A COMPARATIVE METHOD OF FEMORAL STEM STABILITY IN A WALKING SIMULATOR.

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Introduction.
Any development of new prosthetic design or cementing techniques should be evaluated in laboratory in order to prevent a failure. Prior to clinical trials, in vitro study of implant stability allows measurements of implant micromotion and migration. The availability of a two station hip dynamic simulator using a pair of human proximal femurs would allow the comparison of a conventional prosthesis, used as a standard with either a new prosthesis or a new cementing technique. This comparison would be validated only if a left-right symmetry of prosthetic behavior can be demonstrated.

The purposes of this study was to measure the micromotion and subsidence of a standard cemented prosthesis on a 10^5 loading cycles and to compare the symmetry of the mechanical performance of both prostheses.

Methods.
Human femurs harvesting: Femurs were harvested within 24 hours after death and freed from soft tissues. Bones were radiographed to assess shape symmetry and to exclude local disease. They were scanned for bone mineral content by densitometry (QDR-2000 DEXA, Hologic, Waltham, Mass, USA).
Prosthetic and femurs positioning: A template was developed to reproduce consistently the same femoral neck resection. A 301 straight stem with collar edge Chamley-Kerboull hip prosthesis (Bone and Joint Research, Luxembourg, Luxembourg) was implanted. Cement (Palacos E flow, Schering Plough, Brussels, Belgium) was introduced in a retrograde fashion. During insertion, the use of lazer and fluoroscopy allowed a right-left symmetry of implant positioning.

Walking simulator description: Each femur was loaded cyclically at 1 Hz for 10^6 cycles. The load was applied to the femur by a pneumatic actuator which acted directly on the prosthetic head. One load case reproduced walking force and movement following a M shape curve close to the one of a single limb phase of the slow gait cycle whom the maximum value reached 1,5 times body weight. All tests were performed under load control. To simplify the testing procedure, no muscles action was modelled. The bone was kept moistened throughout the test.

Stability measurement: The initial interface motion between proximal femur and hip component has been measured in both translational and rotational displacement by two commercial digital extensometers. The fixation system of these extensometers has been set exactly at the boundaries of the resection. In this way, bone deformation influence was minimised. We were able to validate only if a left-right symmetry of prosthetic behavior can be demonstrated.

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Migration

Positioning

Micromotion

Subsidence

0.0 1.0 2.0 3.0 4.0

 unloaded right femur

 loaded left femur

 unloaded right femur

 loaded right femur

 unloaded left femur

 loaded right femur

 Figure 1: definitions

An analysis of variance with repeated measures was used through Systat package (Systat 8.0 Data, SPSS Inc.,Chicago, IL). The difference was considered statistically significant if p< 0,02 to account for the few number of specimens.

Results.
Four pairs were tested and carried out to over one million loading cycles. No failure either of bone or cement mantle or loosening of the implant were observed. All specimens showed a rapid positioning phase during the first 100.000 cycles (34 +/- 27 µm) followed by a decrease of the subsidence rate (4 +/- 6 µm by 10^5 cycles) until the end of the testing. Throughout the test, we found a good symmetry between right and left sides (a mean of 173 micrometers total axial displacement on the left and 180 microns on the right).
Satisfactory implant stability either postoperatively or at mid-term simulation was also observed. The right-left symmetry is shown in figure 2 where, for a representative specimen, the unloaded and loaded curves are indicated over 1 10^5 cycles.

Discussion.
In this work, we quantified the degree of prosthesis stability observed immediately after implantation and during a period of 6 months to one year of a slow walking patient’s life.
The analysis of the curve reveals that the greater part of the migration took place during the first 100.000 cycles which corresponds to about 2 months of a patient’s life. We have to insist on the limitations of this model. In this in-vitro study, we did not take into account of particulate debris of cement which might play a role on the longevity. We were dealing with dead bone without self adaptive capacity. Moreover, the effects of muscles and soft tissues with shock absorption capacity were not included. The mechanical conditions in this model are subsequently more severe than in a living patient. Despite these limitations, the mechanical behavior of the bone-prosthesis construction can be reasonably extrapolated to an in-vivo situation. In the future, we should be able with this simulator to better evaluate and to understand new implantation method and prosthesis design.

References.

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