Optimization of a dynamic spinal implant: Selection of a polymer material

[12] Lucie Monède-Hocquard, [1]* Michel Mesnard, [3] António Ramos, [4] Olivier Gille

[1] Université de Bordeaux, Institut de Mécanique et d'Ingénierie, CNRS UMR 5295, Talence, Fr.
* m.mesnard@i2m.u-bordeaux1.fr
[2] Société S14 Implants, Pessac, Fr.
[3] University of Aveiro, TEMA, Biomechanics Research Group, Aveiro, Pt.
[4] Centre Hospitalier Universitaire, Service Orthopédie, Bordeaux, Fr.

SUMMARY

"Dynamic stabilisation" systems are developed to treat disorders of the spinal column. In contrast to arthrodesis, the aim is to conserve intervertebral mobility. When developing innovative concepts, mechanical tests need to be carried out in order to validate the different technological solutions.

The present study focuses on the B Dyn dynamic device (S14 Implants, Pessac, Fr.), the aim being to optimise the choice of polymer material used for one of the components. Phase one consisted of static tests on the implant, as a result of which polyurethane (PU) was selected, material no.2 of the five elastomers tested. In phase two, dynamic tests were carried out. The fatigue resistance of the system was tested over five million cycles with the properties of the polymer elements being measured using dynamic mechanical analysis after every million cycles. This analysis demonstrated changes in stiffness and in the damping factor which guided the choice of elastomeric material.

INTRODUCTION

The fusion technique is frequently used in spinal surgery. It is currently the landmark surgical treatment but it suppresses completely and definitively the mobility of the segment operated on [1]. As a result, more recently "non-fusion" technologies have been developed [2]. The purpose of these dynamic stabilisation devices is to limit further development of the disorder by retaining partial mobility. In contrast to disc prostheses and facet replacement devices, when posterior dynamic stabilisation (PDS) systems are used, the entire disc and facets can be preserved [3].

The B Dyn device is a new lumbar implant which belongs to the category of PDS devices with pedicle screw fixation systems. It consists of four parts: two metal rods and two flexible elements made from polymer (Fig. 1). Each of the two B Dyn implants is fixed to the vertebrae with titanium pedicle screws. The piston rod has three main functional mobilities: one translation and two rotations (Fig. 1).

First, this study describes the influence of the material of which the ring is made on the mechanical performance of the device under traction. The results of these static tests are then used to preselect the elastomeric material. Next, the behaviour of the B Dyn assembly with the chosen material is evaluated under dynamic conditions.
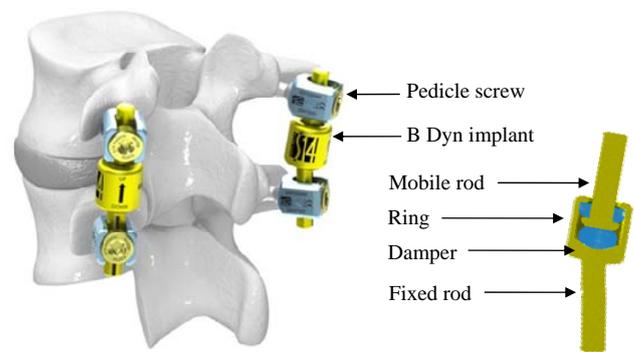
Figure 1: B Dyn spinal assembly.

METHODS

Static tests

The purpose of the static tests was to evaluate the transmitted stress, the range of displacement and the limits of damage to the implant when subjected to uniaxial traction. The polymer material of which the ring was made was the only variable parameter. The load/displacement ratio recorded for each material was used to compare the mechanical performances of the rings and determine the parameters for dynamic tests.

Five elastomeric materials were tested. They are numbered 1 to 5 in increasing order of stiffness. For each one, three samples were tested. Tests were carried out on a universal machine at ambient temperature with a displacement of 1mm per minute. The test was stopped when displacement reached 2.5mm that correspond to 2.5 times the maximum anticipated for standard use.

Displacement, stress and time were recorded during each test. Mean stress was calculated for each material then compared for identical displacements (1mm and 2 mm).

Dynamic tests

In order to create similar conditions to those in which the B Dyn is implanted, it was immersed in saline solution. The environment must be taken into account when carrying out fatigue tests as it may affect the performance of the devices. These tests were carried out using a protocol based on ISO 12189 [4]. The assembly consisted of two UHMWPE blocks, standard springs and two implants held by polyaxial

screws (Fig. 2). The solid blocks represented the vertebrae while the springs simulated the stiffness of the intervertebral disc estimated at between 700 N/mm and 2,500 N/mm [4]. The stiffness of each of the three springs interposed in parallel between the blocks was 375 N/mm. Therefore the equivalent stiffness was 1,125 N/mm.

UHMWPE block
B Dyn implant
Springs
Saline solution
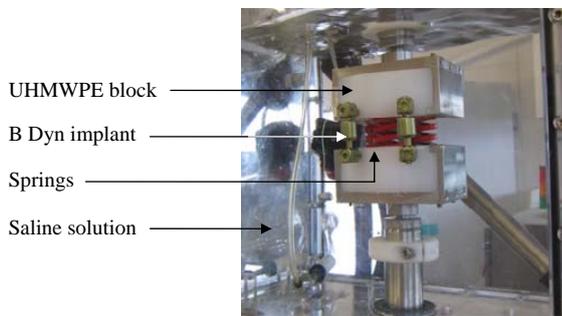
Figure 2: Fatigue test apparatus.

