DO UNLOADING PERIODS AFFECT MIGRATION CHARACTERISTICS OF CEMENTED FEMORAL COMPONENTS ? AN *IN VITRO* EVALUATION WITH THE EXETER STEM

N. VERDONSCHOT, M. BARINK, J. STOLK, J. W. M. GARDENIERS, B. W. SCHREURS

Prosthetic migration has been identified as a marker for future revision of cemented total hip reconstructions. This could be tested at a pre-clinical stage with dynamic loading experiments. The purpose of this study was to assess the effects of resting periods, which are a considerable part of the daily activity cycle, on the migration characteristics of femoral cemented stems.

Ten polished Exeter stems were implanted in composite femurs and loaded either with a continuous load or a discontinuous load. Continuous loading involved 345,600 loading cycles at 1 Hz, whereas the discontinuous loading involved loading at 1 Hz for 2.5 hours and a resting period of 21.5 hours for a period of four days. Hence, a total of 36,000 loading cycles were applied to these reconstructions.

The subsidence patterns of the prostheses were considerably affected by the resting periods. The prostheses exhibited a step-wise migration pattern with migration steps of about 50 microns after every resting period, whereas the continuously loaded prostheses showed a more gradual migration pattern. The final subsidence of the specimens when loaded with resting periods was significantly less than the subsidence measured without resting periods. However, these specimens were loaded with fewer loading cycles. If this was taken into account, the discontinuously loaded specimens had a four fold higher average migration per loading cycle than the specimens that were loaded continuously.

In conclusion, the resting periods had a considerable effect on the migration patterns, which should be realized when these stems are analyzed with pre-clinical tests.

Keywords : total hip replacement ; pre-clinical testing ; bone cement creep ; migration.

Mots-clés : prothèse totale de hanche ; tests précliniques ; fluage du ciment ; migration.

INTRODUCTION

It is generally accepted that high stem migration is a predictor of early failure of cemented femoral hip prostheses. This is supported by various studies which show that within a group of patients having received the same type of prosthetic implant, those with a high migration are at risk for future revision (5, 8, 14). However, there is little or no evidence that one critical migration limit can be defined beyond which all prosthetic implants are at risk, nor should migration rates be mixed with different designs. It would be extremely valuable if these critical values could be established for the different hip systems available on the market.

Pre-clinical tests (*in vitro* and computer simulation studies) could assist in this. Many papers have been published which discuss pre-clinical test results of different implants (e.g. 3, 7, 11). Usually these tests, which consist of *in vitro* experiments or computer simulations, underestimate the migration rates of implants. The Exeter stem design has been

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studied quite extensively because of its interesting capability of allowing a relatively high subsidence in combination with excellent clinical results (6). This phenomenon may be explained by the force closed fixation principle of the Exeter stem (7). Alfaro-Adrian and co-workers (1) showed that the Exeter stem subsides 1-1.2 mm after 1-2 years post-operatively. This amount of subsidence is very similar to that published by Huiskes *et al.* (7) who reported an *in vivo* subsidence of 1.1 mm after one year. The subsidence of the Exeter stem has also been assessed with *in vitro* experiments (7). In this study a subsidence of 0.187 mm was found after 300,000 loading cycles. Hence, the amount of migration generated in the *in vitro* test was considerably smaller than found *in vivo*. Using computer finite element simulations, the migration of the Exeter stem has been simulated assuming that migration was due to creep (12) or due to micro fractures in the cement (13). In the former study a subsidence of only 0.07 mm after 5 million loading cycles was reported due to creep. In the latter study the subsidence of the stem was only 0.05 mm after 25 million loading cycles. Hence, it seems to be quite difficult to reproduce *in vivo* migration rates in tests that are meant to serve as pre-clinical tests.

