In vitro load history to evaluate the effects of daily activities on cemented hip implants

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The loads acting on the hip joint during daily activities contribute to the failure of the fixation of cemented hip stems. An *in vitro* analysis of newly designed prostheses is necessary prior to *in vivo* clinical trials. *In vitro* pre-clinical testing procedures up to now have consisted in simulating only one or two conditions.

The goal of this work was to define a procedure to assess the long-term effect of the most stressing activities on the integrity of the cement mantle. Thus, a cyclic load of constant amplitude is not acceptable. All activities inducing high loads need to be included, so as to replicate the most critical scenario from a fatigue point of view.

The following activities were included in the load history: stair climbing and descending, car entry and exit, bathtub entry and exit, and stumbling. Load values and direction were assigned to each activity, based on the literature. A typical week was defined for a patient, based on statistics from the literature. An *in vitro* simulation running for 2 weeks was able to replicate the load peaks occurring in 24 years of patient activity. Stem-cement elastic micromotion and permanent migration are continuously recorded at 5 locations. The cement mantle is inspected by means of dye penetrants after test completion to quantify the fatigue damage in the cement mantle. The load history was successfully applied to two different designs and is therefore ready for future applications to evaluate the long-term performance of the new prostheses and the effects of daily activities on implant outcomes.

Key words: in vitro loads, hip implants, synthetic composite femur

1. Introduction

Aseptic loosening of cemented implants is the most frequent reason for revision (MALCHAU et al. [26]; NIH [31]). Aseptic loosening is a multifactorial phenomenon involving interfacial failure (JASTY et al. [20], [21]; NIH [31]), bond failure (NIH [31]), bone remodelling (NIH [32]), cement failure (LEWIS [25]; VERDONSCHOT and

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HUISKES [43]; NIH [31]) and cement-stem fretting (NIH [32]; WIMMER et al. [45]). Because of implant failure, revision surgery is necessary.

The primary failure mechanism of bone cement *in vivo* is fatigue. Fatigue failure is driven by the application of repeated loads generated during daily activity. Some activities generate higher peak loads than others (BERGMANN et al. [5], [6]). The highest loads are the ones that contribute predominantly to a fatigue failure (COLLINS [10]). McCORMACK et al. [28] established that the damage accumulation in the cement mantle occurs due to torsional loading, which happens especially during activities such as rising from a chair or stair climbing. Loosening of total joint prostheses is also related to the fragmentation of the acrylic cement mantle surrounding the prosthesis and the biologic consequences to the particulate acrylic (JASTY et al. [21]). Wear of the fractured surfaces, by producing PMMA debris, accelerates bone destruction (TOPOLESKI et al. [43]).

Events associated with cement failure are stem micromotion and subsidence (JASTY et al. [21]), and small and large cracks disrupting the cement mantle (VERDONSCHOT and HUISKES [44]). Micromotions contribute to the failure of the hip prosthesis fixation due to debonding of the interfaces (HARRIGAN and HARRIS [17]). Especially the rotational torque, due to normal daily use, promotes loosening of the femoral components (SUGIYAMA et al. [42]). There are two interfaces in a cemented implant: the cement–stem interface and the cement–bone interface. The cement–prosthesis interface is the most critical region for debonding (JASTY et al. [20], [21]; HARRIS [18]).

It would be useful to test *in vitro* hip implants prior to clinical trials to evaluate the effects of the geometry, materials and daily loading of the prosthesis on the long-term stability and on the fatigue lifetime of the cement mantle. To the authors' knowledge, preclinical procedures up to now have consisted in simulating only few load conditions. Moreover, debonding is not an immediate event, but a fatigue process (VERDONSCHOT and HUISKES [44]), therefore a long-term evaluation of the cemented implant is necessary.

Two activities were simulated in a biomechanical analysis (MALONEY et al. [27]). The femurs were loaded under conditions that simulated single-leg stance and under conditions that simulated stair climbing, but it was not a fatigue test. An accelerated fatigue testing procedure consisted in simulating two load conditions (STYLES et al. [41]), with a baseline simulating normal walking, single load excursions simulating sit/stand and stumble, and block load excursions simulating stair climbing/descent and fast walking/jogging. However, that study did not discriminate among critical activities.

A test procedure on implanted human cadaver femurs (SPEIRS et al. [40]) applied two sinusoidal forces, varying in a range from 1 to 4 BW, for a total of 3000 cycles. The loading patterns simulated *in vivo* forces measured on the femoral head during gait. That study had the limitation of simulating only one activity, and for only few cycles.

