Biomechanical study of a pathologic lumbar functional spinal unit and a possible surgical treatment through the implant of an interspinous device

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Abstract

This research work investigates the disease of a lumbar functional spinal unit (FSU) and its surgical treatment. In particular, this study focuses on the implant of an interspinous device, for which two possible materials have been considered: a titanium-based alloy (Ti6Al4V) and a superelastic alloy (Ni-Ti).
The assessment of the biomechanical compatibility was achieved by means of the finite element method, in which suitable constitutive laws have been adopted for the annulus fibrosus and for the metal alloys. The aim of the model was to simulate the effect of radial tears on the annulus fibrosus in comparison with the healthy FSU, as well as the surgically treated segment. We have considered axial compression and flexion in the sagittal plane.

The computational model has shown that the most important clinical aspect of the disc disease is the loss of bearing capacity of the nucleus pulposus, due to fluid loss. Moreover, the finite element model has shown that both the implants were able to achieve their main design purpose, which is to diminish the forces acting on the apophyseal joints. Nevertheless, the Ni-Ti implant has shown a more physiological flexural stiffness with respect to the Ti6Al4V implant, which exhibited an excessive stiffness and permanent strains (plastic strains), even under physiological loads.

Introduction

Nowadays, the pathology of the intervertebral disc has gained increasingly more relevance from the medical point of view, even for its related social costs, because it involves a large share of the population.

The intervertebral disc is a cartilaginous material that serves to absorb shock and provide for flexibility in joints of the spine. The disc contains two anatomically distinct regions: the gelatinous nucleus pulposus located in the centre of the disc, and the highly ordered fibro-cartilaginous annulus fibrosus in the periphery. The annulus fibrosus consists of layers of parallel collagen fibres, called lamellae, which are arranged in alternating orientations above and below the axial plane. This unique anatomy plays an important role in the biomechanical properties of the annulus fibrosus and the disc.

Lifting weights, hard work or maintaining incorrect positions may overload and damage the lumbar spine, in particular the intervertebral discs. If the overloading increases considerably, the intradiscal pressure may rise to dangerous levels and produce radial or circumferential tears in the external portion of the disc, i.e. the annulus fibrosus (see Figure 1) [1].

Figure 1. Degenerated lumbar intervertebral disc with circumferential and radial tears: mid-axial slice.
In the long term, a degenerative disc disease may be the consequence of repeated mechanical damages and biochemical modifications. As first stage, the degeneration causes a loss of water content in the nucleus pulposus and the mechanism of stress transmission across the intervertebral disc changes drastically. Because of the water loss, the annulus fibrosus is overloaded and the overall stiffness of the FSU decreases [2, 3].

In presence of radial tears, the nucleus may penetrate into the annulus fibrosus, in the damaged regions, and may cause a protrusion and eventually a hernia, when the annulus is completely broken. Thus, the bulge or the hernia can compress the neural structures and cause low back pain.

Note that this pathology can occur even in healthy young people, but it is more likely to occur in aged people.

Moreover, the loss of the bearing capacity of the nucleus pulposus increases the force magnitude transmitted through the articular facets of the apophyseal joints [4]. The overloaded facets react biologically in the long term by the deposition of a bone callus, which may compress the nerve roots and cause pain [5, 6].

In the most severe situations, the pharmacological therapy and the physiotherapy may not be sufficient to relieve pain and the surgical treatment may be the last option for the patients.

One possible surgical treatment consists of two steps: i) the removal of the herniated nucleus pulposus and ii) the implantation of an interspinous device. The surgeons call the first step nucleotomy and the second “dynamic stabilization”, because the device stabilizes the FSU by carrying part of the compressive load acting on the apophyseal joints, decompressing the neural structures, pre-stressing the posterior ligaments and partially stabilizes the FSU by damping the dynamic loads.

Currently, many types of devices are available, with different shapes, materials and having different clinical purposes. These devices are mostly implanted in the FSU between the spinous processes of the two vertebrae; other types are screwed into the posterior pedicles of the vertebrae.

The materials adopted are metal alloys, in particular titanium-based alloys, or polymers, in most cases silicones or polyurethanes.

The device studied in this paper is “U” shaped (see Figure 7, left) and is inserted between the spinous processes. It is designed with the main purpose to decrease the forces acting on the articular facets of the apophyseal joints. Nowadays, a titanium-based (Ti6Al4V) device is commercially available, but clinical data about the success or failure rates in a sufficiently long time are not such to give a definitive answer.