There are various reasons which explain this phenomenon. In general, these reasons relate to optimal implantation assumptions in the tests, material and interface properties that are constant in the tests but may be subjective to degradation or remodeling. In addition, the loading conditions around the hip joint are extremely complex and very difficult to mimic in these tests. Loading magnitudes and angles vary continuously (2) and periods of loading are followed by periods of relatively low loads, such as sitting down or bed rest (10). These periods of low loads are usually discarded in pre-clinical tests and dynamic mechanical loading tests are run for a particular number of loading cycles at a constant load level, usually at an unrealistically high frequency. This may be acceptable if one is interested in the fatigue behavior of the metal implant itself. However, if one is interested in obtaining realistic migration data for cemented total hip reconstructions, simplification of these loading parameters may affect the behavior of cemented reconstructions to a considerable level because the cement, being a visco-elastic material, may relax during the resting periods.

The purpose of this study was to assess the effects of resting periods on the migration of femoral cemented stems. Hence, the central question that was addressed was whether resting periods affect subsidence patterns to a significant degree or whether these unloading periods have a negligible effect and can be discarded in *in vitro* tests.

MATERIALS AND METHODS

Ten polished Exeter stems (37.5 mm offset, Stryker-Howmedica-Osteonics) were implanted by an experienced surgeon (J. W. M. G) in composite femurs (Sawbones, Malmö, Sweden, type 3106). Pre-planning and operative procedures were performed as realisticly as possible. After resecting the femoral head, the femur was opened by a broach and prepared for implantation (reamed with 37.5N°1). A 10-mm bone cement plug was inserted using the plug insertion instrument. Two packages of Surgical Simplex bone cement (Stryker-Howmedica-Osteonics) were mixed according to the instructions of the manufacturer using hand mixing techniques. After 4 minutes the cement was injected in a retrograde fashion using the Howmedica cement gun. The bone cement was pressurized for 2 minutes using the gun and a proximal seal. Subsequently the prosthesis was inserted.

The composite bone was resected at 33 cm distal to the femoral head center and was potted with PMMA in a metal cylinder (total length finally 34 cm). The composite bone was put into a 38° C water bath for 36 hours to allow for polymerization of the cement and water absorption. After this time period the dynamic loading program (either continuous or discontinuous) was applied to the reconstruction.

Both continuous and discontinuous tests (each consisting of 5 specimens) lasted for 4 days. Continuous loading involved loading at 1 Hz for 4 days. Hence, a total of 345,600 loading cycles were applied. Discontinuous loading involved loading at 1 Hz for 2.5 hours each day (and a resting period of 21.5 hours). Hence, a total of 36,000 loading cycles were applied to these reconstructions.

The load was applied solely to the prosthetic head and simulated the load during stance phase of normal walking. To obtain a realistic loading angle, the reconstructions were placed in an anatomical position after which

