Finite-element analysis of failure of the Capital Hip designs

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The Capital Hip implant was a Charnley-based system which included a flanged and a roundback stem, both of which were available in stainless steel and titanium. The system was withdrawn from the market because of its inferior performance. However, all four of the designs did not produce poor rates of survival. Using a simulated-based, finite-element analysis, we have analysed the Capital Hip system. Our aim was to investigate whether our simulation was able to detect differences which could account for the varying survival between the Capital Hip designs, thereby further validating the simulation.

We created finite-element models of reconstructions with the flanged and roundback Capital Hips. A loading history was applied representing normal walking and stair-climbing, while we monitored the formation of fatigue cracks in the cement.

Corresponding to the clinical findings, our simulation was able to detect the negative effects of the titanium material and the flanged design in the Capital Hip system. Although improvements could be made by including the effect of the roughness of the surface of the stem, our study increased the value of the model as a predictive tool for determining failure of an implant.

The Capital Hip (3M Health Care Ltd, Loughborough, UK) was introduced in the United Kingdom in 1991. The design was thought to be similar to that of the Charnley system (DePuy, Leeds, UK), which is considered to be the ‘gold standard’ in total hip arthroplasty. Like the Charnley, the Capital Hip system comprised a flanged and a roundback design, although the flange of the Capital Hip differed from that of the Charnley design because of patent restrictions. The former was shaped as a proximal wedge, while the Charnley system had an undercut flange. Both designs of the Capital Hip were available in either monobloc or modular versions. The monobloc stems were made of stainless steel, while the modular versions were made of titanium alloy (Ti6A4V).

A few years after its introduction it became clear that the rate of revision of the Capital Hip was higher than expected. In response to this, the clinical protocol for the preparation of the femoral cavity was changed by the manufacturer to improve proximal and intramedullary rasping. However, in 1997, the Capital Hip system was withdrawn from the market for commercial reasons after which the Medical Devices Agency issued a hazard notice ordering the review of all patients who had had the system implanted.1 After the withdrawal of the Capital Hip system, several studies were conducted to investigate its survival. A rate of loosening of up to 16% after 26 months was reported by Massoud et al,2 while Ramamohan et al3 found a rate of failure of 20% after 34 months. Roy et al4 reported a rate of failure of only 9% after follow-up for three years. There were, however, differences between these studies concerning the size and type of the rasp, the type of cement and the type of design of the Capital Hip which was used. In an investigation by the Royal College of Surgeons of England,5 a distinction was made between the various designs of the Capital Hip and their findings showed different rates of survival for the different designs. They reported that the stainless-steel stem had a better survival than the titanium-alloy stem, and also that the roundback performed better than the flanged stems (Table I). This indicated that not all of the designs of the Capital Hip had an inferior performance. However, almost 50% of the patients had had the inferior titanium flanged stem, while only 9.4% had the superior stainless-steel roundback design.5

McGrath et al6 analysed titanium-alloy Capital Hip retrievals from failed reconstructions and investigated clinical and radiological data,
as well as periprosthetic soft tissue. They described a sequence of events leading to the failure of the Capital Hip implant. First, lateral debonding was seen, followed by subsidence and calcar resorption. Subsequently, there was fragmentation of the cement mantle and osteolysis. Examination of the surface of the stem showed a typical pattern of wear in the anterolateral and posteromedial areas. This sequence of events corresponded to the damage-accumulation-failure scenario, as described by Huiskes.7

The Capital Hip disaster stresses the need for a reliable pre-clinical test to prevent inferior designs from entering the orthopaedic market. We have developed a simulation based on finite-element analysis for testing implants against the damage-accumulation-failure scenario.8 With this simulation, we have been able to differentiate between an inferior and a superior design, in accordance with clinical survival rates.9 In the current study, we simulated failure for the four designs of the Capital Hip stem. The aim was to investigate whether our finite-element simulation was able to differentiate between stainless-steel and titanium-alloy stems, and secondarily between the roundback and flanged designs, in accordance with the findings of the Royal College of Surgeons of England.5 This would further validate our finite-element-based simulation for use as a pre-clinical test.

