1. ABSTRACT

The paper presents a finite element approach to the biomechanical evaluation of a metal alloy interspinosus device, implanted in the L4-L5 motion segment. The surgical procedure, which implies the resection of some ligaments and the removal of the nucleus pulposus, was also considered in the computational analyses. The material constitutive models for the metal alloys, as well as for the soft biological tissues are implemented. The annulus fibrosus has been considered as a non-linear incompressible and anisotropic material, subjected to finite strains. The interspinous implant was modeled both considering the commercial titanium-based metal alloy (Ti6Al4V), and a superelastic Shape Memory Alloy (Ni-Ti). The computational analyses were able to describe accurately the biomechanical behaviour of the lumbar motion segment in terms of static and kinematics, for both physiological and pathological conditions and related surgical treatments. The models predicted that the devices are able to reduce the force acting on the bone structures (i.e. the apophyseal joints), but the biomechanical compatibility conditions were partially met only by the SMA device.

2. INTRODUCTION

According to the surgical experience, the main purpose to assuaging the patient low back pain, associated to the degenerative disease of the lumbar motion segment and to the disc slipping, is achieved by spacing the two adjacent vertebrae with an interspinosus device, which must be reliable in a sufficient long time period, easy to implant and easy to remove during the revision surgery.

Keywords: Finite Elements, Intervertebral Disc, Soft Biological Tissues, Titanium Alloy, Shape Memory Alloy.
The present study is based on the achievement of a correct understanding of the biomechanics of a healthy and nucleotomized lumbar motion segment and the role played by each anatomical structure of the system, in order to develop a reliable computer model, able to predict the effectiveness of the interspinosus device, in terms of its biomechanical compatibility.

Many computational and experimental studies are devoted to understand the mechanical behavior of a spine motion segment, but the complexity of the anatomy and of the *in-vivo* loading conditions are such, that scattered results and some discrepancies are found. Therefore, a computational study of the functional spinal unit L4-L5, in healthy and treated conditions (nucleotomy and interspinosus device implant), has been carried out through a three-dimensional finite element model, using the commercial finite element code ABAQUS (Hibbit, Karlsson & Sorensen, Pottucket, RI, USA). L4-L5 has been chosen, because this is the most stressed spinal segment. A “U” shaped device implanted between the spinosus processes of the two vertebrae has been investigated; two different metal alloys have been considered as possible materials for the implant: a titanium alloy (Ti6Al4V) and a nickel-titanium Shape Memory Alloy (Ni-Ti, SMA).

The main objective of the finite element analyses is to compare the biomechanical behavior of the healthy L4-L5 segment, with that of the surgical treated segment. In particular, axial compression, flexion and extension in the sagittal plane, axial rotation (torsion) and lateral flexion have been simulated.

2. MATERIALS AND METHODS

2.1 The healthy L4-L5 segment

A three dimensional reconstruction of the L4 and L5 vertebrae was performed by using 3D segmentation techniques from CT images (Fig. 1a). Since the vertebrae exhibit a much higher stiffness than other structures, it is expected that the deformation of the segment is primarily due to intervertebral disc and interspinosus device deformation. Consequently perfectly rigid vertebrae are assumed.

![Fig. 1 FE model of L4-L5 segment: healthy (a), with interspinosus device (b).](image)
Because water is the most component of nucleus pulposus, it is modelled as an incompressible fluid able to carry only hydrostatic pressure.

The annulus fibrosus consists of collagen fibres embedded in the extra-cellular matrix and arranged in concentric layers. The orientation of the collagen fibres differs from layer to layer in an alternate fashion, forming an angle with the disc plane variable in the hoop direction (from $\pm 23^\circ$ ventrally to $\pm 57^\circ$ dorsally; average $\pm 33^\circ$) $^5$.

In order to have a correct interpretation of the biomechanical role of the intervertebral disc, an accurate non-linear anisotropic constitutive law has been considered for the annulus fibrosus, allowing for finite strains. The constitutive law is based on the definition of a free energy function, given by two different contributions: the first is related to the isotropic and incompressible extra-cellular matrix, the second is related to the non-linear elastic collagen fibres, characterized by a specific orientation in the material $^5$. An uncoupled volumetric-deviatoric formulation for the strain energy function, allowing for an easy handling of the incompressibility constraint, together with a hybrid element formulation have been used. The constitutive law for the annulus fibrosus has been implemented into a suitable FORTRAN subroutine, linked to the FEM code. The effect of all ligaments (pre-stretched) was included in the FEM analyses of the healthy segment.