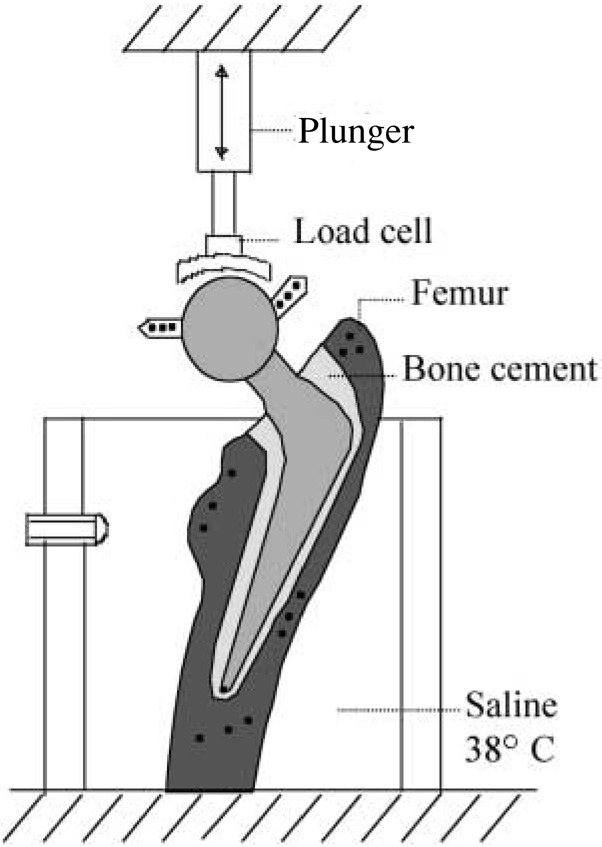

Fig. 1. — Schematic representation of the experimental set-up showing the fixated reconstruction and the loading plunger of the MTS machine. RSA markers were attached to the prosthesis (six to the prosthetic head and one to the tip of the prosthesis) and the bone. Testing environment was saline at 38°C.

they were adducted and endorotated for 15° and 30°, respectively. During the loading and unloading periods, the reconstructions were constantly kept in a water bath at a temperature of 38° Centigrade.

RontgenStereophotogrammetric Analysis (RSA) was used to determine the migration of the stem relative to the bone. For this purpose tantalum beads (0.8 mm in diameter) were inserted in the bone (9 beads) and on to the prosthesis (7 beads), one of them being attached to the tip of the prosthesis surrounded by the centralizer which also protected the bead during insertion and possible migration (fig. 1). This RSA marker at the tip of the stem was also used as the origin of the RSA coordinate system. Hence, translations were expressed as translations of the tip, whereas rotations of the stem relative to the bone are irrespective to the origin of the coordinate system. The overall reproducibility error of our RSA system was about 40 microns.

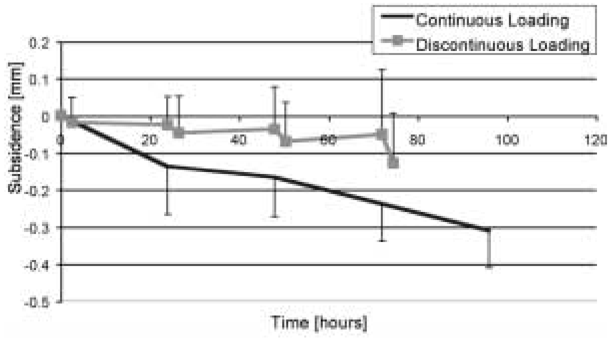

Fig. 2. — Average subsidence curves as a function of time (hours). The continuously loaded specimens show a continuous subsidence patterns. The discontinuously loaded specimens subside only during the relatively short loading periods and seem to recoil a little during the unloaded periods. Error bars indicate the standard deviations of the 5 measurements.

To analyze whether the migration was due to cement cracks or other phenomena (e.g. cement creep) the specimen with the highest prosthetic migration was sectioned with a diamond saw and the slices were stained to visualize possible cracks.

RESULTS

Rotations and translations other than subsidence of the stem were very small for all specimens. The subsidence patterns of the prostheses were considerably affected by the resting periods albeit that the standard deviations were relatively large relative to the average migration (fig. 2). The prostheses exhibited a step-wise migration pattern with migration steps of about 50 microns after every resting period, whereas the continuously loaded prostheses showed a more gradual migration pattern. The final subsidence of the specimens when loaded with resting periods was less than the subsidence of the specimens loaded without resting periods ($p = 0.04$, one-sided Student's t-test). However, these specimens were loaded with only one tenth of the number of loading cycles. If this was taken into account, the discontinuously loaded specimens had a four fold higher average migration per loading cycle than the specimens that were loaded continuously. Interestingly, the prostheses which were loaded with resting periods seemed to recoil a little during the resting periods. Variations within each

Table I. — The average subsidence (N = 5) with standard deviations in the continuous and discontinuous loading groups

