables 2 and 3. A mesh convergence analysis was performed on the model describing the reference configuration considering the von Mises stress on the screw head and on the rod in the transverse plane. The investigated model presented 23,074 elements for the rod, 140,619 elements for the polyaxial screw (16,855 and 126,156 for its head and body, respectively) and 151,218 elements for PE block. The contribution of each geometrical parameter on the load on the device (screw and rod) was quantified in terms of von Mises stress increase normalized on the reference configuration. Considering that a 2% deviation from maximum load is usually allowed in experimental

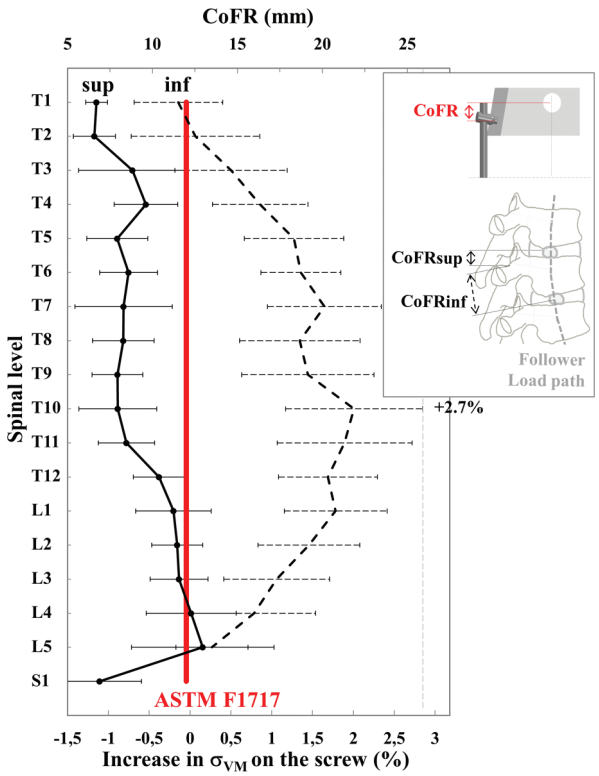


**Figure 3.** Centre of fixation to rotation (CoFR) as a function of the spinal level: comparison between the value settled by ASTM F1717[2] and data from our patients' database taken referring to the superior/inferior FSU, CoFRsup/CoFRinf, respectively (average value ± standard deviation). The lower horizontal axis shows the corresponding percentage increase in the von Mises stress on the screw compared to the reference configuration.
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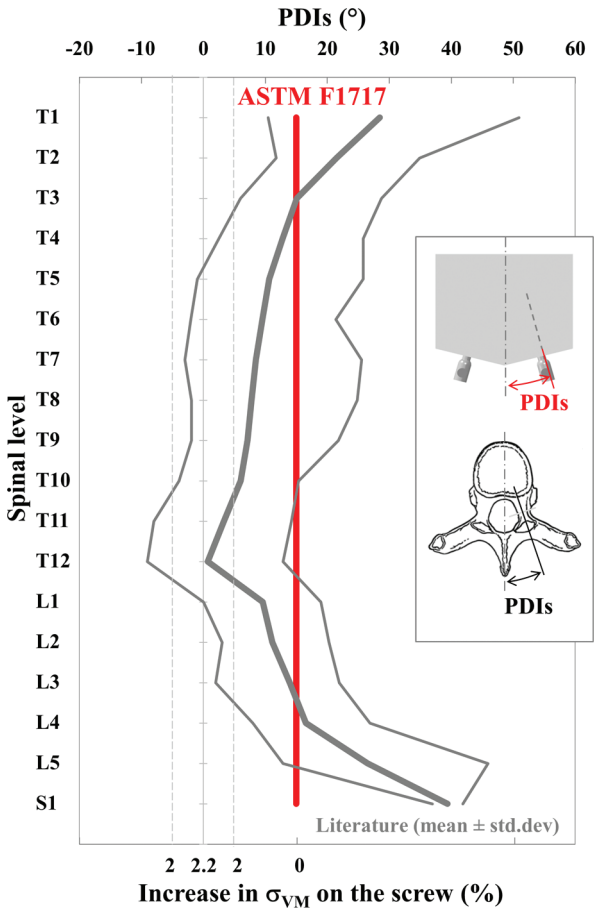


