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Effect of undersizing on the long-term stability of the Exeter hip stem: A comparative *in vitro* study

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ABSTRACT

Background: Even for clinically successful hip stems such as the Exeter-V40 occasional failures are reported. It has been reported that sub-optimal pre-operative planning, leading to implant undersizing and/or thin cement mantle, can explain such failures. The scope of this study was to investigate whether stem undersizing and a thin cement mantle are sufficient to cause implant loosening.
Methods: A comparative in vitro study was designed to compare hip implants prepared with optimal and smaller than optimal stem size. Exeter-V40, a highly polished cemented hip stem, was used in both cases. Tests were carried out simulating 24 years of activity of active hip patients. A multifaceted approach was taken: inducible and permanent micromotions were recorded throughout the test; cement micro-cracks were quantified using dye penetrants and statistically analyzed.
Findings: The implants with an optimal stem size withstood the entire mechanical test, with low and stable inducible micromotions and permanent migrations during the test, and with moderate fatigue damage in the cement mantle after test completion. Conversely, the undersized specimens showed large and increasing micromotions, and failed after few loading cycles, because of macroscopic cracks in the proximal part of the cement mantle. While results for the optimal stem size are typical for stable hip stems, those for the undersize stem indicate a critical scenario.
Interpretation: These results confirm that even a clinically successful hip prosthesis such as the Exeter-V40 is prone to early loosening if a stem smaller than the optimal size is implanted.

1. Introduction

The Exeter is one of the most frequently used hip stems, accounting for 21.8% of the cemented stems implanted in Europe (Scheerlinck et al., 2004). It is a clinically successful stem, with a survival rate of 98.5% at 7 years and over 95% at 10 years (Kärrholm et al., 2008; Stea et al., 2008). While the average survival rate in itself is excellent, there are hospitals/divisions where higher failure rates are reported (Kärrholm et al., 2008; Stea et al., 2008). Implant failure may be due to a number of factors, related to the patient, the device, and the surgical technique. There are two causes of failure of cemented hip stems by aseptic loosening, which are related to the surgical technique: (i) sub-optimal pre-operative planning (Ebramzadeh et al., 2004), and (ii) excessively thin cement mantle (Ebramzadeh et al., 1994).

Incorrect choice of the stem size is a relatively common problem related to pre-operative planning, both in cemented and cementless hip stems (Barrack, 2000; Giannikas et al., 2002; Viceconti et al., 2003). It has been reported that stem undersizing by two stem sizes occurs in 10% of the cases with anatomical uncemented hip stems, when pre-operative templating is based on standard radiographs (Viceconti et al., 2003). Stem undersizing in cemented arthroplasty has been associated to excessive stress in the cement mantle (Harrington et al., 2002; Janssen et al., 2009), which can lead to early aseptic loosening (Verdonschot, 1996). It has been suggested that the use of pre-operative planning software enabling a full three-dimensional virtual visualisation would reduce the incidence of such problems (Lattanzi et al., 2003; Viceconti et al., 2003).

Insufficient cement mantle thickness is primarily caused by insufficient reaming of the femoral canal (Scheerlinck et al., 2006). In fact, it has often been shown that a mantle thicker than 2–3 mm reduces cement stress and micromotions (Ramaniraka et al., 2000). Conversely, more cracks are found both *ex vivo* (Kawate et al., 1998) and *in vitro* (Mann et al., 2004) where the cement mantle is thin. In

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fact, even in the case when cracks grow at the same rate across the cement mantle, a reduced thickness is expected to decrease the time needed for a crack to break through the entire mantle thickness (Hertzler et al., 2002).

In vitro testing is able to discriminate between successful and critical hip stems (Maher and Prendergast, 2002; Britton and Prendergast, 2005; Cristofolini et al., 2007a,c; Zhang et al., 2008). *In vitro* testing has also been able to explain early failure of a specific cemented stem in relation with excessively thin cement mantles (Cristofolini et al., 2007b).

The scope of this work was to assess if, given a clinically successful hip stem, sub-optimal planning (stem undersizing) and sub-optimal implantation (thin cement mantle) is sufficient to cause implant failure. In order to test this hypothesis, composite femurs implanted with Exeter-V40 stems of different sizes were tested *in vitro* to investigate implant micromotions and cement fatigue damage.

2. Methods

A mechanical testing procedure that was extensively validated (also in comparison against *ex vivo* retrievals) was recently proposed for quantifying long-term hip implant damage both in terms of implant-bone micromotions and of cement fatigue damage (Cristofolini et al., 2007a,c; 2003). As revision rates are extremely low, failures are most likely to occur in the most demanding patients for implant survival, i.e. the young, active and heavy patients that are most likely to apply higher and most frequent loads (Dorey and Amstutz, 2002; Kilgus et al., 1991). A loading profile has recently been proposed that enables simulating 24 years of activity of a very demanding patient (Cristofolini et al., 2007c; 2002).