Continuous Loading			Discontinuous Loading		
Time [hours]	Subsidence [mm]	SD [mm]	Time [hours]	Subsidence [mm]	SD [mm]
0	0	0.000	0	0	0.000
24	-0.1364	0.130	2.5	-0.0188	0.067
48	-0.1672	0.106	24	-0.0246	0.075
72	-0.2384	0.101	26.5	-0.0468	0.099
96	-0.30975	0.099	48	-0.0368	0.114
			50.5	-0.0695	0.104
			72	-0.05025	0.173
			74.5	-0.12725	0.134

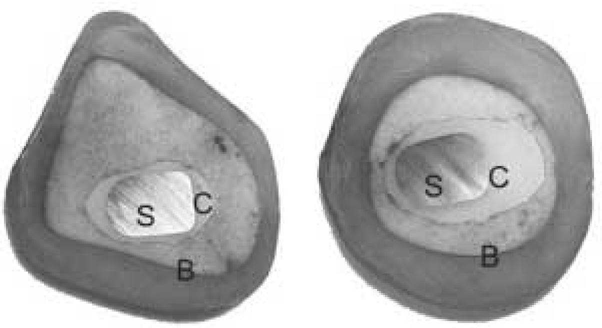

Fig. 3. — Two transverse sections (one at the minor trochanter level (a) and one at the mid-stem area level (b)) of the specimen that produced the highest subsidence values. The stem was surrounded by a complete cement and cement cracks were absent. The cement mantle on the images were digitally colored to enhance visualization. S = stem ; C = cement ; B = bone.

group were relatively large resulting in standard deviations of the average subsidence values of about 0.1 mm (Table I).

Analysis of the sectioned specimen that had a subsidence of 0.378 mm, showed that the Exeter was very well placed in the center of the cement mantle (fig. 3). Furthermore, no cracks in the cement were found. The migration results suggest that stem-cement debonding has occurred. However, this was difficult to detect on the slices because the stem was pressed against the cement mantle closing gaps at the stem-cement interface.

DISCUSSION

In this study the effect of resting periods on the migration pattern and values of a cemented Exeter stem was analyzed. For this purpose an *in vitro* study was performed on 5 cemented implants with continuous dynamic loading and on 5 specimens subjected to a discontinuous dynamic loading profile having 2.5 hours of loading and a subsequent resting period of 21.5 hours. Obviously the latter situation cannot be considered as realistic but we chose for these loading times because it would generate an extreme effect of resting periods on the migration pattern. Composite femurs were used in this study as substitutes for cadaver bones. Although it has been shown that these composite femurs adequately mimic the mechanical characteristics of real bones in a global sense (4), the internal characteristics of the composite femurs are very different from the real cancellous bone structure. This may affect the cement penetration and subsequent migration results. Nevertheless, we chose to use these bones because cadaver femurs would limit the duration of the tests, increase the variability in the results, increase the costs and their availability was limited. Maher *et al.* (9) demonstrated that the amount of prosthetic migration with these composite femurs can be similar to those found with cadaveric bones.

In this study we obviously simplified the loading profile to a large extent with the exception that we included the alternating loading and unloading periods. Muscle forces were not included and constant loading angles were applied. Recently, Bergmann *et al.* (2) published data about the hip contact forces generated during daily activities measured with telemetrized instrumented hip prostheses.

They showed that the loading angles of the peak hip contact force generated during daily activities vary in the frontal plane from 7° (during standing) to 16° (during sitting down), whereas in the transverse plane these angles vary from 1° (during sitting down) to 46° (during stair rising). The magnitudes of the peak contact forces varied from 1.4 times body weight during knee bending to 2.6 times body weight during stair descent. Morlock *et al.* (10) measured the duration and frequencies of daily activities during the day. They showed that sitting down was the most frequent activity covering over 44% of the daily time. Walking contributed only 10% of the daily activities. Realizing that these measurements were performed only during the day, and consequently did not include the bed rest periods, it is clear that the loads on the reconstruction are relatively low during most of the time. Hence, unloading periods comprise a considerable part of the daily activity patterns of patients.