**Figure 4.** Pedicular inclination with respect to the sagittal plane (PDIs) as a function of the spinal level: comparison between the value settled by ASTM F1717[2] and data[20–53] from our literature review (Table 1). The lower horizontal axis shows the corresponding percentage increase in the von Mises stress on the screw compared to the reference configuration. Note that the relationship between PDIs and the stress is non-linear (cosinusoidal with a maximum at 0°).
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practice,[61] a percentage variation of 2% was assumed to be significant, so that only those parameters overcoming this threshold will be deeply discussed in this article.

The *anatomical* and *overall worst-case* conditions combining the most influent anatomical parameters and also the mechanical ones were then investigated as a function of the spinal level: these scenarios represent the percentage stress variation which a spinal fixator could undergo once implanted at a specific thoracolumbar level within a population of physiologic patients. These conditions were also compared with the *average* case condition obtained combining the physiological mean values for each parameter.

## Results

The values used in the standard for the anatomical parameters (Table 2) are generally within the physiological ranges (Figures 3–5(a) and (b)) of the thoracolumbar spine, or they describe its upper limit (Figures 2 and 5(c)). Only three parameters have a significant percentage stress increase on the screw head, which is the component most commonly subjected to failure in clinical practice.[5–10]

BMA demonstrates a significant increase from an average value of about 18.9 mm at T1 level, up to beyond 35 mm between T6 and L4, and then it slightly decreases at sacral level (Figure 2). ASTM F1717 standard suggests a BMA value (40 mm) which is slightly beyond the upper limit for the thoracolumbar segment. Among all the investigated parameters, BMA plays the most significant role in increasing the stress on the device, reaching a + 7% on the screw (rod = + 6.1%) in correspondence to the upper variability range found at L1 level. Since BMA represents the lever arm of the applied load, its relation with the percentage stress increase is linear ($R^2 = 1.00$).

CoFRsup was found to have an average value almost constant between 6 and 10 mm in the thoracic region, then it significantly increases reaching a maximum value of 13.0 mm at L5 (Figure 3). CoFRinf shows higher values than CoFRsup, with a significant increases from T1 to T10 (moving from 11.5 mm up to