In finite element approaches, only one load condition was used from WHEELER et al. [45] and from VERDONSCHOT et al. [44]. With the same method, HARRIGAN and

HARRIS [17] studied the effects of cement prosthesis debonding under loads simulating gait and stair climbing.

The goal of this study was to define a load history that can represent a conservative, though realistic, loading scenario of an active hip patient to be applied in pre-clinical *in vitro* testing. The most severe loads occurring during a hypothesized prosthetic life of 24 years were simulated (which corresponds to a total of about 1 million loading cycles, see below). A loading spectrum is proposed that includes all the critical activities (i.e. generate high axial force and torque) which are likely to occur in hip patient.

2. Materials and methods

The *in vitro* test is based on a set-up used for primary stability test (MONTI et al. [29]). It consists in applying physiological loads on implanted synthetic femurs. The single load cycle reproduces one among various types of physiological activities. The maximum load value depends on the particular type of activity considered.

2.1. List of loading activities

Force values to be used as an input for the test protocol were derived from the literature. There are mainly two methods in the literature to investigate the forces occurring *in vivo* on the hip implant. One is based on movement analysis (PAUL [34]–[36]; CROWNINSHIELD [11]; ANDRIACCHI et al. [2]; PATRIARCO et al. [33]; ROBINSON et al. [37]; ANDERSON et al. [1]; FITZSIMMONS et al. [14]), whereas the second consists in direct telemetric force measurement (RYDELL [39]; ENGLISH [13]; DAVY et al. [12]; HODGE et al. [19]; GRAICHEN and BERGMANN [15]; KOTZAR et al. [24]; BERGMANN et al. [3]–[7]).

| Activities | References | | |
|-------------------|---|--|--|
| Single and | made available from Free University, Berlin, link http://www.medizin.fu- | | |
| double leg stance | berlin.de/biomechanik, 1994 | | |
| Walking | Rydell [39]; Paul [36]; English [13]; Bergmann et al. [5]; Anderson et al. [1] | | |
| Running | Bergmann et al. [5] | | |
| Physiotherapy | Bergmann et al. [4] | | |
| Load carrying | Bergmann et al. [7] | | |
| Stair climbing | Rydell [39]; Paul [36]; Andriacchi et al. [2]; Davy et al. [12]; Fitzsimmons et al. | | |
| | [14]; Bergmann et al. [6] | | |
| Stair descending | Rydell [39]; Paul [36]; Andriacchi et al. [2]; Fitzsimmons et al. [14]; Bergmann et al. [6] | | |
| Sitting down | Robinson et al. [37]; made available from Free University, Berlin, link | | |
| | http://www.medizin.fu-berlin.de/biomechanik, 1994 | | |
| Standing up | Robinson et al. [37]; made available from Free University, Berlin, link | | |
| | http://www.medizin.fu-berlin.de/biomechanik, 1994 | | |
| Head standing | made available from Free University, Berlin, link http://www.medizin.fu- | | |

Table 1. Loading activities

| | berlin.de/biomechanik, 1994 | |
|----------------|----------------------------------|--|
| Bath tub entry | Fitzsimmons et al. [6] | |
| Bath tub exit | Fitzsimmons et al. [6] | |
| Car entry | Fitzsimmons et al. [6] | |
| Car exit | Fitzsimmons et al. [6] | |
| Stumbling | Rydell [39]; Bergmann et al. [5] | |

Data for the loads occurring in a wide range of activities are available in the literature, as reported in table 1.

2.2. Selection of relevant activities

The aim of this load history was to simulate a critical but likely range of activities, usually performed by an average patient in a long time after the operation. However, it is practically not achievable to simulate *in vitro* all the activities recurring in the patient's life, as this would require a time comparable with the patient's life time. In order to make the test affordable, only the most critical activities were taken into account. Thus, stair climbing and activities even more severe were simulated, as stair climbing has demonstrated to be critical for the torsional stability of the implant (Crownshield et al. [11]; Sugiyama et al. [42]; Bergmann et al. [6]; McCormack et al. [28]). Therefore, activities such as standing, normal gait, sitting down, standing up and load carrying were excluded from the simulation. The second criterion used to select the activities was to simulate only the likely ones for a total hip patient, in a long period after the operation. This way, activities such as running and head standing were excluded. Physiotherapy was excluded as well, because it is usually less load bearing than stair climbing, and also because it is only relative to a short period after the operation.