The results showed that inclusion of these resting periods increase the subsidence rate (microns per cycle) by a factor of four. Hence, *in vitro* subsidence results will become closer to the *in vivo* findings. Huiskes *et al.* (7) reported a subsidence of 0.187 mm after 300,000 loading cycles. If they would have used resting periods this could have been about 0.75 mm. This is quite close to the values reported *in vivo* by Huiskes *et al.* (7) and Alfaro-Adrian *et al.* (1).

The specimen with most migration was sectioned and had no visible cracks in the cement. This suggests that the subsidence is, at least for a large part, due to creep and stress relaxation of the cement and sliding of the prosthesis at the stem-cement interface after unloaded periods, and not caused by cement cracks. Clinical results support this suggestion because if subsidence of the Exeter would be caused by cement fractures, the *in vivo* results would not be so favorable (6).

Theoretically, the effect of these resting periods on the migration pattern is most pronounced in force closed prosthetic stems like the Exeter (smooth tapered components). The mechanism is explained in fig. 4. The stability of an implant relies on a balance between the external applied force and the interface stresses produced at the stem-cement interface. If loaded, a tapered (force closed) design will subside, generating stresses at the interface (fig. 4b). These stresses balance the external force and provide the holding power of the prosthesis. When the load is applied for a certain period, the prosthesis subsides due to creep of the cement, without a considerable change of the interface stresses (fig. 4c). When the prosthesis is unloaded, it remains stuck in the cement mantle due to frictional forces (fig. 4d). The frictional forces generated are directed oppositely to the shear stresses in the loaded case. In this way these stresses prevent the prosthesis to 'pop out' of the cement mantle after unloading. This 'holding power' depends on the taper angle of the prosthesis and the coefficient of friction at the interface. Higher taper angles and lower coefficients of friction will facilitate sliding back (popping out) of the prosthesis after unloading. During a period of unloading, the stresses at the interface and in the cement mantle gradually reduce due to stress relaxation in the cement, thereby reducing the holding power of the prosthesis in the cement mantle (fig. 4e). When the prosthesis is subsequently loaded, the interface stresses do not balance the external force anymore, which leads to a sudden migration step of the stem into the cement, thereby increasing the stresses at the interface until a new balance between the external force and interface stresses is reached again (fig. 4f). For a shape closed design (e.g. collared stems) the same phenomenon occurs, but this is much less related to any (visible) migration. If such a stem is loaded, the interface stresses again balance the external force, but in this case primarily in the collar region. This requires virtually no migration of the stem when a proper collar-cement contact is present. After unloading there will be very little migration (recoil) and an immediate stress release in the cement in the collar region. There will probably be some remaining stresses in the cement mantle but not to the extent of force closed designs. Obviously, these stresses will relax over time during the resting periods. In summary, the migration characteristics of force closed prostheses are more sensitive to the resting periods than those of shape closed designs.

