Pre-clinical Evaluation of the Biomechanical Behavior of Implantable Devices for Orthopedic and Spinal Surgery
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Abstract— The assessment of the suitability of the biomechanical performances of a medical device intended to replace either a function or tissue, is a primary issue in the pre-clinical evaluation of a new device. Such evaluation is usually performed by means of either experimental facilities or computational simulation or, better, by the interaction of both the methodologies. Difficulties arise when trying to combine the need of simulating the complexity of the biological response to the implant with the necessity of maintaining a reproducible and simple experimental procedure. At LaBS, devices for the treatment of pathologies of lower limbs and spine are subjected to purposely designed experimental protocols and numerical simulations in order to take into account requests regarding their anatomical, functional and surgical compatibility, as well as their mechanical reliability in time. Two examples of such pre-clinical studies are here given: in particular the impact of different surgical techniques used in the implant of an interspinous device on its functional compatibility has been investigated by means of an experimental animal model; the fatigue resistances of the tibial tray of a polymethyl methacrylate (PMMA) knee spacer have been predicted and validated by means of a combined computational and experimental procedure, using advanced stress criterion based on stress invariants.

I. INTRODUCTION

The assessment of the suitability of the biomechanical performances of a medical device intended to replace either a function or tissue, is a primary issue in the pre-clinical evaluation of a new device.

Purposely designed experimental protocols and numerical simulations are needed in order to take into account requests regarding the biomechanical compatibility of implantable devices: in particular, the surgical compatibility can be studied through specific animal models; the fatigue resistances of the tibial tray of a polymethyl methacrylate (PMMA) knee spacer have been predicted and validated by means of a combined computational and experimental procedure, using advanced stress criterion based on stress invariants.

A. Interspinous device

Interspinous devices are widely used for the treatment of lumbar stenosis. The DIAM (Medtronic Ltd., Memphis, TN, USA) is an interspinous implant made of silicone secured in place with two laces. The device can be implanted by a posterior access with sacrifice of the supraspinous ligament or by a lateral access with preservation of the ligament. The aim of the present work is the evaluation of the role of the laces, the supraspinous ligament, the device size and positioning in determining the capability of the device in reducing the segmental lordosis and in stabilizing motion.

B. PMMA knee spacer

Infection of a knee prosthesis is still one of the major concerns about the reliability in time of this implantable device: the preferred treatment of this condition has turned out to be the use of a knee spacer in the two-stage reimplantation technique.

The advantages of this technique associated to the use of a mobile spacer lay in the possibility for the patient to move during the interim period, thus decreasing the risk of muscle contracture due to immobilization, and to release antibiotics directly on the site of infection.

Fatigue reliability is a primary requirement to avoid catastrophic failures of implants in vivo, but also to ensure the correct function and life expectancy of device. So far, experimental tests have played the major role in the evaluation of fatigue resistance of orthopaedic devices: standardized protocols are usually adopted to ensure that implants are rigorously tested in a valid and appropriate manner that represents the in-vivo failure modes. However, fatigue tests involve rather high costs due to the large number of tested specimens and very long test duration. The implementation of finite element analyses has become a valid tool in biomechanical design not only to evaluate new technological solutions but also for the reliability assessment of pre-existing devices.

II. METHODS

A. Interspinous device

Biomechanical tests in flexion-extension on eight porcine spines (L2-L5) implanted with the DIAM with and without the laces and the supraspinous ligament have been performed.

The tests were performed by using a servohydraulic axial-torsional testing machine MTS 858 Bionix (MTS Systems, Minneapolis, MN, USA). An apparatus able to
convert the vertical force produced by the testing machine into moments in flexion and extension combined with compression was designed (Fig. 1).

An opto-electronic system, BTS Smart-e equipped with Smart Analyzer software (BTS Bioengineering SpA, Milano, Italy) consisting of six infrared emitters and six CCD cameras positioned around the testing machine was used to determine the movements of the segments of the lumbar specimen by tracking the trajectories of spherical markers attached onto the vertebrae. Three markers were positioned on each vertebra.

The bending moment applied to the specimen was calculated as the product of the vertical force and its lever arm, that is the distance between the force axis and the sagittal position of the center of the L3-L4 functional spine unit, measured via the opto-electronic system based on the position of the L3 markers.

All the spine specimens were subjected to tests in both flexion and extension; each test consisted in the application of three cycles up to a specific moment (3 Nm in both flexion and extension).

