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Selection of polymer material in the design optimization of a new dynamic spinal implant

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Abstract. "Dynamic stabilization" systems have been developed in recent years to treat degenerative disorders of the spinal column. In contrast to arthrodesis (fusion), the aim here is to conserve intervertebral mobility to maximize comfort. When developing innovative concepts, many mechanical tests need to be carried out in order to validate the different technological solutions. The present study focuses on the B Dyn® "dynamic stabilization" device (S14® Implants, Pessac, France), the aim being to optimize the choice of polymer material used for one of the implant's components. The device allows mobility but also limit the range of movement. The stiffness of the ring remains a key design factor, which has to be optimized. Phase one consisted of static tests on the implant, as a result of which a 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 B Dyn® system was tested over five million cycles with the properties of the polymer elements being measured using dynamic mechanical analysis (DMA) after every million cycles. This analysis demonstrated changes in stiffness and in the damping factor which guided the choice of elastomer for the B Dyn® implant.

Keywords: design optimization; elastomers; mechanical behavior; mechanical tests; spinal implant

1. Introduction

In France, almost three million people suffer from back pain, due mainly to degenerative diseases of the spine. Degeneration is a natural phenomenon, of genetic origin in 75% of cases, and causing changes in the properties of the intervertebral discs (loss of cushioning, collapse, rupture). One consequence can be disc herniation.

The initial treatment for disc degeneration consists primarily of conservative therapies (drugs, immobilization, physical therapy, injections, re-education, etc.). Five per cent of patients aged 30 or over who suffer from back pain do not experience any relief. Surgical implants are then a

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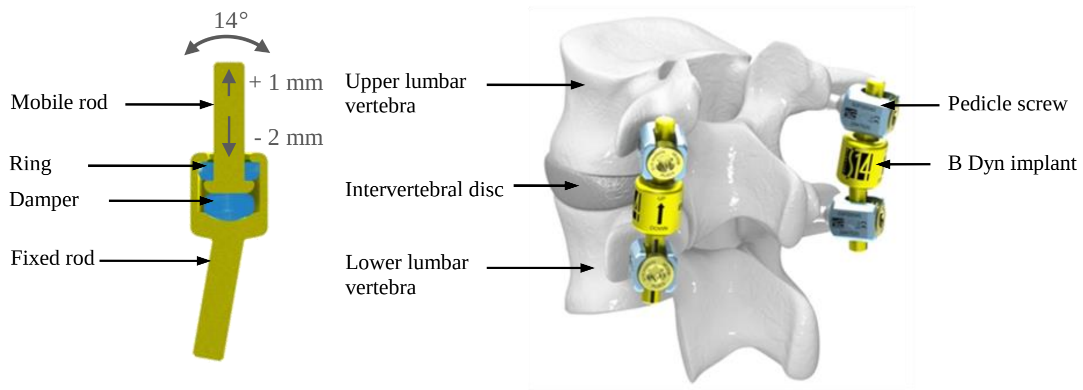
second treatment option to reduce pain and improve quality of life.

The fusion technique is frequently used in spinal surgery; it is currently the landmark surgical treatment (Guigui 2007, Barrey 2013). It suppresses completely and definitively the mobility of the segment operated on. Traditionally, fusion combines instrumentation using a posterior approach (pedicle screws and rods) with a bone graft. Even though the clinical results may be satisfactory, this technique can have some negative consequences: loss or screw breakage, pseudo arthrosis (lack of consolidation around the operated area), deterioration of adjacent levels, etc. and many authors have also become interested in the consequences of fusion for the adjacent vertebrae (instability, herniated disc, stenosis, etc.) (Aota 1995, Ekman 2009, Etebar 1999, Kumar 2001, Schlegel 1996).

As a result, more recently "non-fusion" technologies have been developed (Anand 2008, Lau 2007, MSAC 2007, Serhan 2011). The purpose of these systems, which are also called dynamic stabilization devices (standard term), is to limit further development of the disorder by retaining partial mobility while relieving intra-discal pressure and the load on the articular facets. In contrast to disc prostheses and facet replacement devices (McAfee 2007), when posterior dynamic stabilization (PDS) systems with pedicle screws are used, the entire disc and facets can be preserved (Araghi 2007, Barrey 2008, Molinari 2007, Schroeder 2011, Molinari 2013).