All the degrees of freedom of the L5 vertebra were constrained and the L4 was loaded with a force applied to its centre of mass (4000 N) in order to simulate compression, and with moments in order to simulate flexion (60 Nm) and extension (-60 Nm) in the sagittal plane, lateral flexion (40 Nm) and torsion (15 Nm) $^1$.$^6$. A 1000 N preloading compression force was considered in all analyses, in order to simulate upper-body weight and muscle actions in an erect standing position $^3$.

2.2 The treated L4-L5 segment

Because the surgical treatment implies the resection of the supraspinous and the interspinous ligaments, these ligaments have been removed in the model of the treated situation (Fig. 1b).

The titanium alloy has been simulated through an isotropic elastic-plastic material, with linear isotropic hardening and von Mises yield surface (Fig. 2 left).

The nickel-titanium alloy is expected to work exploiting its superelastic behaviour in the temperature ranges of the human body (37°C); a suitable constitutive law, able to account for the reversible stress-induced solid phase transformation (Fig. 2 right), has been implemented into the finite element code through a suitable FORTRAN subroutine $^7$.

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**Fig. 2** Uniaxial stress-strain curve for the Titanium based alloy (left) and for the Shape Memory Alloy (right).
2. RESULTS

Validation of the FEM model was achieved by comparing the results obtained for the healthy situation, with those available in literature. In particular the percentage of compression load carried by the apophyseal joints have been investigated; moreover axial compression force versus axial displacement and flexion/extension moment versus rotation have been considered.

2.1 Vertical load on the apophyseal joints

Nucleotomy implies an increase in the load carried by the apophyseal joints in all cases, except in extension. During flexion, the joints are always totally unloaded. The titanium device, which is stiffer than the SMA device, relieves almost all the force, except in lateral bending; the SMA device shows a smaller degree of unloading (Fig. 3), when it enters in the superelastic regime,.

![Vertical load on the apophyseal joints](image)

Fig. 3 Vertical load on the apophyseal joints: (a) compression 1200 N; (b) extension 47 Nm; (c) torsion 4 Nm; (d) lateral bending 30 Nm.

2.2 Compression

Under compression loading, the segment exhibits a non-linear stiffening behaviour. The nucleotomized segment presents a loss of stiffness; whereas the responses of the models with implanted device (made either of titanium or of SMA) are close to the one of the nucleotomized, for compression forces greater than 1000 N (Fig. 4).
Fig. 4 Mechanical response to a compression loading for the healthy and treated L4-L5 motion segment.

2.3 Flexion – Extension

Under flexion loading, the healthy and the nucleotomized segments have practically the same behaviour. The segment treated with the SMA device presents a flexional stiffness comparable with the healthy segment, whereas the titanium device is too stiff and is subjected to irreversible deformations for rotations greater than 2° (Fig. 5).

Fig. 5 Mechanical response to flexion-extension moments for the healthy and treated L4-L5 motion segment; red dots: start of irreversible deformation in the Ti6Al4V device.

The analyses confirm that under extension loading, the nucleotomy procedure destabilizes the L4-L5 segment, which presents a loss of stiffness. The implant of the SMA device is not able to restore the physiological stiffness: the treated segment has the same behaviour as the nucleotomized one. The titanium device appears to restore partially the healthy conditions, but for rotations greater than 2°, it enters in a range of
irreversible deformations. The diagrams of torsion and lateral bending are not reported. However, the SMA device seems to be able to recover the biomechanical behaviour of the motion segment in terms of lateral bending stiffness, but appears to be too stiff in axial rotation. On the other hand, the titanium device is probably excessively stiff for these two loading situations, in all cases it is stiffer than the SMA device.

3. DISCUSSION

These results show that the implant of the “U” shaped interspinous device (made of titanium or SMA) is able to solve in all cases the problem of the overloading of the apophyseal joints, which is the main purpose of the device. The two devices are compatible with the physiological situation, but the SMA device is probably “biomechanically” better to prevent the risk of bone reabsorption in the joints. However, only the SMA device appears to be able to restore healthy-compatible stiffness, but only in flexion and lateral bending. In all other cases, none of the two devices is able to recover a physiological biomechanical behaviour of the motion segment, in terms of axial, extensional and torsional stiffness. It is still to be understood, whether this stiffness mismatch can cause some long-term consequences to treated patients. A different design of this interspinous implant is probably needed for a complete fulfilment of the biomechanical compatibility constraints. A further topic of interest is the fatigue behaviour of the SMA device, which was not being studied in this work. These issues belong to the future development of the research.

4. REFERENCES