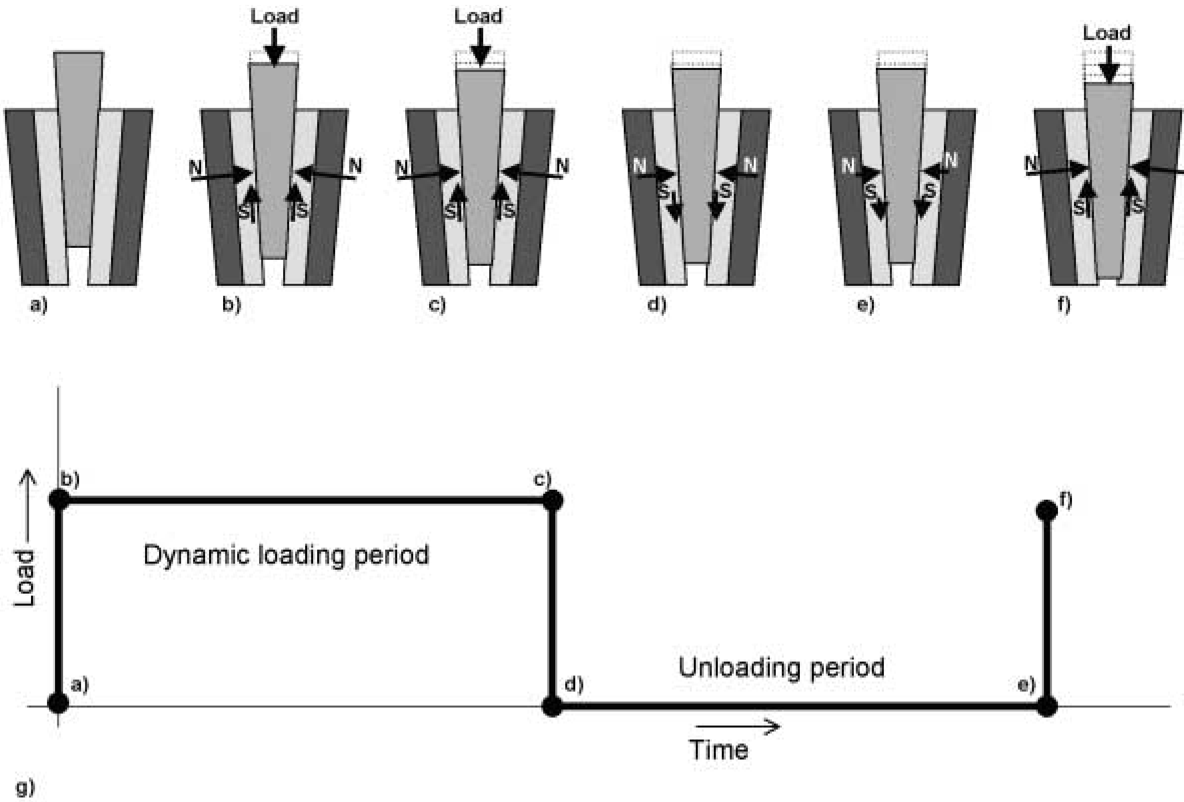

Fig. 4. — Schematic representation of the subsidence and interface stresses in a tapered stem surrounded by a cement mantle and bone. These quantities are shown before and after a loading period and after an unloading period.
a) : unloaded configuration ; no stresses are assumed to be created. b : directly after loading the stem subsides into the cement mantle thereby creating normal (N) and shear (S) interface stresses. These stresses balance the external load (Load). c) : During the loading period the stem subsides a little more, without considerable change of the interface stress distribution. d) : When the load is reduced to zero, the stresses in the cement mantle reduce. However, the stem remains stuck in the cement mantle due to frictional forces that create shear stresses at the interface which are directed in the opposite direction and lower than created in the loaded situation. e) : after an unloaded period the stresses relax and with them the interface stresses. f) : When load is applied again, the interface stresses do not balance the external load anymore and the stem subsides until higher interface stresses are generated that balance the external load again.
Note : the length of the arrows indicate the magnitude of the interface stress component.

An interesting finding of the migration results of the prostheses that were loaded discontinuously was that the prostheses recoiled a small amount during the resting periods. It is unlikely that this migration occurs at the stem-cement interface, but is more likely caused by the fact that the cement creeps due to the stresses. The prosthesis is pushed into the cement during the loading period, forcing the cement mantle to shear in distal direction. When the reconstruction is unloaded, residual stresses in the opposite direction will remain which are the driving force of the cement to creep in proximal direction, thereby dragging the prosthesis in proximal direction without any necessary slip at the stem-cement interface.