The first aim of the present paper is to assess the biomechanical compatibility of the titanium-based “U” shaped device for the “dynamic stabilization”.
Furthermore, we have investigated a new possible material for the implant and its relevant effects on the biomechanical behaviour of the spinal segment. To this purpose, we have considered a superelastic alloy (Ni-Ti). Since it is expected to work exploiting its superelastic behaviour, the Ni-Ti alloy is able to withstand large strains (up to 7%) without undergoing plastic (irreversible) deformations, in contrast to the Ti6Al4V device that, under the same loading conditions, could develop plastic strains as shown in the results reported in the following. The phase transformations occurring in the Ni-Ti material provide the device with an overall compliance, which is more compatible with the physiologic behaviour of the FSU.

The assessment of the biomechanical behaviour of the damaged FSU and of the treated FSU has been carried out by using a finite element model with suitable implementation of material constitutive laws for the biological tissues and for the metal alloys.

**Numerical model of the L4-L5 Functional Spinal Unit**

**The healthy L4-L5 motion segment**

The anatomy of the L4-L5 FSU was reconstructed in a three-dimensional geometric model by making use of the automatic segmentation technique, starting from Computer Tomography scans (CT): 101 axial sections taken from the abdomen of a male subject having a healthy lumbar spine and an approximate body weight of 70 Kg. The vertebral body, the spinous processes, the transverse processes and the articular processes were reconstructed for both the vertebrae.

The CT technique is not able to recognize the soft tissues with the required contrast level and Nuclear Magnetic Resonance (NMR) data were not available, therefore the geometrical model of the intervertebral disc was obtained using a CAD tool, on the basis of an approximate anatomy with elliptical shape. The maximum and minimum axes of the ellipse were 54 mm and 38 mm, respectively. The intervertebral disc is modelled as the compound of the annulus fibrosus, surrounding the nucleus pulposus, and the two cartilaginous endplates, providing a top and bottom bounding of the disc. The total height of the disc is 12 mm and the annulus fibrosus is 10 mm height. The ratio between the volume of nucleus pulposus and the volume of the total disc is $3/7$ according to [7].

The anterior and posterior longitudinal ligaments, as well as the flavum, intertransverse, interspinous and supraspinous ligaments were modelled as one-dimensional strings with attachment sites obtained from anatomical images. A linear elastic behaviour and a suitable pre-stretching condition were considered [8-11].
The overall deformability of the mechanical system is localized in the soft tissues, i.e. in the intervertebral disc and ligaments; therefore the bone structures were considered as ideally rigid bodies and were discretized on their outer surface only, using about 26000 rigid plate triangular surfaces. This rigid surface does not have finite element variables but the six rigid body degrees of freedom and has the purpose to impose the correct kinematic compatibility conditions with the disc and ligaments.

The annulus fibrosus was discretized using 2160 three-dimensional eight-noded isoparametric solid elements, with hybrid pressure-displacement formulation. It is modelled through a constitutive law, suitable for describing the mechanical behaviour of anisotropic materials subjected to finite strains. The constitutive law relies on the definition of a strain energy function, which considers the material as a composite made of an isotropic incompressible matrix and two families of reinforcing fibres, representing the extra-cellular matrix and the collagen fibres respectively.

A decoupling of the deformation gradient $F_{ij}$ into an isochoric part $\overline{F}_{ij}$ and a volumetric part allows for an easy handling of the incompressibility constraint. According to [12]:

$$F_{ij} = J^{1/3} \overline{F}_{ij}$$

where $J$ is the determinant of $F_{ij}$.

Following this definition, the right Cauchy-Green tensor $C_{ij}$ can be decoupled in the same way:

$$C_{ij} = J^{2/3} \overline{C}_{ij} = J^{2/3} \overline{F}_{ki} \overline{F}_{kj}.$$  

The existence of an elastic strain energy function is postulated, depending on the two invariants $(\overline{I}_1, \overline{I}_2)$ of $C_{ij}$ and on two pseudo-invariants:

$$\overline{I}_4 = n_i^k C_{ij} n_j^k, \quad k = 1 \div 2,$$

which are related to the fibres stretch, accounting for two preferential material directions, which are defined by the two unit vectors $n_i^k$. These are the orientations of the reinforcing fibres in the undeformed configuration.

The strain energy function can be written as follows:

$$W = \frac{\mu}{2} (\overline{I}_1 - 3) + \sum_{\mu=1}^{2} \frac{k_1}{2k_2} \exp \left[ k_2 (\overline{I}_4 - 1)^2 \right] - 1 + p(J - 1),$$
where $\mu$ is the shear modulus of the material ($\mu = 1.33$ MPa); $k_1$ and $k_2$ are parameters for the fibres, $k_1$ is measured in stress units ($k_1 = 3$ MPa), $k_2$ is dimensionless ($k_2 = 45$); $p$ is the hydrostatic pressure in the material. The material constants used in the numerical simulations are those reported in [12].