Thus, of all the activities listed in table 1, only the seven listed below were considered as the most critical ones. They can be itemized as follows:

- stair climbing,
- stair descending,
- bathtub entry,
- bathtub exit,
- car entry,
- car exit,
- stumbling.

2.3. Definition of the load values

Accepting these assumptions, a simulation of 24 years of patient activity, involving about 1 million load cycles, runs in about 12 days at 1 Hz (see below). The load values and directions were defined based on the following criteria:

- For stair climbing, stair descending and stumbling the load data are directly obtained from BERGMANN et al. [5], [6]. The work from Bergmann was chosen as it monitors a sample of hip patients with state-of-the art telemetric direct force measurement. These data are comparable to those derived from the other authors (RYDELL [39]; PAUL [36]; ANDRIACCHI et al. [2]; DAVY et al. [12]; FITZSIMMONS et al. [14]). The force components recorded by BERGMANN were first converted from the femur-based reference system (BERGMANN et al. [5]) to the one used in this study (RUFF et al. [38]; HARMAN et al. [16]; MONTI et al. [29]). The moments were derived based on the geometry of the composite femurs to measure the lever arms.
- The values chosen for stair climbing and descending are the average of the maximum forces measured on patient EB, when he climbed and descended stairs fast. The patient EB was selected because the authors remarked that the other one, JB, had an abnormal gait also before the operation (BERGMANN et al. [5]).
- The value chosen for stumbling is the one corresponding to the patient JB, who presents higher loads, in order to carry out the most demanding simulation.
- For bathtub entry or exit (the load acting on the hip is the same in these two activities), car entry and car exit, in the literature the only values of calculated resultant forces were available (FITZSIMMONS et al. [14]). All the force and moment components were calculated presuming that the direction of the resultant forces was similar to other activities, for which more data is available. Therefore, for bathtub entry or exit, force and moment components were derived by scaling them during stair climbing (made available from Free University, Berlin, link http://www.medizin.fu-berlin.de/biomechanik, 1994). The scaling factor was the ratio between the resultant forces in the two activities. Similarly, force and moment components for car entry and car exit were derived from sitting down and standing up (made available from Free University, Berlin, link http://www.medizin.fu-berlin.de/biomechanik, 1994).
- Force peak and moment peak values are not synchronous in most activities (BERGMANN et al. [5], [6]). However, the peak force and peak moment values were assumed to act synchronously. This way the maximum peaks act at the same time, thus the simulation is more demanding.

The activities simulated and the respective load components (axial force, torque and bending moment) are reported in table 2. Since a small-size femur (Pacific Research Labs Medium Composite Left Femur Mod. 3103, Vashon Island, WA; CRISTOFOLINI et al. [8]) was used, a body weight of 550 N was fixed. This weight is suitable for the small-size composite femurs (Pacific Research Labs, personal communication) and has been used in similar investigations (MONTI et al. [29]).

Table 2. Activities simulated and the respective load components. The forces are reported as a percentage of BW (body weights), and the moments in % BWm (percentage of body weights per meter)

| Activity | Axial force [% BW] | Torque [% BWm] | Bending moment [% BWm] |
|---------------------|-----------------------|-------------------|---------------------------|
| Stair descending | 404 | 4.40 | 5.08 |
| Stair climbing | 370 | 4.60 | 3.00 |
| Car exit | 534 | 5.16 | 5.26 |
| Bath tub entry/exit | 498 | 6.19 | 4.03 |
| Car entry | 587 | 6.34 | 6.91 |
| Stumbling | 807 | 7.01 | 11.92 |

2.4. Definition of the frequency for each activity

The number of loading cycles occurring in one day for stair climbing and stair descending was established according to dedicated studies (MORLOCK et al. [30]) that measure the duration and frequency of daily activities in total hip patients. Another similar study (JUN MA [23]) provided comparable data. The study of Morlock was preferred as it used a larger and a younger (and therefore more active) patient sample, leading to the most demanding estimate of load frequencies.

A conservative estimate of car usage, based on a survey of the Italian Car Association (ACI), indicated a car usage twice a day. A bathtub usage once a day would be a conservative estimate. A pessimistic (and hence more demanding) estimate of stumbles occurring to an average hip patient suggested a frequency once a week.

The fatigue test consists of about 1 million loading cycles (freq.: 1 Hz). It simulates the load peaks occurring in 1252 weeks (based on modular repetition of 7 days and 1 stumble) of the average patient activity. Table 3 reports the sequence of activities and the number of cycles for each activity in 1 day.