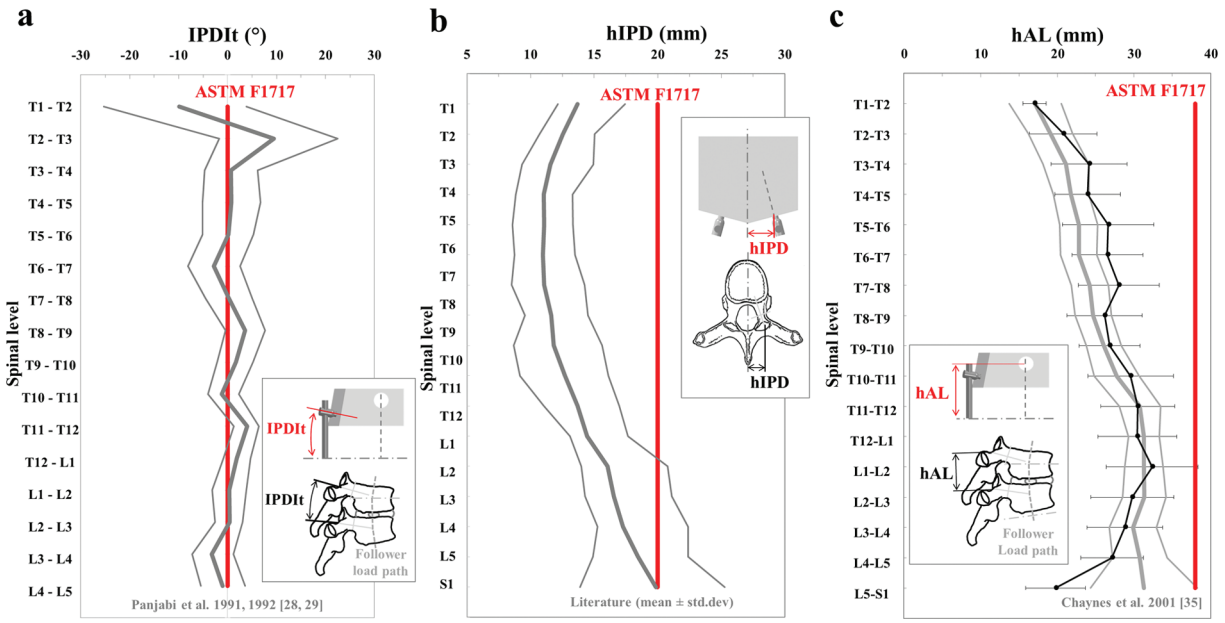


**Figure 5.** (a) Interpedicular inclination with respect to the transverse plane (IPDIt), (b) half of the interpedicular distance (hIPD) and (c) half of the active length (hAL) as a function of the spinal level: comparison between the value settled by ASTM F1717[2] and data[20–53] from our literature review (Table 1).
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21.9 mm), followed by a dramatic decrease in the lower lumbar levels (13.5 mm). Compared to CoFRsup, the value assumed by ASTM standard for CoFR (12 mm) could represent an average value in the lumbar region, while it may represents a lower limit for the overall thoracolumbar segment for CoFRinf. The relation between CoFR and the percentage stress increase was found to be linear with $R^2 = 1.00$, leading to a maximum increase of 2.8% considering the upper limit of CoFRinf at T10.

According to literature data, PDIs shows a typical trend from a relatively stable average value in the mid-thoracic region (between 0° and 10°) up to 35° even moving to T1 level or descending to L5 (Figure 4). The standard suggested value of 15° seems to represent an average value for the overall thoracolumbar region. Since changes in PDIs cause a change in the projection of the lever arm of the applied load, the relationship with the stress increase is cosinusoidal ($R^2 = 0.99$) with a maximum at 0° (lower limit of the mid-thoracic segment): in this condition, the stress increases up to 2.2%.

Other anatomical parameters play a marginal role (Figure 5 and Table 2).

Among the mechanical parameters that could have an important effect on the stress on the screw, the most important one is SHIt (Table 3). It can lead to a maximum stress increase of + 6.1% on the screw, reached when the head of the screw is tilted at 45° in the cranial direction.

Also, the unsupported screw length ($d_0$) plays a significant role, leading to a maximum increase of 3.1% when moved from 2 to 3 mm. Is important to note that according to our reference configuration, $d_0$ was set by default to 2 mm, as already suggested in ASTM F2706:[58] this assumption produces a percentage stress increase of 4.4% on the screw (3.8% on the rod), if compared to the current version of ASTM F1717 which totally neglects this parameter ($d_0 = 0$ mm). Other investigated mechanical parameters play a marginal role in increasing the stress on the device (Table 3).

Since not all combinations of parameters are anatomically allowed, we combined the average values for the most important variables (BMA, CoFRinf and PDIs) to obtain the *average* case curve depending on the spinal level. FEM simulations run combining the different parameters confirmed the applicability of superposition of effects principle: even if the effect of non-linearities is not absent, they contribute below the assumed threshold of 2%, so that the overall percentage stress increase could be potentially obtained summing the contribution of each parameter. The current version of ASTM F1717 describes a set-up configuration which leads to a stress level on the device close to the upper thoracolumbar limit found in an average patient taken from a physiological population (Figure 6).