The collagen fibres are anatomically arranged in concentric layers within the annulus fibrosus. 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 $\pm 33^\circ$).

The healthy nucleus pulposus was treated as a cavity filled with an incompressible fluid, i.e. the nucleus pulposus bears a hydrostatic state of stress only. The finite element code used in this study treats the fluid-filled cavity through membrane elements on the boundary of the cavity. A single finite element variable is assigned to the fluid, i.e. the fluid pressure, which is obtained by enforcing the incompressibility constraint.

Each cartilaginous endplate was discretized by using 650 eight-noded three-dimensional isoparametric solid elements. They have been modelled using an isotropic linear elastic constitutive law with Young modulus of 23.8 MPa and Poisson ratio of 0.28 [12].

The contact between the two articular facets of the apophyseal joints was simulated through suitable gap elements, able to impose a kinematic unilateral constraint along a prescribed direction, i.e. the vertical direction in the present model [13-17].

Simulation of the pathologic conditions

In this study, we have considered a disc damage characterized by a radial tear in the annulus fibrosus, originating from its inner part and extending to its outer part. The tear is located in the postero-lateral region. Three different stages of disc damage were considered: i) a radial tear extending in the 30% of the annulus radial thickness; ii) a radial tear extending in the 65% of the radial thickness and iii) a complete rupture of the annulus fibrosus and loss of fluid in the nucleus pulposus. A sketch of the healthy and of the three pathologic conditions is reported in Figure 2.

The radial tear was simulated by removing elements from the annulus fibrosus through the whole height of the disc, according to [14].

Two loading conditions were considered: axial compression and flexion rotation (bending in the sagittal plane). A maximum force of 2 kN was applied in the compression loading case. A maximum bending moment of 60 Nm was applied in flexion; in this latter case, a compression preloading force of 1000 N was applied. This allows taking into account the effect of the body weight above L4 and of the muscle forces acting in the erect standing position [18-20].

Forces and moments are applied to the centre of mass of the L4 vertebra, whereas the six degrees of freedom of the L5 vertebra were constrained.
Figure 2. Sketch of the healthy and pathologic annulus fibrosus (top) and his finite element discretization (bottom).

The analyses of axial compression have shown that the radial tears do not affect the overall axial stiffness of the damaged FSU, for both the 30% and 65% amount of damage. A considerable loss of stiffness is predicted in the case of complete rupture of the annulus fibrosus, see Figure 3 (left). This phenomenon is essentially due to the loss of the bearing capacity of the nucleus pulposus that occurs in the simulation of this particular pathological condition. Indeed, the physiological role of the nucleus pulposus is to transmit part of the vertical load by increasing its hydrostatic pressure and applying the pressure to the internal wall of the annulus fibrosus. In these conditions, the collagen fibres are subjected to a tensile stress. If the nucleus pulposus looses its functionality, the load bearing mechanism of the whole system changes drastically and the disc becomes more compliant.

Figure 3. Compressive axial force, applied to the L4 centre of mass versus L4-L5 relative displacement (left); axial force sustained by the apophyseal joints for a total applied axial force of 1200 N (right).
Furthermore, the fundamental role played by the nucleus pulposus appears when calculating the force transmitted through the apophyseal joints. Indeed, for both the 30% and 65% amount of damage the forces transmitted through the apophyseal joints do not change significantly, whereas the total annulus rupture and the loss of the hydrostatic pressure within the nucleus increase the loads on the joints considerably. The load applied on the joints is about 27% of the total compressive load (1200 N) in the case of complete rupture of the annulus fibrosus; in all the other situations the load applied on the joints is about 19% of the total force magnitude; see Figure 3 (right).

The damaged disc exhibits a bulge in a location close to the radial tear; in particular, the bulge increases considerably in the case of the damage extent of 65% with respect to the undamaged and 30% of damage extent cases. From the clinical point of view, the bulging causes a reduction of the free space in the intervertebral foramen with possible compression of the spinal cord or the nerve roots, depending on the bulge location i.e. posterior or postero-lateral, respectively. The complete rupture and the loss of the hydrostatic pressure within the nucleus reduce the bulge in the posterior locations and increase that in the anterior and lateral locations (see Figure 4). In the real pathological situation in case of complete rupture, the development of the hernia occurs, but the proposed numerical model does not account for this circumstance.