In conclusion, the resting periods had a considerable effect on the migration patterns of the Exeter stem. Discontinuous loading produced a step-wise migration pattern and the average subsidence rate (mm per loading cycle) increased by a factor of four. Hence, *in vitro* tests of cemented femoral implants should include resting periods in their loading profile if their goal is to produce realistic critical migration characteristics of prosthetic designs, particularly if these prostheses rely on force closed stability.

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SAMENVATTING

N. VERDONSCHOT, M. BARINK, J. STOLK, J. W. M. GARDENIERS, B. W. SCHREURS. Hebben rustperioden effect op het migratiepatroon van gecementeerde heupprothesen ? Een in-vitro studie met de Exeter prothese.

Migratie van gecementeeerde prothesecomponenten kan worden gebruikt als een indicator voor toekomstige revisie en kan worden geanalyseerd met *in-vitro* belastingstesten. Daar een prothese een groot gedeelte van de tijd nauwelijks belast wordt (zgn. rustperioden), werd in deze studie het effect van deze rustperioden op het migratiegedrag van gecementeerde femorale prothesen onderzocht.

Tien gepolijste Exeter stelen werden gecementeerd in kunstbotten. Vijf prothesen werden continu dynamisch belast, terwijl vijf andere prothesen werden belast afgewisseld met rustperioden.

Het migratiepatroon van de prothesen werd sterk beinvloed door de rustperioden. De prothesen die belast werden met rustperioden lieten een stapsgewijs migratiepatroon zien, terwijl de continu belaste prothesen een meer geleidelijk verlopend migratiepatroon vertoonden. De uiteindelijke migratie van de prothesen met rustperioden was significant kleiner dan de migratie van de continu belaste prothesen. Als de migratie per belastingcyclus werd berekend, bleek dat de prothesen met rustperioden vier maal zo veel migreerden als de prothesen met een continue belasting.

De conclusie van deze studie is dat de rustperioden de migratie en het migratiepatroon van gecementeerde prothesecomponenten zeer sterk kunnen beinvloeden. Huidige testmethoden die geen rustperioden bevatten kunnen geen realistisch migratiepatroon voorspellen.

RÉSUMÉ

N. VERDONSCHOT, M. BARINK, J. STOLK, J. W. M. GARDENIERS, B. W. SCHREURS. La migration des tiges fémorales cimentées est-elle affectée par des périodes de mise en décharge ? Etude in vitro de la tige Exeter.

On a reconnu à la migration des implants une valeur prédictive d'une révision ultérieure. Cette migration peut être évaluée par des tests pré-cliniques de mise en charge dynamique. Ce travail avait pour but d'établir l'effet de l'introduction dans les tests, de périodes de repos, qui représentent une partie considérable du cycle d'activité quotidienne, sur la migration de tiges fémorales cimentées.

Dix tiges Exeter polies ont été implantées dans des fémurs en matériau synthétique et mises en charge de façon continue ou discontinue. Dans le premier cas, elles ont subi 365.000 cycles de mise en charge à la fréquence de 1 Hz ; dans le second cas, on a alterné des périodes de mise en charge de 2,5 heures à 1 Hz avec des périodes de mise en décharge de 21,5 heures, pendant une durée de 4 jours, donnant un total de 36.000 cycles de mise en charge.

Le mode d'enfoncement des tiges a été considérablement affecté par les périodes de repos. Avec la mise en charge discontinue, les prothèses ont présenté une migration par paliers, avec des enfoncements de 50 microns au terme de chaque période de décharge, tandis qu'elles ont présenté un type de migration plus continu avec la mise en charge continue. L'enfoncement total était nettement moindre après la mise en charge intermittente, qui avait certes comporté un nombre moins élevé de cycles de mise en charge. Si l'on prend en compte ce facteur, les tiges soumises à une mise en charge de façon discontinue avaient présenté une migration quatre fois plus importante que les autres, par cycle de mise en charge.

En conclusion, les périodes de repos ont eu un effet marqué sur le mode de migration ; il faut en tenir compte dans les tests précliniques.