The *anatomical worst-case* condition as a function of the spinal level demonstrates that a pedicle screw implanted in the spinal segments from T6 to L4 and S1 could undergo a significantly higher stress when compared to the reference condition (Figure 6). The worst-case condition according to anatomy is located at L1 level (BMA = 43 mm, CoFRinf = 23.8 mm and PDIs = 0°) and can increase the stress on the screw up to 10.8% (rod = + 8.9%) when compared to our reference configuration, 15.2% when compared to the current version of ASTM standard. The *overall* worst-

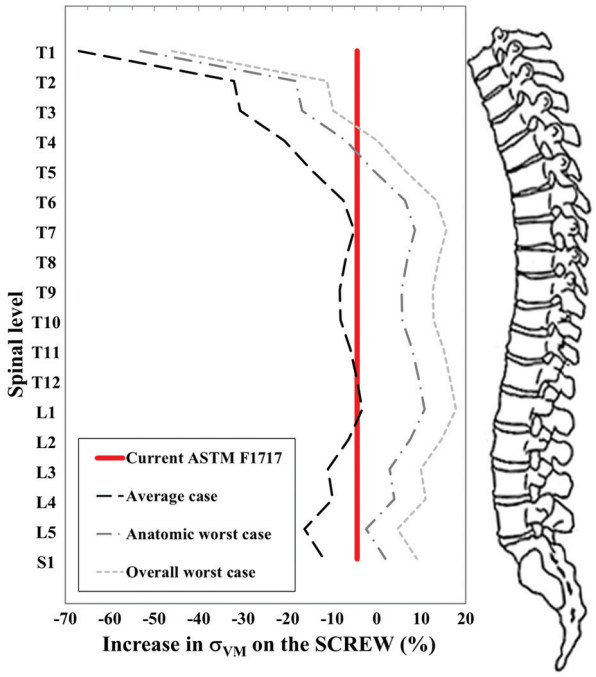


**Figure 6.** Percentage increase in von Mises stress obtained combining the average value of the three most important anatomical parameters (average case: BMA, CoFRinf and PDIs), their worst-case value (anatomical worst case: BMA, CoFRinf and PDIs) and also the most important mechanical parameters (overall worst case: BMA, CoFRinf, PDIs and SHIt) as a function of the spinal level. The most critical level is located at L1 (BMA = 43 mm, CoFRinf = 23.8 mm and PDIs = 0°). 0% corresponds to our reference condition, while 4.4% must be added in order to compare the simulated conditions with the current version of ASTM F1717.[2]
ASTM: The American Society for Testing and Materials.

case condition was obtained also taking into account the most influent mechanical parameter (SHIt): we obtained an overall stress increase of 17.8% with respect to our reference configuration, up to 22.2% in comparison with the current version of ASTM F1717.

## Discussion

Preclinical evaluation of any orthopaedic device is a crucial step to assess its long-term mechanical reliability, to obtain the approval for the clinical use and guarantee its safety for any patient.[1] The ASTM periodically publishes and updates its standards, describing how to assess, evaluate and compare mechanical performance of orthopaedic devices in only one specific reference configuration, often a pathological *worst-case* scenario. This is the aim of the standard ASTM F1717,[2] currently taken as a reference for the evaluation and comparison of posterior spinal fixation devices.[12–19] Clinical experience demonstrated a significant rate of failures of these devices, especially at screw level,[5–10] and mainly due to fatigue loading during walking in everyday life.[4]

This clinically relevant problem was considered by ASTM, which collected the experience done by previous experimental studies.[11,62–64] First, in order to represent a 'worst-case scenario' for the implant, a vertebrectomy model was implemented. Since posterior fixation method is often coupled with the use of cages and bone grafts, which restore the load-bearing capacity of the anterior column, assuming that an entire VB is missing guarantees a high safety coefficient for patients, once the device survives the tests. Second, two PE blocks were used as vertebral elements in order to provide consistency in the fixation medium, minimize scattering of data due to the intervariability of cadaveric specimens (e.g. bone mineral density, size and shape) and allow for interlaboratory comparability of results. The geometrical description of these blocks, as well as the one of the entire experimental set-up, was originally based on mean skeletal measurements of two-level constructs and a set of values proposed.[11] In the literature,[20–53] there are much data dealing with the morphometric/anatomical features of the pedicles and of the VBs (Table 1). However, only[35] few investigated the features describing a complete FSU in relation to pedicle screw fixation. This information is very important, since it determines the overall geometrical configuration of spinal fixation devices and would be useful to determine an experimental set-up for preclinical evaluation of spinal fixators close to the clinical condition. The first version of ASTM F1717 accepted the set of values proposed by Cunningham et al.,[11] but also referred to unpublished data. The relations between the parameters describing the experimental standard configuration and the anatomical features of a specific VB or FSU are sometimes unclear and never investigated quantitatively.