Materials and Methods
Finite-element models of reconstructions with the roundback and flanged Capital Hip stems were created. For this purpose, silicone moulds were made from two original implants obtained from the Medical Devices Agency (one standard stainless-steel roundback and one standard titanium flanged stem (Fig. 1a)). The silicone moulds were used to make casts of dental plaster, which were subsequently scanned by CT. Three-dimensional geometrical computer models were created from the CT data, using custom-written software. Also a CT scan of a cadaver femur was made. Next, the geometrical models of the Capital Hip were virtually ‘implanted’ into the CT data of the cadaver femur in another custom-written program. The resulting three-dimensional models of the reconstructions were converted into finite-element models of eight-node brick elements (Fig. 1b). The cement mantle was defined by the geometry of the rasp, which was 2 mm oversized with respect to the implant, and by the geometry of the intramedullary canal. Hence, a minimum thickness of the cement mantle of 2 mm was obtained. The cortical bone was assumed to be transversely isotropic, while all other materials were assumed to be isotropic (Table II). The material properties of the cortical and trabecular bone were taken from Stolk et al10 and those of the bone cement from Murphy and Prendergast,11,12 representing Cemex RX bone cement (Tecres, Verona, Italy). The roundback and

| Table I. Survival of the different Capital Hip designs as reported by the Royal College of Surgeons of England5 |
|-------------------|----------------|----------------|
| Hip design        | Stem material  | Loosening rates (%) |
| Modular flanged   | Titanium alloy | 9.1             |
| Modular roundback | Titanium alloy | 6.1             |
| Monobloc flanged  | Stainless steel| 4.4             |
| Monobloc roundback| Stainless steel| 1.5             |

* these are given for the seven-year period before the release of the MDA hazard notice in 19981

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**Fig. 1a** – Photograph showing the two Capital Hip stems with their typical cross-sectional shapes. **Fig. 1b** – Longitudinal cross-sections of the finite-element models which were used in the study.
flanged designs were both analysed using material properties of titanium alloy and stainless-steel to allow analysis of all four versions of the stem. The cement-bone interface was assumed to be bonded and the cement-stem interface to be debonded from the start of the simulations. The coefficient of friction for this interface was assumed to be 0.25 in all cases.

During the simulations, the models were fixed at the distal end of the femur while a loading history of 20 million cycles was applied. The loading history consisted of an altering load of normal walking and stair-climbing. The stair-climbing and walking loads were applied in a ratio of 1:9 cycles, which is representative for active patients. The hip contact force and the muscle forces during these activities were taken from Heller et al.\textsuperscript{14} Fatigue failure of the reconstructions with the Capital Hip stems was simulated using an algorithm which has previously been described by Stolk et al.\textsuperscript{8} Based on the local cement stresses and the number of loading cycles, the algorithm predicted cement creep and the formation of microcracks (also referred to as damage) in the cement mantle. For the calculation of creep, a relation was used which was derived by Verdonschot and Huiskes.\textsuperscript{15} The fatigue properties of bone cement were taken from Murphy and Prendergast.\textsuperscript{11,12} These were used to calculate the accumulation of damage in the cement. Once the damage had locally reached a critical level, a macrocrack was assumed to occur, which was accounted for by reducing the cement stiffness of the particular element almost to zero in the direction perpendicular to the crack. Subsequent failure of adjacent ele-

<p>| Table II. The cortical bone was modelled as transversely isotropic. See Figure 1 for the definition of the x, y and z directions |</p>
<table>
<thead>
<tr>
<th>Part of model</th>
<th>Material</th>
<th>Elastic modulus (GPa)</th>
<th>Poisson’s ratio*</th>
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</thead>
<tbody>
<tr>
<td>Stem</td>
<td>Titanium alloy</td>
<td>110</td>
<td>0.3</td>
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<tr>
<td></td>
<td>Stainless steel</td>
<td>210</td>
<td>0.3</td>
</tr>
<tr>
<td>Cement</td>
<td>Polymethylmethacrylate</td>
<td>2.4</td>
<td>0.3</td>
</tr>
<tr>
<td>Trabecular bone</td>
<td>0.4</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>Cortical bone</td>
<td>$E_x, E_y = 7.0; E_z = 11.5$, $V_{xy}, V_{yz}, V_{zx} = 0.4$</td>
<td>$G_{xy}, G_{yz} = 3.5; G_{zx} = 2.6$</td>
<td></td>
</tr>
</tbody>
</table>

* Poisson’s ratio is a dimensionless parameter
† E, Young’s modulus for the three specific directions
‡ G, the Shear modulus for the three specific directions

Graph showing the formation of cement cracks around the various Capital Hip stems. The total number of cracks was normalised by division by the total number of cement cracks ultimately possible.
ments indicated that the macrocrack propagated through the cement mantle.