This apparatus was then pretensioned to a compression of 1.5 mm, which was greater than the displacement imposed during the test (1 mm) and was chosen in order to maintain contact between the springs and the block.

An oscillation of +/- 1 mm around the initial position was applied to the assembly, at a frequency of 3 Hz for 5 million cycles. The test was interrupted after each million cycles so that a dynamic mechanical analysis of the polymer elements could be carried out. A series of three tests was carried out; thus six implants were tested. For each test, all the elements were changed. Stress, displacement and time data were recorded for each test. The diameter and height of the polymer elements were also measured every million cycles.

RESULTS AND DISCUSSION

Load ratio Rc, is defined as: Rc = load measured on material no.x / load measured on material no.1, where x = 2 to 5. This ratio represents the change in relative values for loads as a function of displacement. For a quasi static displacement of 1 mm, Rc was around 1.1 and 0.9 for materials no.2 and no.3 respectively. For material no.4 Rc was 2.3 and 2.7 for material no.5. For a displacement of 2 mm, Rc of materials no.2 and no.3 was 2.4 and 2.5 respectively. For material no.4 Rc was 5.8 and for material no.5 it was 6.7.

All three fatigue tests reached 5 million cycles. No deterioration in the implant and no damage to the polymer elements were visible after 5 million cycles. Fig. 3 and 4 show the readings for changes in the dimensions of the dampers and rings after every million cycles. These data are expressed in the form of dimension ratios, where Er is the thickness ratio and Dr the diameter ratio: Er = thickness of the element at n cycles / thickness in initial state and Dr = diameter of the element at n cycles / diameter in initial state. For the dampers, results revealed a 2% loss in thickness compared with the initial state after the first two million cycles. After 3 and 4 million cycles thickness had decreased by 7% and 17% respectively. At the end of the test, loss in thickness was 14%. There was no significant relative variation in the diameter in the course of the cycles. Readings for the rings showed a loss in thickness of 24% compared with the initial state after 1 million cycles. This value remained constant until 3 million cycles. At 4 million cycles the readings for the rings were not the same, -20% for ring 1 and -27% for ring 2. The decrease in thickness was calculated to be 27% for both at 5 million cycles. The

variation in diameter was not significant with regard to the results (-7% for ring 1 and -1% for ring 2).
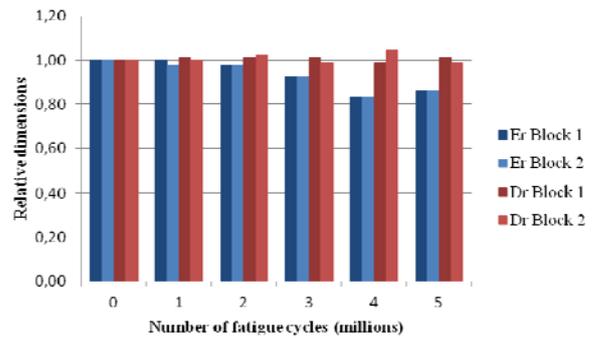
Figure 3: Dimensions of dampers.
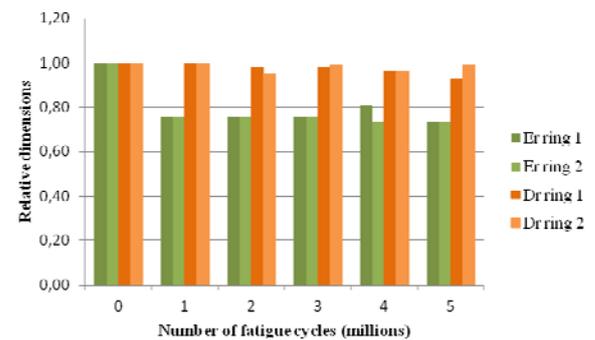
Figure 4: Dimensions of rings.

The tests performed on material no.1 gave load values that were far below those for the other four materials (4.5 to 7.5 times less for a 2.5 mm displacement). Materials nos. 4 and 5 differed from nos. 2 and 3 in that they were capable of bearing loads that were more than twice as great. According to the chemical composition and results of oxidation tests (manufacturer), material no.2 presents a better resistance to ageing (oxidation) than material no.3. As a result of the relative values for loading material no. 2 was selected.

CONCLUSIONS

The thickness of the dampers decreased during the first 4 million fatigue cycles while the thickness of the rings reduced by 1/4 during the first million cycles. This study will be followed up with a fatigue test on a larger number of cycles in order to confirm this stabilisation.

ACKNOWLEDGEMENTS

REFERENCES
1. Guigui P. et al. Conséquences cliniques et radiologiques des arthrodèses lombaires et lombosacrées. Alternatives à l'arthrodèse lombaire et lombosacrée, *Cahiers SOFCOT*, 96, 62-72, 2007.
2. Serhan H. et al. Motion-preserving technologies for degenerative lumbar spine: The past, present, and future horizons. *SAS Journal,* 5, 75-89, 2011.
3. Molinari R.W. Dynamic stabilization of the lumbar spine. *Current Opinion in Orthopedics*, 18, 215-220, 2007.
4. ISO 12189. Implants for surgery - Mechanical testing of implantable spinal devices - Fatigue test method for spinal implant assemblies using an anterior support. *International standard*, 2008.