Table 3. Sequence of activities and number of cycles for each activity. Additionally, stumbling was assumed to occur once a week

| Activities | Number of cycles per day | |
|---------------------|--------------------------|--|
| Stair descending | 27 | |
| Car entry | 1 | |
| Car exit | 1 | |
| Stair climbing | 27 | |
| Bath tub entry/exit | 2 | |
| Stair descending | 27 | |
| Car entry | 1 | |
| Car exit | 1 | |
| Stair climbing | 27 | |

2.5. Test set-up

The stems are inserted into synthetic composite femurs. Composite femurs were chosen as they are better reproducible than cadaveric specimens (CRISTOFOLINI et al. [8]) and are suitable for torsional stability testing (HARMAN et al. [16]).

The test set-up is based on a previously defined one with the hardware used for the analysis of primary torsional stability test (MONTI et al. [29]). The implanted synthetic femur is placed under a bi-axial servohydraulic testing machine (858 Minibionix, MTS Corporation) using a custom-made system of constraints. The machine applies a cyclic load to the specimen. The load consists of an axial force, a bending moment and a torque, as described above. The bending moment is applied by the eccentric axial force.

During the test, the local interface cyclic and permanent displacements in the direction of rotation, about the femoral long axis, are measured by means of four LVDTs (D5/40G8, RDP Electronics, Wolverhampton, UK). The LVDTs are placed at four well-defined positions along the stem. A custom-made procedure for the frames of LVDTs was developed to measure the shear motion close to the cement–stem interface.

The cyclic and permanent sinkage of the stem along the femoral long axis are measured by means of a single-arm extensometer (MTS, n° 632.06H-20) placed at the base of the stem neck. The test set-up is shown in figure 1. Additionally, after test completion the cement mantle is inspected for fatigue damage. The stem is extracted after the test and the femur is opened and sliced. The slices are treated with dye penetrants to assess and quantify the presence and development of fatigue cracks in the cement.

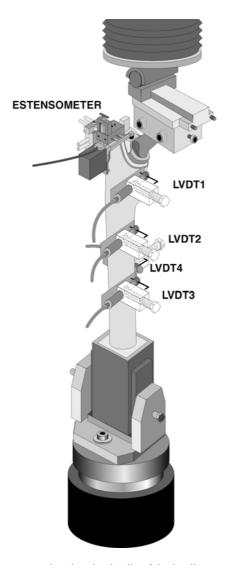


Fig. 1. The test set-up, showing the details of the loading system and the position of the micromotion transducers

3. Results and discussion

The protocol was successfully implemented and preliminarly applied to two cemented designs (CRISTOFOLINI et al. [9]). The measurement system had an accuracy better than 2.3 μ m, as previously found (Monti et al. [29]). Additionally, differences less than 1 μ m were found between subsequent peaks corresponding to the same activity. Also, the difference in the amplitude of the elastic motion was typically less

than 2 μ m between cycles. A typical trend of axial and rotational micromotion is shown in figure 2. The highest values of elastic micromovements are recorded when the implant is subjected to the load peaks corresponding to the highest load-bearing activity. This means that the measure is sensitive to the different loads and that the movements of the stem depend on the activity simulated.

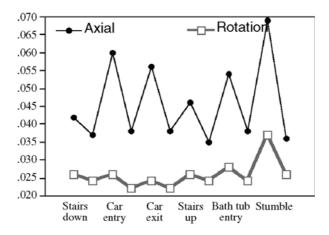


Fig. 2. Typical trend of axial and rotational micromotion (in millimeters)

Some aspects of the definition of the present load history need to be discussed: in fact, a large difference in activity levels exists both between patients and between different days (or periods) for the same patient. Thus, when designing a reasonable and conservative (i.e. more demanding) load history this was borne in mind. First of all, mean of the maxima (rather than just the mean) was adopted for the load values, when available. Additionally, the highest force and moment values through the cycle were used, though they do not occur always synchronously in reality. A further problem appears if a sequence effect is suspected for the fatigue damage caused by the different activities. Since the sequence of activity is generally different for each patient (and each day for the same patient),

The only reasonable approach was to generate an average day (and average week) with the activities evenly distributed through the day and regularly alternated. This way, on an average, the same fatigue damage is induced as for a real patient (though the damage generated by each day in the patient's life is possibly different).

Thus, the physiological load history presented is an effective compromise between an applicable test and a realistic simulation. It is expected that the developed protocol is able to discriminate between hip prosthesis with different clinical outcomes.

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