During the simulations, the crack formation process in the cement mantles surrounding the different Capital Hip designs was monitored, as well as the peak stresses in the cement. Furthermore, the migration of the stems with respect to the bone, as a result of creep and crack formation in the cement mantle, was calculated. Lastly, the contact between the stem and the cement mantle during the failure process was analysed in order to locate areas where burnishing could be expected.

Results

There were distinct differences between the different Capital Hip designs regarding the formation of cracks in the cement mantle. At the onset of the simulation, the roundback titanium stem showed the largest amount of cement damage, but eventually the rates of crack formation around the two flanged designs were higher (Fig. 2). After 20 million loading cycles, the largest amount of damage was found in the cement mantle surrounding the flanged titanium design, while the roundback stainless-steel stem produced the least amount of cement damage. The development of damage around the flanged designs showed several stepwise increases during the simulations. These occurred at moments when stair-climbing loads were applied to the models, causing high concentrations of stress in the cement mantle (Fig. 3).

Not only the rate of crack formation, but also its pattern differed between the designs. In both the flanged and the roundback designs, cracks were initially formed in the proximomedial region below the collar and distally below the tip of the stem (Fig. 4). In the reconstructions with the flanged designs, the proximal damage zone expanded from medial to lateral, via the posterior side. In the mid-part of the cement mantles, a crack was formed at the lateral side. This appeared in all cement mantles, except for that surrounding the roundback stainless-steel stem. The medial damage zone below the collar and the lateral crack at the level of the mid-stem propagated towards the tip of the stem. For the flanged designs, this effect was more pronounced than for the roundback designs.

Analysis of the migration of the prosthetic head also showed differences between the flanged and the roundback designs. The migration of the flanged designs in the posterior direction was much higher than that of the roundback designs, indicating increased rotation of the stem about its longitudinal axis (Fig. 5). In the medial and distal directions, the differences between the type of design were very small. The titanium-alloy stems, however, seemed to migrate slightly more in these directions than the stainless-steel stems.

The stem-cement interface was debonded from the start of the simulation and therefore the stem did not contact the cement mantle over the entire surface. During the loading history, the areas of contact varied in size and location.
However, in both the flanged and the roundback designs, contact was mainly detected medially at the posterior side and laterally at the anterior side (Fig. 6). The location and size of the area of contact were virtually independent of the stem material and type of loading which had been applied to the models.

**Discussion**

In accordance with the study of the Royal College of Surgeons of England, our simulation was able to demonstrate the detrimental effect of the flanged design and of the titanium-alloy stem material on the formation of cement fatigue cracks. However, in contrast with that study, our simulations showed that the effect of the design of stem was larger than that of the stem material. Hence, in comparison with the clinical data, in our model the effect of the change in the type of material was underestimated with respect to the effect of the change in geometry.

Obviously, our finite-element models are limited in the extent to which the failure process of actual reconstructions with the Capital Hip system can be simulated, which is a possible explanation for the discrepancy between our results and the clinical scores. An important shortcoming in the models is that the formation of polymethylmethacrylate (PMMA) particles and their subsequent effect on failure of the implant cannot be predicted by our simulation. McGrath et al. studied periprosthetic soft tissue from retrieved Capital Hip implants and found large numbers of PMMA particles, which implied that biological reactions to PMMA particles were involved in the failure process of
these implants. In addition, the Royal College of Surgeons of England\textsuperscript{5} reported that the surface roughness of the titanium-alloy Capital Hip stems typically was higher than that of the stainless-steel Capital Hips. Since rougher stem surfaces have a higher abrasive potential, the titanium-alloy stems have caused more pronounced osteolytic reactions. This may explain why clinically the stem material was the primary design parameter involved in the failure of the Capital Hip, while it was secondary to the geometry of the stem in our simulation.