The B Dyn® device (S14® Implants, Pessac, Fr.) 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 (piston rod and fixed rod) and two flexible elements made from polymer (ring and damper) (Fig. 1(a)). The device has a total height of 38 mm and a diameter of 12.5 mm. The portions of the rods connected to the screws have a diameter of 5 mm. Two B Dyn® devices and four screws (spinal mounting) are required to ensure the stabilization of a spinal segment. Each implant is fixed to the lumbar vertebrae with titanium pedicle screws (Fig. 1(b)). After implantation the piston rod has three main types of functional mobility: translation and two types of rotation (Fig. 1(a)).

The main function of the B Dyn® system is to stabilize the lumbar segments during three types of anatomical movement (flexion-extension, lateral bending and axial rotation). It must therefore allow mobility but also limit the range of movement of one vertebra in relation to the other.



(a) (b)

Fig. 1 (a) B Dyn® implant, (b) B Dyn® spinal assembly

The patient's movements are dampened by the polymer elements of the two implants. Flexion, a movement that is repeated very often in the course of daily activity, brings the rings into play (traction load on the implants), which limit the range of movement.

Several design solutions have been studied and undergone mechanical testing to ensure simultaneously both mobility and control of the range of intervertebral movement (Guerin 2009). When searching for a technological solution, the stiffness of the ring remains a key design factor, and one which has to be optimized. An inappropriate degree of stiffness could either fail to limit range of movement, or it could generate movement in the screws and hence reduce the lifetime of the system.

The biocompatible polymers selected for this implant were elastomers commonly used for medical applications: polyurethane (PU) and polydimethylsiloxane (PDMS) (Christenson 2004, Colas 2004, Curtis 2004, Hsu 2004, Thomas 2007, Staniszewski 2014). However, during repeated use, there is a phase difference between the imposed load and the response of the material. Some of the mechanical effort applied to the material during each cycle is dissipated and can cause a break in the joints, structural changes or it may be converted into heat.

The post clinical study of one hundred thirteen patients has pointed out a necessary surgical recovery in four cases where the initial silicone ring was degraded due to an accidental overload of the implant. In these cases of surgical recovery, the two devices are replaced by metal rods (fusion).

First, this study describes the influence of the material of which the ring is made on the mechanical performance of the B Dyn® implant under traction. The results of these static tests are then used to preselect the elastomeric material to be used.

Next, the behavior of the B Dyn® assembly with the chosen material is evaluated under dynamic conditions.

2. Materials and methods

2.1 Static tests

The purpose of these static tests was to evaluate the transmitted load, the range of displacement and the limits of damage to the B Dyn® 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 elastomers were tested, one PDMS and four PU. For reasons of confidentiality, they are numbered 1 to 5 in increasing order of hardness (70 Shore A to 55 Shore D). The PDMS material is the no.1, considered in the following as the reference material. For each material, three samples were tested. Tests were carried out on a universal testing machine (INSTRON) at ambient temperature with displacement of 1 mm per minute. The test was stopped when displacement reached 2.5 mm (2.5 times the maximum anticipated by the manufacturer, for standard implant use).

Displacement (mm), load (N) and time variables were recorded during each test. Mean load was calculated for each material then compared for identical displacement values (1mm and 2 mm).

2.2 Dynamic tests

There are specific norms for mechanical tests on spinal assemblies which provide guidelines for the materials and methods to be used in the experimental protocol (F1717-11 2011, ISO 12189 2008).

Two dynamic tests were carried out in this study: fatigue test and Dynamic Mechanical Analysis (DMA). The fatigue tests were done on a B Dyn® spinal assembly; tests were interrupted after every million cycles so that DMA could be carried out. The elastomer elements (rings and dampers) of the B Dyn® were tested by DMA at the same time, each time tests were interrupted. The material of the rings was the same for all dynamic tests. It was chosen at the end of the static tests.