Considering the anatomical parameters (Table 2), only three have a strong effect on the stress on the implant. The equivalent lever arm of the total force applied on the assembled construct or treated spinal segment (BMA) has the strongest influence on the stress on the device, and it seems to be deliberately set to overestimate the average value found within the thoracolumbar segment (Figure 2). However, according to our data, this value is not safe enough, since it does not take into account the physiological variability found in the lower thoracic and lumbar regions.

CoFR is another important parameter, but its definition within ASTM standard is unclear. Depending on the specific FSU addressed (Figure 3), its value can change significantly: ASTM settled a value which may represent an average referred to the superior FSU (CoFRsup), but would be safer to take as a reference the inferior one (CoFRinf). Moreover, the loading configuration suggested by the standard is reversed (the lower PE block is upside down): these assumptions guarantee symmetry of the experimental set-up and allows for applying a uniform moment on the rod, thus distributing the probability of fatigue crack initiation and propagation over a higher portion of the bar.

The standard suggests triangulating the screws achieving a PDIs of 15°, which is approximately the average value for the overall thoracolumbar segment (Figure 4). The higher stress increase could be obtained by setting 0°, but triangulation of pedicle screws in the transverse plane is necessary to avoid instability of the assembled construct,[63] and it is commonly used in clinical practice to increase the stability of the fixation method.[3] For these reasons, keeping this parameter according to the current standard could be reasonable.

Concerning the mechanical parameters (Table 3), an unsupported screw length ($d_0$) of 2 mm was assumed in the reference configuration. This parameter, already included by ASTM in a similar standard test method,[58] significantly contributes to the overall lever arm of the bending moment acting beneath screw head. Stress intensification occurs in this region due to the discontinuity of moment of inertia, sharp tip radius and low cross-sectional area.[6] This explains the weakness of screw-based posterior fixation devices experienced in clinical practice.[5–10] On one hand, it is necessary to keep this distance to allow the polyaxial screw head free to rotate to adjust according to rod curvature; on the other hand, this distance is strictly design dependent and can highly differ according to the manufacturer. However, since authors are not used to report this length, we think that ASTM should standardize it in order to improve comparability of results and to avoid misleading successful results (e.g. an excessive insertion depth could reduce the stress on screw head of about 4.4% leading to a higher fatigue life).

Polyaxial pedicular screws are becoming more and more used in clinical practice, since they give freedom to the surgeon in contouring the rods, finally restoring a natural spinal curvature for the patient. However, the current standard does not take into account the screw head tilting, which significantly affects the stress on the screw up to a 6.1%. The only reason to keep this parameter unchanged could be to allow for the comparability of results obtained for mono- and polyaxial pedicular screw-based fixators.

Since only a few combinations of the anatomical parameters are physiologically allowed depending on the spinal level, we considered the average and worst-case conditions. We found that a spinal fixator tested according to the current version of ASTM F1717 undergoes the highest stress levels found within the lower thoracolumbar level for an average patient taken from a physiological population (Figure 6). This finding combined with the vertebrectomy assumption could guarantee a reasonable margin of safety. However, the standard does not take into account the physiological intervariability, since it could underestimate up to 10.8% of the stress values experimented in the anatomical worst-case condition found at L1 level (BMA = 43 mm, CoFRinf = 23.8 mm and PDIs = 0°).

The *overall* worst-case scenarios obtained considering also the contribution of the most important mechanical parameters (SHIt) highlighted that the current version of the standard suggests a configuration which is not safe enough for most of the thoracolumbar segments (Figure 6). The most critical level is L1, with a maximum stress increase of 17.8% according to our reference configuration (22.2% with respect to the current version of ASTM F1717). According to our models, the whole thoracolumbar segments below T5 could potentially undergo a stress level significantly higher than the scenario described by the current version of the standard: the standard could be updated in order to guarantee a more reasonable safety coefficient and reliability of the spinal fixator for a wider range of patients. The primary limitation of this study is the simplified geometry assumed for the spinal implants, as well as the linear elastic material properties used and the tie constraint at screw–block interface: these assumptions are justified by the comparative nature of our numerical investigation.