The stress distribution in the annulus fibrosus is symmetric with respect to the mid-sagittal plane. The occurrence of the annulus damage causes an

![Figure 4. Bulging in the axial plane of the annulus fibrosus calculated along a mid-axial external path, in the hoop direction. The path starts in the anterior portion of the annulus as in the sketch. An axial external force of 2000 N is applied.](image)
increase of stress in the tissue close to the tip of the tear. The von Mises stress calculated for the 65% damage is 100% greater than that calculated for the 30% damage case (see Figure 5), whereas a complete rupture of the annulus increases the stress in the anterior and lateral regions.

In Figure 6 (left), a colour contour plot of the von Mises stress in the disc is displayed. Note the stress peak at the postero-lateral location. A top view of the von Mises stress distribution in the 65% damaged disc is reported in Figure 6 (right).

**Figure 5.** Von Mises in the axial plane of the annulus fibrosus calculated along a mid-axial external path, in the hoop direction. The path starts in the anterior portion of the annulus. An axial external force of 2000 N is applied.

**Figure 6.** Von Mises stress in the intervertebral disc for an applied axial compression force of 2000 N.
The clinical relevance of this result is that the stress peak induced by the
tears, may cause the complete rupture of the annulus and eventually leads to
the hernia [1].

Further numerical analyses, aimed at simulating flexion in the sagittal
plane, have shown that the tear do not affect substantially the behaviour of the
FSU in terms of moment-rotation relationship. This result indicates that the
nucleus pulposus does not play a relevant role under sagittal flexion.

**Numerical model of the interspinous implant for
“dynamic stabilization”**

As described in the above section, the pathologic conditions of the
intervertebral disc may have three main clinical consequences: i) increase of
rupture risk for the partially damaged annulus fibrosus, ii) loss of FSU axial
stiffness in case of complete rupture of the annulus and iii) overload of the
articular facets on the apophyseal joint.

The aim of the present section is to investigate the biomechanical effects
induced by the surgical implant of the “U” shaped interspinous device with
respect to the three above-mentioned factors.

The numerical model of the treated FSU consisted of the finite element
grid for the tissues: the bone structures (i.e. vertebral bodies and posterior
processes), the annulus fibrosus and the cartilaginous endplates; and the finite
element grid of the device inserted between the spinous processes (see Figure
7). Only the outer surface of the two vertebrae was discretized as rigid
surfaces. The finite element mesh for the device consists of 690 eight-noded
isoparametric solid elements. Only the portion of the device having a structural
relevance was taken into account and discretized.

During the surgical procedure, the annulus fibrosus is incised and the
nucleus pulposus is removed (nucleotomy); therefore, the numerical model does
not take into account of the hydrostatic pressure within the nucleus pulposus.

![Figure 7. The interspinous device (left); the finite element model of the L4-L5 lumbar motion segment with the implanted interspinous device (centre) and the finite element discretization of the interspinous device (right).](image-url)
Two different devices were considered: a commercially available titanium based device and an innovative device made of a superelastic Ni-Ti alloy.

The Material model for the titanium alloy (Ti6Al4V) is an elastic-plastic model with linear isotropic hardening and von Mises yield surface. The yield stress is 790 MPa, the ultimate stress is 860 MPa, the Young modulus is 110 GPa and the Poisson ratio is 0.3.

The material model for the Ni-Ti device is based on the simulation of the phase transformation, which is activated when a stress-based criterion is fulfilled. The transformation causes a stiffness decrease and a plateau in the stress-strain uniaxial response. Once the transformation is completed, the stiffness increases to that of the generated phase. The Young modulus is 75 GPa, the Poisson ratio is 0.3, the yield stress, above which irreversible strains occur, is 700 MPa. The stress threshold above which the phase transformation occurs is 105 MPa [21, 22].

The static boundary conditions simulate the axial compression and the flexion in the sagittal plane through the application of a maximum axial force of 2 kN and a maximum bending moment of 60 Nm; the kinematic boundary conditions were the same as those used in the numerical analyses described in the above section.

The simulation of the axial compression has shown that the implant of the devices does not enhance the stiffness of the segment, with respect to that of the complete damaged disc.

Moreover, the simulation has shown that the devices are able to reduce the force acting on the apophyseal joint; note that this is the main design purpose for such kind of devices.

Under an axial force of 1200 N and the implant of the Ni-Ti based device, the forces acting on the apophyseal joints are 58% of that acting in case of complete rupture of the disc before implantation. The force acting in the case of titanium-based device is about ten times lower (see Figure 8 left): this unloading is considered excessive in respect of the healthy situation with regards to the bone shielding phenomenon; moreover, in this case the damaged annulus fibrosus is overloaded.