2.2.1 Fatigue tests

The purpose of these tests was therefore to test the fatigue resistance of the entire assembly with the B Dyn® implants incorporating the elastomer that had been preselected following the static tests. The spinal assembly was considered satisfactory if the fatigue test reached five million cycles with failure in none of the assembly parts (ISO 12189 2008).

In order to create similar conditions to those in which the B Dyn® spinal assembly is implanted, it was immersed in saline solution.

These tests were carried out in compliance with the international standard ISO 12189 (standard for fatigue testing of spinal implant assemblies using an anterior support) (ISO 12189, 2008).

The assembly consisted of two ultra-high molecular weight polyethylene (UHMWPE) blocks, standard springs and two B Dyn® implants held in place by polyaxial screws (Fig. 2). The solid blocks represented the vertebrae (upper and lower) while the springs simulated the stiffness of the intervertebral disc under compression estimated from the literature at between 700 N/mm and 2,500 N/mm (ISO 12189 2008).

The stiffness of each of the three springs (coded red in accordance with standard 10243) interposed in parallel between the UHMWPE blocks was 375 N/mm. The equivalent stiffness was therefore 1,125 N/mm.

The traction resistance of the two blocks was 40 MPa and they were fixed to the test machine by means of metal frames.

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

Next, the pedicle screws, measuring 5.5 mm in diameter and 30 mm in length, were screwed into the blocks, and the two B Dyn® implants were placed in the screw heads and held in position by the plugs.

The entire assembly was then placed in a physiological vessel, and immersed in a solution of distilled water with 9 g/L of NaCl, which was heated and maintained at 37°C by means of a thermocouple.

The test was conducted under sinusoidal wave and imposed displacement. 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. After the DMA, the B Dyn® implants were reinstalled and the vessel refilled with a solution of distilled water with 9 g/L of NaCl. Once the

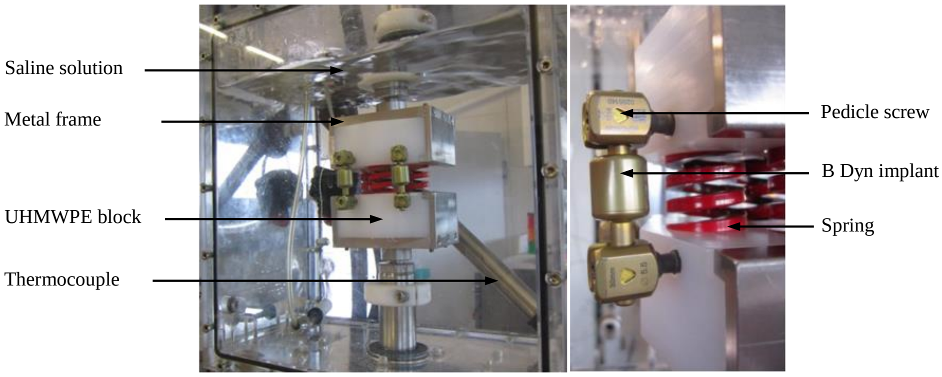


Fig. 2 Fatigue test apparatus

solution was heated to 37°C, the test was continued.

A series of three tests was carried out; thus six implants were tested (each assembly was composed of two implants). For each test, all the elements in the assembly were changed. Load, displacement and time data were recorded for each test. The diameter and height of the polymer elements were also measured every million cycles.

2.2.2 Dynamic Mechanical Analysis (DMA)

In this study, the purpose of the DMA tests was to assess changes in the behavior of the elastomer elements after several fatigue cycles. For this, we were interested in two parameters: damping and stiffness. The DMA tests were carried out with a viscoanalyser (DMA+ 150, METRAVIB) and the data were processed using DYNATEST (METRAVIB) software.

The four elements made of polymers (two rings and two dampers) were tested before the dynamic testing (initial state) then every million cycles (numbered 1 to 5).

The samples were compressed at a frequency of 3 Hz and a temperature of 37°C. Each test lasted five minutes. In order to maintain contact between the sample and the compression plates throughout the test, an initial compression (static compression) was applied to the samples. The dynamic deformation then oscillated around this initial position.