Considering the constraint of having a parametrical model of a posterior spinal fixator which is simple, to give general indications to all designers/engineers, but at the same time not describing any specific design, it appeared reasonable to simplify the spinal implant features neglecting thread geometry, simplifying screw head geometry and assuming a conventional fillet radius at screw head. Surely, a different implant design (i.e. lower screw head diameter ($Ø_0$), lower fillet radius at screw head (R), higher screw head diameter, more sharp transition between screw body and screw head) may significantly affect the results, resulting in a very different percentage stress increase.

In this light, we are not aware of the correspondence between the numerical stress increase and the actual reduction in terms of fatigue life of a specific spinal fixation device. In order to overcome this limitation, an experimental investigation according to the worst-case scenarios would be needed. However, considering the intrinsic statistical scatter of fatigue results, in our opinion, the stress increase may lead to a significant reduction in the number of cycles to failure. Considering a typical Wöhler's curve for Ti6Al4V-based devices,[65] which is the main material used for interpedicular screws, the effect of an increase in the stress level on the device would be more relevant in the low-cycle fatigue range (slope is higher). Indeed, this is the region where we will concentrate our attention in the future experimental investigations.

The linear elastic material properties for PE and Ti alloy and tie constraint at screw–block interface appear to be reasonable assumptions, allowing for the comparison of different scenarios under homogeneous loading conditions. Moreover, neglecting any preload due to the insertion of the interpedicular screw within the block allows for considering only the effect of the vertical load applied. All of these assumptions are, of course, simplifications of the real situation, where the insertion of the interpedicular screw within the bony structures would produce an initial residual stress/damage on the surrounding bone, which may influence the

stress values on the device; moreover, in reality, some micromotions are expected to occur upon loading. This aspect may be crucial in the early stage of screw osseointegration, where a not perfect coupling at screw–bone interface may occur. In this light, the assumption that bone and screw are ideally bonded, despite resulting in a stiffer construct than in reality, may reasonably represent a scenario, where complete osseointegration has already occurred.

Another important limitation deals with the systematic approach used to implement the sensitivity analysis. In fact, we started our study analysing the variation of one single parameter at a time keeping all the others fixed. This method is based on the definition of a reference configuration and does not take into account the effect of interaction between different parameters. In order to partially overcome this limitation, we also combined the effect of either the three most important anatomical parameters (BMA, CoFRinf, PDIs) and the mechanical parameters (SHIt and $d_0$). In order to also take into account the other remaining parameters, the application of a full-factorial approach, or a more practical Taguchi analysis, may be needed in future.[66]

Besides these limitations, we think that the current version of ASTM F1717 standard should be improved, in order to provide a more quantitative, reliable and updated method for scientists and designers. This will be beneficial to improve and support preclinical evaluation of posterior spinal fixators.

## Conclusion

The current version of ASTM F1717[2] standard suggests a set of values which seem to be arbitrarily chosen to represent, as much as possible, an average two-level fixation construct and to guarantee a margin of safety which is unknown. Our study sheds light on this aspect, measuring the quantitative value within the thoracolumbar segment of some important never-reported biomechanical parameters (BMA and CoFR), explaining the anatomical/biomechanical meaning of all the parameters describing standard test set-up and investigating their influence on the stress on the device. Our comparative parametric investigation demonstrates a significant (up to a 22.2%) maximum increase in the stress on the device, compared to the standard actually in use. Despite not confirmed by experimental tests, this result goes towards a revision of the standard in order to take into account the anatomical *worst-case* scenario we found at L1 level (BMA = 43 mm and CoFRinf = 23.8 mm). Moreover, we propose to standardize the unsupported screw length, as already considered in ASTM F2706,[58] or at least to mandatory report its measure while testing a new device.


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