The ROM of the specimens was calculated as the difference between the rotation observed for the maximal moment applied and the neutral position both in flexion and extension. The rotation was defined as the angle between L3 and L4 in the sagittal plane; the zero value was defined in the unloaded condition for the intact spine after hemifacetectomy.

The neutral position was conventionally determined for each one of the configurations described below as the rotation relative to the zero value.

Five configurations were tested for each specimen (Fig. 2), in both flexion and extension, after an initial check of the mild instability due to the hemifacetectomy at the considered level. The five configurations were the following: (a) – spine after hemifacetectomy (control specimen); (b) - configuration (a) after insertion of the DIAM in L3-L4, without laces; (c) - configuration (b) after fixation with the laces; (d) - configuration (c) after resection of the SSL; (e) - configuration (d) after removal of the laces.

The configurations representing the most common clinical uses of the DIAM were the (c), which simulated the lateral access with preservation of the SSL, and the (d), resembling the standard posterior access. As stated above, the configuration (b) was also reported to be employed, considering the SSL to be sufficient to secure the device in place.

B. PMMA knee spacer

Mechanical components of implantable devices usually undergo multiaxial loading, due to the complex geometries or external loadings. As a consequence, simplified theoretical approaches are not effective and multiaxial fatigue criteria (Sines, Kawada, ) are used.

![Fig. 2. Tested configurations](image)

The fatigue limit concept in multiaxial stress conditions can be reduced to the idea of separation of the whole stress space into two parts, the unsafe and the safe one. Hence, the fatigue criterion can be solved as an inequality, \( \sigma^* \leq \frac{\sigma_{\text{lim}}}{\eta} \), where \( \eta \) and \( \sigma_{\text{lim}} \) are a suitable safety factor and the...
Satisfaction of this inequality implies that the stress state induced by the external cyclic load remains within the safe part of the stress space. Accordingly, a computational approach to predict fatigue life has been developed at LaBS, based on the implementation of finite element analyses and application of multiaxial fatigue criteria: the sketch of the followed path is represented in Fig. 3.

The tibial component of a polymethyl methacrylate (PMMA) knee spacer produced by Tecres S.p.a. (Sommacampagna, Verona, Italy) was considered for the analysis. The material exhibits a linear elastic mechanical behaviour and shows a brittle fracture-mode: the fatigue curve of the is reported in Fig. 4.

The Young modulus was assumed equal to 2.70 GPa and the Poisson coefficient variable between 0.4 and 0.5. The adopted test protocol is the one of the ISO 14879 standard test for tibial plates.

The developed numerical approach has been applied to evaluate the device fatigue behaviour: numerical results have been obtained by using ABAQUS ver.6.5.1 and a purposely made post-processing implementation of multiaxial fatigue criteria (Sines, Kawada).

The numerical results have been compared to experimental test carried out at LaBS on the spacer tibial component to obtain its fatigue curve (Villa and Carnelli, 2000) at three different load levels (400, 500 and 600 N until fracture or 0.5 Mcycles were reached.

III. RESULTS

A. Interspinous device

Results are summarized in Fig. 5

After implantation of the DIAM device, a shift in the neutral position towards kyphosis and a modification of the ROM is observed.

If the SSL is preserved (b) the neutral position is more flexed, from 0 to 2.5 degrees.

The use of the laces (c) induces a less flexed neutral position with a reduction of 40%; moreover, a reduction of the ROM in flexion of 33% and a recovery in extension of 57% is observed.

After the cut of the SSL (d), the neutral position is more flexed by 47%, ROM in flexion increased by over 20%, while decreased by 12% compared with the config. 2. In extension the ROM decreased by 48%.

Without the SSL and the laces (e) the neutral position was more flexed, with an increase of 260%, with respect to (c). In extension the excessive flexed condition of the neutral position increased the ROM by over 48%.

B. PMMA knee spacer

All the criteria were able to identify the most critical points on the spacer upper surface.

Simpler criteria (Sines) for ductile materials were not able to predict the fatigue behaviour of the device, in comparison with data from literature.

On the contrary, advanced stress criteria for brittle materials (Kawada) allowed to have predictions that have nicely matched the experimental curves, provided that the correct value of the Poisson coefficient was chosen.

Fig. 6 reports the obtained results at different values of such coefficient: a strong dependence on the value of Poisson ratio is detectable and, in particular, the best fitting of the experimental data is achieved with 0.45 Poisson coefficient value (Fig. 7).
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