A static compression rate of 33% was applied to the dampers; the dynamic tests were carried out with a compression rate of 5%. For the rings, the static compression rate was also 33% and the dynamic compression rate was 1% (above this value, the stress caused a rebound in the sample which disrupted the readings). Two non-intrinsic characteristics of the material can be obtained for any sample geometry. First, the stiffness is the ratio of the force and of the displacement. Then, the damping factor (or loss factor) also called tan(delta) (or tanδ) expresses the ratio of the energy dissipated by damping and the elastic energy stored during one cycle. Stiffness K (N/m) and tanδ were measured during each test.

3. Results

3.1 Static tests

Material no.1 is defined as the reference material for which the results are given in Fig. 3. To compare the performance of the implant with the other four materials the results are then provided in relative values to the reference material.

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 (Fig. 4) represents the change in relative values for loads as a function of displacement. For a 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.

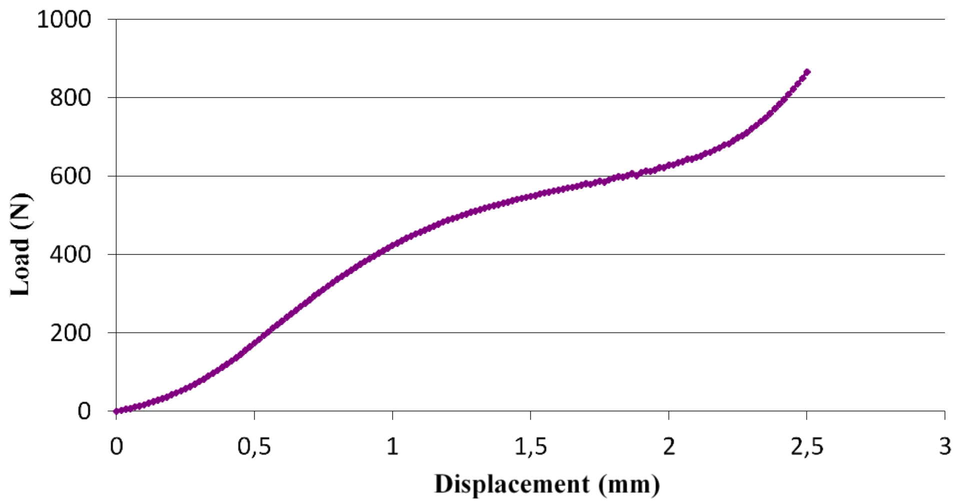


Fig. 3 Static test, reference material (no.1)

