CAN FINITE ELEMENT BASED PRE-CLINICAL TESTS DIFFERENTIATE BETWEEN CEMENTED HIP REPLACEMENT STEMS ACCORDING TO CLINICAL SURVIVAL RATES?

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Introduction: Conventional cemented total hip arthroplasty (THA) implants are highly successful, but some studies still report unacceptably high failure rates for new implants that are introduced on the orthopaedic market [1]. Proper pre-clinical testing of these implants might prevent such disasters. The present study is performed within the frame-work of a large European project, aimed at developing validated pre-clinical tests to test cemented THA implants against the cement damage accumulation failure scenario. According to this scenario damage accumulation in the bulk cement and along the interfaces eventually leads to gross loosening of the implant. Retrieval studies have shown that this is one of the most important failure scenarios for the femoral component [2]. A numerical pre-clinical test was developed in the form of a finite element (FE) simulation that allows monitoring of cement crack formation and stem migration, in cemented THA reconstructions subjected to cyclic loading. The simulation was already validated experimentally in an earlier study [3]. The current study is concerned with the final clinical validation of the simulation. The damage accumulation failure scenario was simulated for four cemented hip stems, with distinct differences in clinical survival rates as reported by the Swedish Hip Registrer. The question was: does a ranking of the stems from superior to inferior, based on the FE predictions concur with a ranking based on the clinical survival rates?

Methods
Four stems were selected from the Swedish Hip Register: the Lubinus SPII, the Exeter Polished, the Charnley Roundback and the Mueller Curved. At 10 years after surgery the survival rates of these implants were 4%, 5%, 8% and 13%, respectively (Fig. 1)[4]. For each stem an FE model was created, representing a cemented THA reconstruction in a composite femur (Fig. 2). The stem-cement interfaces were unbonded around all stems (μ=0.25), as it was assumed that the rate of the debonding process was much higher than that of the failure process of the cement mantle. A loading history was applied to the models, representing 20 million cycles of alternating walking and stair climbing, in a ratio of 9:1 cycles [5].

The FE simulation to model the damage accumulation failure scenario was based on a 3-D continuum damage mechanics approach. Damage (micro-cracks) was thought to accumulate in the cement mantle as a function of the number of loading cycles and the local stress levels and orientations. As damage accumulated, macro-cracks were formed, reducing the load carrying capacity of the cement. The simulation also accounted for cement creep. The simulation was able to predict the locations and orientations of the macro-cracks, and the amount of stem migration attributable to the mechanical failure processes. Fatigue and creep properties of the cement were taken from [6,7].

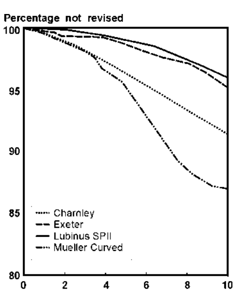

Fig. 1. *Survival curves as reported by the Swedish Hip Register for the stems analyzed [4].*

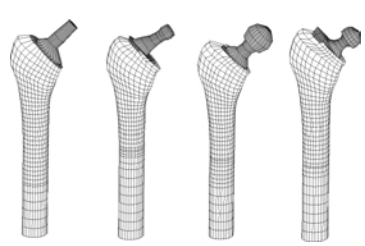

Fig 2. *FE models of cemented reconstructions, with a Lubinus SPII, Exeter, Mueller C, and Charnley stem (from left to right).*

Results: After 20 million cycles, the Mueller C. had produced a considerably higher number of cement cracks than the other three stems (Fig. 3). Cracks were formed around the entire stem (Fig. 5). Proximo-distal damage pathways were formed, and the cracked zones often extended over the thickness of the mantle. The Charnley performed better, with a lower number of cracks. The rate at which proximo-distal damage pathways were formed was lower than around the Mueller C. The Exeter performed even better. Full thickness crack zones were produced only in the proximo-medial region. The crack zones progressed distally at a low rate. The Lubinus performed best, with the lowest number of cement cracks. No full thickness cracks occurred around that stem, and no proximo-distal damage paths were formed. Concerning migration, the Exeter migrated more than the other stems (Fig. 4). From the collared implants, the Lubinus SPII showed the lowest migration values. For all stems, the highest component of migration was torsional.

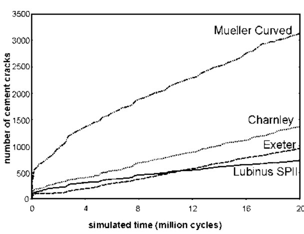

Fig 3. *Number of cracks in the cement around the stems*

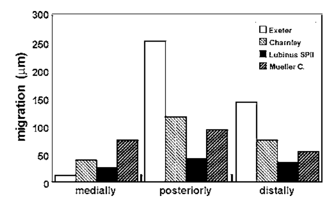

Fig 4. *Migration of head center of the stems after 20 million cycles*

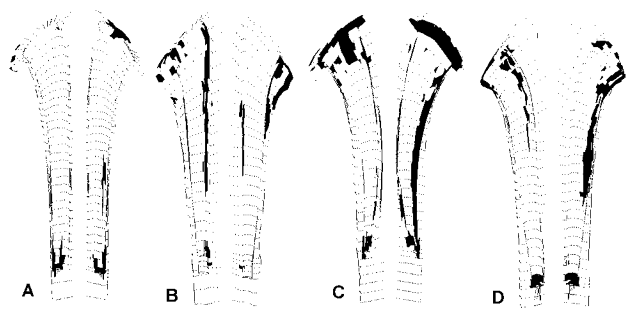

Fig. 5. *The crack distributions in the cement mantles around the Lubinus SPII stem (A), the Exeter stem (B), the Mueller Curved stem (C) and the Charnley stem (D). The cement mantles are split open along the mid-frontal plane, and the inside of the anterior and posterior sides is shown.*

Discussion: Based on the clinical survival rates, the ranking of the stems would be, from superior to inferior: Lubinus SPII, Exeter, Charnley, Mueller Curved. This ranking was reproduced exactly by the FE simulations, when taking the number of cement cracks produced as the ranking criterion. This ranking was further justified by the finding that inferior stems produced proximo-distal damage pathways at a higher rate, and more full thickness cracks. Concerning the migration patterns, the stems behaved according to their design concepts, with the highest migration values for the Exeter stem. For the Exeter stem, high migration values did not accord with high damage accumulation rates.

In conclusion, the FE simulations were able to differentiate between four cemented THA implants, in a clinically valid way. This corroborates the use of the FE simulation for pre-clinical testing purposes.

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References: [1] Sylvain et al, J Arthrop 16:141, 2001; [2] Jasty et al, JBJS 73B:551, 1991; [3] Stolk et al, 48th ORS, Dallas, TX; [4] Herberts et al, Acta Orthop Scand 71:111, 2000; [5] Morlock et al, J Biomech 34:873, 2001; [6] Murphy et al, J Biomed Mater Res 59:646-654, 2002; [7] Verdonschot et al, J Biomed Mater Res 29: 575, 1995.

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