2.1. Specimens

The present study was carried out on a total of ten Exeter hip stems (Exeter-V40, Howmedica, Mahwah, NJ, USA), which is a Cr–Co–Mo highly polished cemented stem. They were implanted by a pool of skilled surgeons in composite femurs (Mod. 3103, Pacific Research Labs, Vashon Island, WA), using the instrumentation recommended by the manufacturer. An anatomic reference system was established (Cristofolini, 1997; Ruff and Hayes, 1983) to assist in maintaining consistent implantation, and increase repeatability during specimen preparation and testing. To enable reproducible preparation, bone cement (Simplex-P, Stryker-Howmedica, Mahwah, NJ, USA) was mixed using a sealed mixing device (Summit Medical Syringe Type, Summit Medical Group, Bourton-on-the-Water, UK) at 23–25 °C, 40–55% relative humidity. To replicate the worst-case clinical scenario in which the hip stems must still function well, mixing was performed without application of vacuum (which is one of the options indicated by the Manufacturer for Simplex-P). In fact, hand-mixing is still used in the clinical practice between 6% (Gheduzzi et al., 2004) and 50% of cases (Breusch et al., 2000; Stea et al., 2008). Cement was injected in a retrograde fashion prior to stem insertion. The stems were provided with the standard Exeter distal centralizer.

Ten femurs were implanted as follows (specimens were X-rayed to document alignment and mantle thickness):

- *Optimal* specimens: four femurs were prepared with the optimal stem size (Exeter-V40 femoral stem: 37.5 mm offset, No. 2) based on pre-operative templating following the manufacturer's instructions.
- *Undersized* specimens: four femurs were rasped to a smaller size than the *Optimal* one (Exeter-V40 femoral stem: 35.5 mm offset). A stem two sizes smaller than the *Optimal* one was chosen, as errors of between one and three sizes are commonly reported for hip stems (Viceconti et al., 2003). Such stem was slightly shorter, and narrower both in the frontal and sagittal planes than the previous one.
- *Dummy* specimens: two additional specimens were prepared for each type. They were used for optimizing the sectioning procedure and for assessing the absence of artefacts due to stem extraction and cement mantle sectioning (see below).

To provide a comparison against a largely used stem, this study was compared with a previous publication for the Lubinus-SPII cemented hip stem (Bialoblocka-Juszczyk et al., 2010). In that study, six Lubinus-SPII stems implanted in composite bones with the same bone cement (Simplex-P) underwent the same *in vitro* testing as in the present study, using the same type of composite femurs, the same loading and testing equipment, and the same procedure for inspection of the cement mantles. The Lubinus-SPII was chosen for comparison because it has a high survival rate, which is similar to the Exeter-V40: nearly 98% after 10 years (Kärrholm et al., 2008). The use of the Lubinus-SPII as a benchmark for pre-clinical testing has been established in a large European Project (Maher and Prendergast, 2002; Stolk et al., 2002a; Waide et al., 2001).

2.2. Load history

As the focus was on most demanding patients, a severe load history was simulated that replicated 24 years of activity of a very active patient (Cristofolini et al., 2007c). As walking is less detrimental than other tasks for hip joint loosening (Kassi et al., 2005; Stolk et al., 2002b), only stair-climbing and more severe motor tasks were included (Bergmann et al., 2001). All the most relevant activities from a fatigue point of view were included in the accelerated test (Table 1) (Cristofolini et al., 2007c) for a total of 1,000,348 cycles at 0.75 Hz. This procedure has been proven to yield results that are comparable to those found in retrieved cement mantles after *in vivo* cycling (Cristofolini et al., 2007a). To enable comparisons between *Optimal* and *Undersized* specimens, both series were tested so that load was applied with the same offset, resulting in identical bending moment and torsional moments being applied to all specimens (Cristofolini et al., 2007c).

Table 1
Activities in the simulated physiological loading (load values and frequency of occurrence). The load components were based on the literature so as to replicate the most critical scenario for the axial and torsional stability (Cristofolini et al., 2007c). The load history consisted of 1252 simulated weeks (corresponding to a total of 1,000,348 loading cycles).

	Axial force (compression)		Bending moment (frontal plane)		Axial torque (intra-rotation)		Cycles/simulated day
ACTIVITY	*N*	% BW	Nm	% BWm	Nm	% BWm	*N*
Stairs up	2037	370	16.50	3.00	25.30	4.60	54
Stairs down	2223	404	27.94	5.08	24.20	4.40	54
Bath tub entry	2741	498	22.17	4.03	34.05	6.19	1
Bath tub exit	2741	498	22.17	4.03	34.05	6.19	1
Car entry	3229	587	38.01	6.91	34.87	6.34	2
Car exit	2939	534	28.93	5.26	28.38	5.16	2