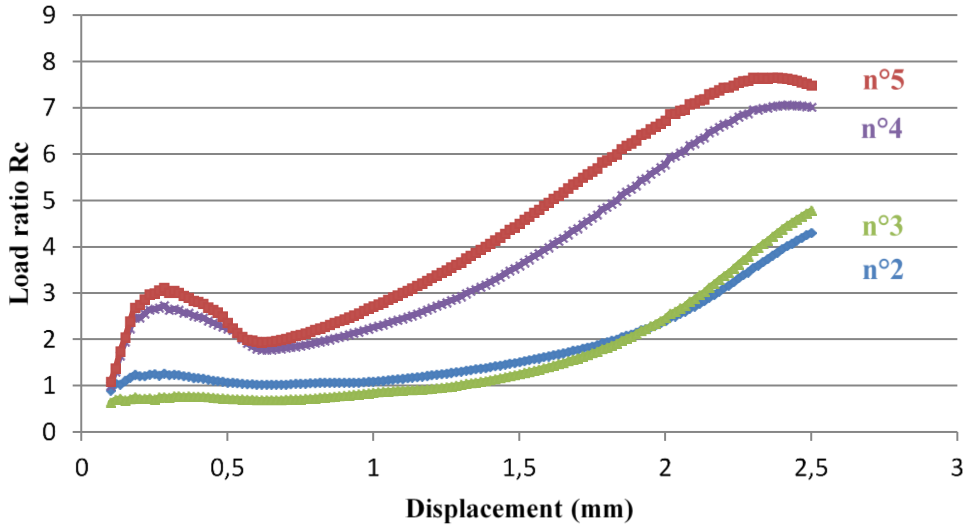


Fig. 4 Static tests, load ratio

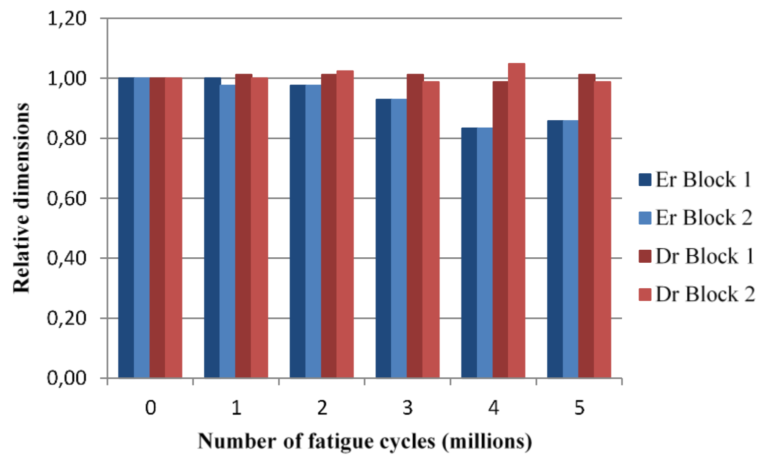


Fig. 5 Changes in dimensions of dampers

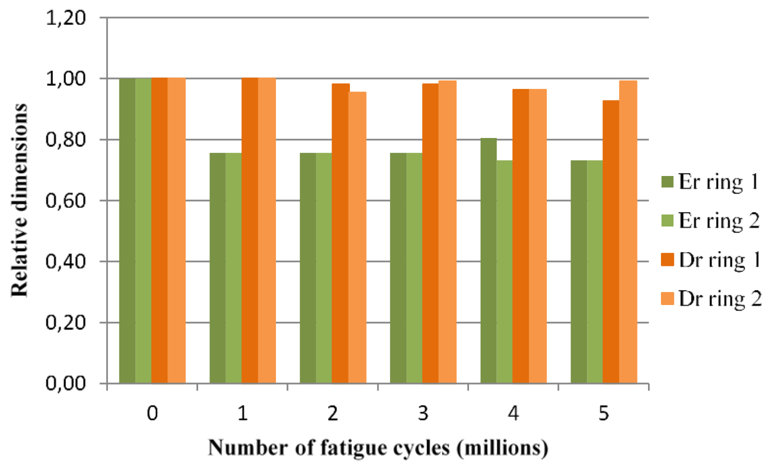


Fig. 6 Changes in relative dimensions of rings

3.2 Dynamic tests

3.2.1 Fatigue tests

All three fatigue tests reached 5 million cycles. No deterioration in the implant or the screws was observed. No damage to the polymer elements was visible after 5 million cycles.

Fig. 5 and Fig. 6 show the readings for changes in the dimensions of the rings and dampers after every million cycles of a fatigue test. To highlight the evolution of dimensions during cycles the 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 of the same element in its initial state,

Dr=diameter of the element at n cycles / diameter of the element in its initial state.

For the dampers (Fig. 5), results revealed a 2% loss in thickness compared with the initial state after the first two million cycles. After 3 million and 4 million cycles thickness had decreased by

7% and 17% respectively. At the end of the fatigue test (5 million cycles), loss in thickness was 14%. There was no significant relative variation in the diameter of the dampers in the course of the cycles.

Readings for the rings (Fig. 6) 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 two 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 rings at the end of the fatigue test, i.e., at 5 million cycles. The variation in ring diameter was not significant with regard to the results (-7% for ring 1 and -1% for ring 2).