There were also limitations to our models which may have affected the correspondence to the survival rates found \textit{in vivo}, regardless of the type of design or implant material. For instance, the cement mantle in our models had a minimum thickness of 2 mm, while in real reconstructions using the original Capital Hip rasps, a minimum cement thickness of 1 mm was obtained.\textsuperscript{5} A thin cement mantle has been associated with earlier failure of cemented hip reconstructions.\textsuperscript{16-18} Furthermore, in our models the stems were implanted such that an optimum cement mantle was obtained, while the Royal College of Surgeons of England\textsuperscript{5} reported that the cementing technique was ‘doubtful’ in 54\% and ‘unacceptable’ in 33\% of the 1899 cases which were studied. Obviously, with a thickness of the cement mantle of only 1 mm, a suboptimal positioning of the implant has significant consequences for the cement mantle surrounding the implant, which affects the rate of survival of the implant. Furthermore, in our simulation we used the fatigue characteristics of Cemex RX bone cement, while for the reconstructions with the Capital Hip mainly CMW (DePuy International Ltd, Leeds, UK) or Palacos (Schering Plough Ltd, Welwyn Garden City, UK) cement was used.\textsuperscript{2,4} However, we think that these effects are evenly distributed over the four types of stem, and would therefore not have affected the ranking which we found in this study.

Despite the limitations of our simulations, some interesting findings which corresponded to the clinical data resulted from our study. In our models, initially, cracks were formed in the proximomedial region of the cement mantle. This was also observed by McGrath et al,\textsuperscript{6} who studied post-operative radiographs of reconstructions with titanium Capital Hip implants. They also examined retrieved implants and noticed patterns of wear in the anterolateral and posteromedial regions due to burnishing of the stems against the cement mantles.\textsuperscript{6} Our simulations showed that these were the main regions where the stems contacted the cement mantle and therefore where loads were transferred between the stem and the cement. Furthermore, our simulations showed that the flanged designs displayed a high level of migration of the prosthetic head in

\textbf{Fig. 6}

Finite-element models showing the areas of contact between the Capital Hip stem and the cement mantle for the flanged and roundback designs. The flanged stem had properties of stainless-steel, the roundback those of titanium alloy. The inside of the posterior part of the cement mantle is shown on the left and the inside of the anterior part on the right in each model. The dark zones indicate the regions where the stem contacted the cement mantle. Although these figures are taken at arbitrarily-chosen moments in the loading history, they are representative of the contact status during the entire simulation.
the posterior direction. The major part of the migration in this direction was caused by rotation of the stem around its longitudinal axis, indicating torsional instability of this particular design. This was also reported by Ramamohan et al., based on finite-element analysis.

The Capital Hip system was equipped with some new features compared with the Charnley system which were introduced to improve survival of the implant. Unfortunately, these features did not have the desired effect. Because of its low modulus of elasticity, titanium was thought to reduce cement stresses. Because of its low modulus of elasticity, titanium was nately, these features did not have the desired effect. Unfortu-
nations indicated that the cement stresses increased with the titanium-alloy material. The titanium stems therefore produced more cement damage which was attributable to the decreased bending stiffness of the titanium with respect to the stainless-steel stems. The flanged design was introduced to provide a better proximal distribution of stress, while our simulations indicated that the flanged designs produced more cement damage in this region than the roundback stems. Additionally, the rotational instability of the flanged designs may have promoted abrasion of the cement mantle, further accelerated by the higher surface roughness of the titanium-alloy stems.

The aim of our study was to investigate whether our finite-element simulation was able to differentiate between the findings of the Royal College of Surgeons of England. Our study showed that the simulation was able to differentiate between stainless-steel and titanium-alloy stems and also between the roundback and flanged designs. However, in our simulation the effect of the design of stem on the crack formation was larger than that of the material of the stem. We attribute this to the differences in surface roughness between the titanium-alloy and stainless-steel stems, which our simulation was unable to detect. Further development of our simulation is necessary to incorporate these effects. Hence, our study has identified areas in which the simulation could be improved, but has further validated its potential to evaluate aspects of the design of stems such as material and geometry at a pre-clinical stage.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References