A MULTI-FACTORIAL ANALYSIS OF THE MECHANICAL STABILITY OF CEMENTLESS HIP STEMS: PRELIMINARY RESULTS

M. Viceconti, A. Pancanti, M. Bernakiewicz, A. Toni
Laboratorio di Tecnologia Medica, Istituti Ortopedici Rizzoli, Bologna/Italy

Introduction
The great majority of total hip replacements fail because of aseptic loosening (Malchau et al., 2000). All other causes reported in the available studies seem more related to accidental factors such as faulty components, surgical errors, etc.

General survivorship studies show that cemented stems perform better than cementless stems. However, in most clinical studies where both fixation techniques are used, cementless stems are preferred for younger subjects. This is relevant, since it has been proved that the young age of the patient at surgery is the most important risk factor for aseptic loosening (Malchau et al., 2000). Once survivorship results are normalised the two types of fixation present similar results. While cementless stems are more prone to early failure, once they are osseointegrated, they tend to perform better than cemented stems (Malchau et al., 2000).

The osseointegration process may fail because of various causes. However, there is agreement among authors that the lack of mechanical stability of the implant in the early phases of osseointegration is probably the most important. Many factors may affect the primary stability of a cementless stem: press-fit, fit and fill, bone quality, rehabilitation history.

Aim of the present study is to investigate the effect of these factors on the primary stability of an anatomical cementless stem in order to understand which of them should be considered more critical in order to minimise the risk of aseptic loosening.

Methods
The study was conducted using the finite element model of a femur implanted with an anatomical cementless stem (AnCAFit, Cremascoli-Wright, Italy). The hexahedral-dominant mapped mesh was generated from the CT data of the implanted femur to accurately replicate the bone-implant interface. Non-linear frictional contact was modelled using face-to-face contact elements. The model was validated against in vitro experimental measurements. The accuracy of the numerical model in predicting the experimental results was evaluated in term of average (RMS) and peak errors, computed with reference to the measured bone surface strains and the measured bone-implant micro-movements. The model predicted the strain measurements with an average error of 320 µε (12% of the peak strain error) (Viceconti et al., 2001) and the micromotion measurements with an average error of 10 µm and a peak error of 14 µm (Viceconti et al., 2000).

Once validated, the model was used to investigate the effect of various factors on the mechanical stability of the cementless implant during a motor task. Four factors were considered: presence of interface gaps, mechanical competence of the bone tissue, type of motor task, and inter-subject variability in the motor strategy.

The presence of thin gaps around the stem surface was simulated using the contact stiffness relaxation technique. This approximate method allows the simulation of gaps as small as 10 µm, which would be impossible to explicitly model (Viceconti et al., 2001).

The bone tissue was modelled as continuous homogeneous material composed by a transversally isotropic cortical bone and an isotropic cancellous bone. The elastic modulus of both materials was assumed function of their average apparent density (Wirtz et al., 2000). By varying the average density of cortical and cancellous bone it was possible to investigate the effect of mechanical competence of the bone tissue on the primary stability of the stem.

In a previous study, it was shown that the bone-implant micromotion is not significantly altered if a simplified load case, based on the joint force and a distal constraint, replaces a complete load case accounting for all muscle actions (Viceconti et al., 2001). Thus, in order to investigate the effect type of the motor task and of the inter-subject variability in the motor strategy on the stability of the stem, it was
possible to use force data recorder by instrumented prosthesis for multiple subjects performing multiple tasks (Bergmann et al., 1999). Four subjects plus an average subject were considered, performing eight different motor tasks. For each task the peak force was used, scaled to the highest body weight among the four subjects (BW = 980 N).

Results

The reference model predicted a peak bone-implant relative micromotion at the calcar during stair climbing of 62 microns. Soft tissue layers with a thickness in the range 0.1-0.2 mm already allowed levels of micromotion high enough to prevent osseointegration on the major part of the stem surface.

The effect of the cancellous bone quality was investigated running the model with alternatively the maximum ($\rho=0.7\text{g/cm}^3$) and minimum ($\rho=0.1\text{g/cm}^3$) average tissue density while keeping constant to the maximum value the density of the cortical bone ($\rho=2\text{g/cm}^3$). The model predicted a peak micromotion of respectively 59 $\mu$m and of 139 $\mu$m. Then the analysis was repeated, this time assigning the minimum value to the cortical bone density ($\rho=1.5\text{ g/cm}^3$). In this case, a peak micromotion of respectively 71 $\mu$m and of 127 $\mu$m was obtained.

The effect of the cancellous bone density, which affected the primary stability more than that of the cortical bone density, was further investigated by predicting the peak micromotion for multiple values of the apparent density in the range from 0.1 g/cm$^3$ to 0.7 g/cm$^3$ (fig. 1).

![Figure 1](image_url)  
**Figure 1.** Micro-movements [$\mu$m] Vs apparent density [g/cm$^3$] of cancellous bone, keeping constant to the maximum the cortical bone density.

The finite element model predicted the peak micromotion for the four subjects performing eight different motor tasks (table 1).

<table>
<thead>
<tr>
<th>Motor Task</th>
<th>Patient-1</th>
<th>Patient-2</th>
<th>Patient-3</th>
<th>Patient-4</th>
<th>Average</th>
</tr>
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<td>125.4</td>
<td>89.2</td>
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<td>119.3</td>
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<tr>
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<td>59.9</td>
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<td>109.8</td>
<td>77.1</td>
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<tr>
<td>standup</td>
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<td>74.2</td>
<td>79.2</td>
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<td>upstair</td>
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<td>91.0</td>
<td>66.0</td>
<td>61.9</td>
</tr>
</tbody>
</table>

**Table 1.** Peak micro-movements [$\mu$m] predicted by the model for each motor task, performed by each patient.

Bone-implant relative micromotion varied between subjects performing the same task (66-145 $\mu$m) as much as in the same subject performing different tasks (69-145 $\mu$m).
**Discussion**

Cementless implants perform better than cemented implants if osseointegration is achieved. However, in a small but significant fraction of patients the osseointegration process fails. In many cases, this is probably due to a lack of primary stability. The present study was aimed to investigate the effect of various factors on the primary stability of an anatomical cementless stem in order to understand which of them should be considered more critical.

The presence of a thin layer of soft tissue or of a blood-filled gap at the bone-implant interface compromises the stability of the stem. The pre-operative planning and the surgical technique are thus critical in achieving a good primary stability.

Bone mechanical quality seems to significantly affect the primary stability of cementless implants only for severe osteopenia. Cancellous bone densities as low as 0.25 g/cm$^3$ produce in the case under study a peak micromotion of less than 100 $\mu$m. Thus, the indication of cementless stem can be extended also to those patients with a moderately osteopenic bone, although still biologically vital.

The results here reported indicate that the motor strategy of each patient affects the implant stability as much as the type of motor task performed. These results once again call for an extensive re-evaluation of the rehabilitation protocols for total hip replacement patients, supported by gait analysis protocols and designed around sound biomechanical concepts.

**Bibliography**


Bergmann G. et al. The hip joint: contact forces, gait data and load cycles. European Commission. RTD project public report, Contract SMT4-CT96-2076. 1999