3.2.2 DMA

Fig. 7 and Fig. 8 show the readings for changes in stiffness and tanδ after each million cycles of a fatigue test. To highlight the evolution of dimensions during cycles the data are expressed in the form of value ratios, where Rr is the stiffness ratio and TDr is tanδ:

Rr=stiffness of the element at n cycles/stiffness of the same element in its initial state

TDr=tanδ of the element at n cycles/tanδ of the element in its initial state

The results of the DMA tests showed an average increase in the stiffness of the dampers of 1% of the initial reading at 1 million and 2 million cycles, which was of little significance. This increase reached 12% at 3 million cycles (average for the 2 dampers). At 4 and 5 million cycles, however, stiffness decreased by 21% and 22% respectively.

Both rings showed an average decrease in stiffness compared with the original value of 11% at 1 million cycles and 12% at 2 million cycles. The loss in stiffness was 9% after 3 and 4 million cycles. At the end of the fatigue test, the average stiffness of the rings had decreased by 2%.

The tanδ average decreased by 3% after 1 million cycles for the dampers. At 2 million cycles it was the same as the original value. We observed an average increase in tanδ for the dampers of 6% at 3 million and 5 million cycles and 13% at 4 million cycles.

For the rings, the tanδ average decreased by 17%, 13%, 23% and 20% after 1 to 4 million cycles respectively. At the end of the fatigue test, the average tanδ had decreased by 7% compared with the original value.

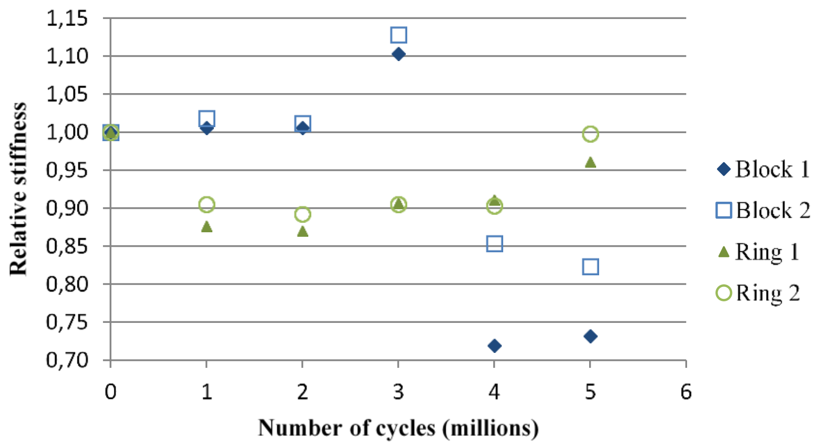


Fig. 7 Changes in stiffness of dampers and rings

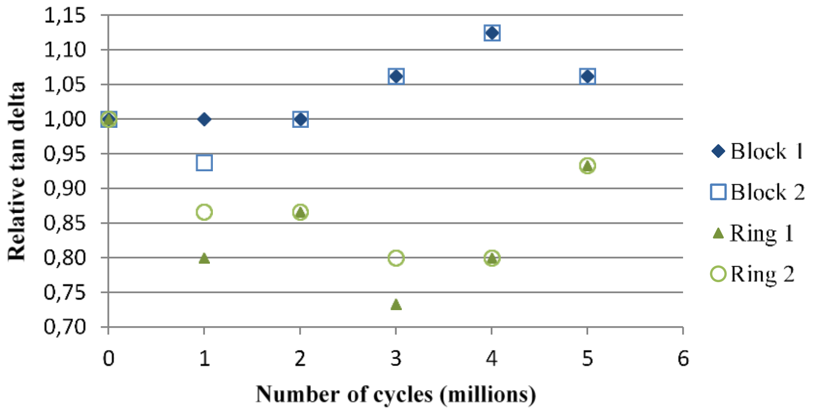


Fig. 8 Changes in tanδ of dampers and rings

4. Discussion

4.1 Static tests

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). In addition, these tests revealed a rapid deterioration in the ring for a displacement of less than 2 mm. Material no.1 did not therefore have suitable qualities to be considered for use in the B Dyn® implant.

Materials nos. 4 and 5 differed from materials nos. 2 and 3 in that they were capable of bearing loads that were more than twice as great.