The two devices exhibited dissimilar behaviour under flexion in the sagittal plane. Indeed, the FSU treated with the Ti6Al4V device was characterized by a high stiffness, whereas the FSU treated with the Ni-Ti device exhibited a flexural stiffness more compatible to that of the healthy segment (see Figure 8 right).

The higher compliance exhibited by the Ni-Ti device is provided by the reversible phase transformations occurring in the superelastic alloy.

Moreover, the numerical simulations have predicted the onset of plastic (i.e. irreversible) deformations within the titanium-based device, for moments greater than 35 Nm. Since data on the magnitude of the physiological loads
acting on the lumbar segments taken from the literature, are discordant, it might be questionable whether in the treated FSU the moment of 35 Nm is clinically meaningful. However, plastic strains occur at a relative rotation between L4 and L5 of about 2°, this limits significantly the range of motion of the FSU treated with a titanium-based device.

**Conclusions**

This research work investigates intervertebral disc diseases and possible surgical treatments with interspinous implants for “dynamic stabilization”.

The major clinical consequences of the disc damage are the loss of axial stiffness of the diseased FSU, loss of height of the intervertebral space, reduction of the range of motion of the segment and increase of the load on the articular facets on the apophyseal joints. Disc damage may be characterized by radial or circumferential tears along the annulus fibrosus and by the fluid loss in the nucleus pulposus. These two circumstances represent two stages of the disc damage evolution. In this work, radial tears have been considered. The fluid pressure in the nucleus acts on the damaged annulus fibrosus; if the tears are not extended to the full width of the annulus (radial distance in the axial plane), the nucleus pressure increases the stress at the tip of the tear, eventually increasing the rupture risk for the annulus. When the rupture of the annulus occurs, the nucleus pulposus herniates and it ceases to withstand the axial load, thus changing the whole stress pattern in the disc. In this pathologic situation the share of axial load sustained by the disc can drastically diminishes from 80% to 30%; this implies the overload of the articular facets.

**Figure 8.** Axial force sustained by the apophyseal joints for a total applied axial force of 1200 N (left); flexion in the sagittal plane: the L4 applied moment versus the relative L4-L5 rotation (right).
The implant of an interspinous device may be effective in restoring the loss of functionality of the damaged FSU.

The suitable shape design and material design for the implant enhance the biomechanical performances of such implants. From the clinical point of view, one of the main advantages of the interspinous implants relies in the relatively simple and mini-invasive surgical procedure from posterior access.

In this research work we have used the numerical simulations in order to investigate the biomechanical behaviour of a damaged disc and to quantify the biomechanical performances of two different interspinous implants. The shape of the implants is that of a commercially available U shaped interspinous device and the materials are a titanium-based alloy and a superelastic alloy, respectively.

The numerical simulations of the biomechanical behaviour of the healthy and damaged FSU have clearly reproduced the biomechanics of a damaged disk with specific reference to the clinical issues. In particular, the loss of stiffness of the damaged FSU and the overload of the articular joints have been put in evidence.

The numerical model for the biomechanical behaviour of the treated FSU has shown that part of the compatibility issues may be accounted for when using a suitable designed implant. Indeed, the overload of the articular joints may be successfully relieved by both the kinds of implants considered in this study. This means that the main goal of the implants is pursued.

Nevertheless, the implants are not able to restore the physiologic stiffness under axial load, whereas the flexural stiffness in flexion exhibits a satisfactory compatibility with the healthy situation, when considering the superelastic alloy.

A number of issues, concerning other possible failure scenarios for the interspinous implants, remain open. The implant is designed to transmit forces to the posterior processes. The strength of the bone tissue in that region may be of major concern in case of patients affected by a bone disease like osteoporosis. A suitable strength analysis of the bone structures should be carried out in order to assess the risk of bone failure. A reliable analysis relies on the knowledge of the strength parameters for osteoporotic bone.

This issue moves the problem towards a patient specific approach, in which the bone strength of each specific patient may be estimated in a pre-surgical stage with appropriate diagnostic tools.

This specific aspect may be included in the selection of the shape and of the material for the device, which is suitably chosen for the patient.

Another failure scenario that is worth to be investigated is the failure of the fixation structures. Indeed, the device is clamped to the posterior process through suitably designed fixation wings. The strength of such wings has not been investigated in this study. However, under some specific loading
conditions, the wings may be subjected to loads that can threaten the gripping to the bone or even lead to the collapse of the wings. This issue belongs to further investigations.

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