Additional tests were carried out beforehand on the adherence of the clamping between the head of the pedicle screw and the titanium rod. They showed that a load of about 1800 to 2000 N caused the rod slip relative to the screw head. However, static tests on materials nos. 4 and 5 showed greater loads than these for a displacement of 2 to 2.5 mm. Both these materials could therefore cause a premature deterioration in the spinal assembly (“screw loosening”, broken screws, separation of the implants, etc.). As a result, materials 4 and 5 were not selected.

According to the descriptions supplied by the manufacturers (chemical composition and results of oxidation tests), material no.2 has a better resistance to ageing (hydrolysis and oxidation) than material no.3.

As a result of our analysis of the relative values for loading in these static tests and the information we had collected (manufacturers material, results of earlier mechanical tests and bibliography) material no. 2 was selected for the ring in the B Dyn® implant.

4.2 Dynamic tests

The Several studies have been carried out to understand the consequences of fatigue on the characteristics of elastomeric materials. However, most tests have used simple traction so that specimens with a maximum surface / volume ratio could be used, and the material would not become overheated (Pichon 2010).

El Fray and Altstadt (2011) tested elastomers using the Stepwise Increasing Strain Test (SIST) method to apply strain. Just as when a specimen is under imposed stress, the dynamic modulus decreases as the strain increases. This drop in the modulus means that the imposed strain increment (using SIST) no longer affects the maximal stress that can be reached. We observed that beyond 15% of imposed strain, maximal stress was virtually constant; this was due to the decrease in the dynamic modulus of the material. The reason for this decrease was the softening under strain due to the stress being relaxed. This is the result of damage to the crystalline structure.

In polyurethane materials, softening is linked with a micro-mixture of phases (flexible and rigid). By creating an intermediate phase, there is a reduction in the strengthening effect of the rigid domains and this is therefore accompanied by a decrease in the modulus.

The Mullins effect is a softening phenomenon under stress, observed during the first few cycles of traction when there is major strain on elastomers (Diani 2009). Energy dissipation is virtually static, in other words it is independent of the speed of loading and results in a reduction in rigidity when loadings are consecutive.

When carrying out a cyclic compression test on elastomers, Qi and Boyce (2005) observed several phenomena that were similar to those previously observed in traction. In particular, the Mullins effect, where mechanical properties that depend on the “history” of the material (strains that the material has undergone determine responses during subsequent tests) stabilize after a few cycles.

The elastomer material of which the ring is made (PU) is not exactly the same as that used for the damper (PDMS). Their molecular structures are different and their behavior evolved differently when they were subjected to loads in fatigue tests. The DMA tests did indeed show different changes in stiffness and in $\tan\delta$ for the damper and the ring. Results showed a variation in the material characteristics during the fatigue test, as has been described in previous studies.

Regarding the geometry of the dampers and the rings, these also evolved differently in the course of the fatigue cycles. The thickness of the dampers decreased gradually during the first 4 million fatigue cycles, but after 4 million cycles, no further loss of thickness was observed. The thickness of the rings, however, reduced by 1/4 during the first million cycles, but there was virtually no further variation in their geometry during the following cycles. The geometry of the rings and the dampers seemed to stabilize after several cycles. This observation is in agreement with that of Qi and Boyce (2005) who noted a stabilization in mechanical properties after the first cycles.

This study will certainly be followed up with a fatigue test on a larger number of cycles (e.g., 10 million) in order to confirm this stabilization. In addition, a study of standard specimens will be carried out to determine the intrinsic properties of the two materials and compare them. An analysis of the dynamic modulus could be compared with the results in the study by El Fray and Altstadt (2004).

5. Conclusions

This study allowed the selection of a polymer material to optimize the B Dyn® implant design and behavior.

The results of the static tests pointed out the influence of the ring material on the mechanical performances of the implant under traction and led to choose a polyurethane (PU) that gives the best mechanical properties for long-term performance of the implant. The results of fatigue and DMA tests confirm the choice of this elastomeric material.

This study will certainly be followed up with a fatigue test on a larger number of cycles (e.g., 10 million) in order to confirm the stabilization of the polymer behaviors. In addition, standard specimens will be studied to determine the intrinsic properties of the two materials (PU and PDMS) and compare them.

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