ELSEVIER

Journal of Biomechanics 39 (2006) 1169–1179

JOURNAL OF BIOMECHANICS

www.elsevier.com/locate/jbiomech
www.JBiomech.com

Primary stability of an anatomical cementless hip stem: A statistical analysis

Marco Viceconti[a,*], Giovanni Brusi[a], Alberto Pancanti[a], Luca Cristofolini[a,b]

[a]*Laboratorio di Tecnologia Medica, Istituti Ortopedici Rizzoli, Via di Barbiano, 1/10, 40136 Bologna, Italy*
[b]*DIEM, Facoltà di Ingegneria, Università di Bologna, Bologna, Italy*

Accepted 28 March 2005

Abstract

The primary stability that the surgeon can achieve during surgery is a determinant of the clinical success of cementless implants. Thus, estimating what level of primary stability can be obtained with a new design is an important aspect of pre-clinical evaluation. The primary stability of a cementless hip stem is not only affected by the implant design, but also by other factors such as the mechanical quality of the host bone, the presence of gaps around the bone–implant interface, the body weight of the patient, and the size of the implant. Even the most extensive experimental study can only explore a small sub-set of all possible combinations found in vivo. To overcome this limitation, we propose a combination of experimental and numerical methods. The primary stability of a cementless anatomical stem is assessed in vitro. A finite element model is developed to accurately replicate the same experiment. The model is then parameterised over the various factors that affect the primary stability, and used in a Monte Carlo scheme to assess the primary stability over a simulated population. In this study, the method was used to investigate the mechanical stability of an anatomical cementless stem over more than 1000 simulated cases. Twenty cases were found macroscopically unstable, due to a combination of unfavourable conditions. The rest of the Monte Carlo sample showed on average a peak micromotion under stair climbing loading of $206 \pm 159\,\mu m$. The proposed method can be used to evaluate new designs in conditions more representative of the variability in clinical practice.

Keywords: Cementless hip prosthesis; Primary stability; Statistical finite element analysis

1. Introduction

The term *primary stability* usually indicates the amount of relative micro-movement between bone and implant induced by the physiological joint loading early after the operation, before any biological process takes place. This is different from the so-called *secondary stability*, which is the micromotion under load observed once the biological adaptation process is completed. The failure of cementless hip stems is mostly due to aseptic loosening (Stea et al., 2002). There is wide consensus that the lack of primary stability is the prime risk factor for aseptic loosening of cementless devices (Pilliar et al., 1986). Thus, it is mandatory to assess the level of primary stability that can be achieved by the surgeon for each new prosthetic device.

The primary stability of cementless stems has been tested for two decades in vitro or with numerical models. Most experimental protocols concentrate on one (Phillips et al., 1991; Harman et al., 1995) or two (Burke et al., 1991; Whiteside et al., 1993) motor tasks. There is a general agreement that, among the most common activities performed in the first months post-operatively, stair climbing and other tasks generating similar torques are most challenging in terms of stem stability (Burke et al., 1991; Whiteside et al., 1993; Bergmann et al., 1995; Harman et al., 1995). Indeed, this task is the most commonly simulated in vitro, in a more or less accurate

*Corresponding author. Tel.: +39 051 6366864; fax: +39 051 6366863.
E-mail address: viceconti@tecno.ior.it (M. Viceconti).

0021-9290/$ - see front matter © 2005 Elsevier Ltd. All rights reserved.
doi:10.1016/j.jbiomech.2005.03.024

way. These authors have developed an in vitro procedure for testing the primary stability based on stair climbing loads (Harman et al., 1995; Monti et al., 1999) that has been applied to several cementless stems (Monti et al., 2001) including the design used for this study (Baleani et al., 2000; Viceconti et al., 2001a). The same device was subjected to a finite element study, where the bone–implant micromotion measured in vitro at various locations of the interface were accurately predicted by the finite element model when the contact was simulated using face-to-face large sliding frictional contact elements (Viceconti et al., 2000).

Some surgical factors have been modelled in numerical models (e.g. Harrigan and Harris, 1991; Viceconti et al., 2001b). However, in all numerical studies, cementless stems are implanted under deterministic conditions: the stem size is selected based on the bone size, maximal cortical contact is sought, average body weight and level of activity is simulated, etc. However, in a follow-up study it was found that the presence of gaps at the bone–implant interface drastically decreases the primary stability of the same cementless stem (Viceconti et al., 2001b). It is reasonable to presume that also the mechanical properties of the host bone, the size of the femur and the body weight of the patient may affect the primary stability. Similarly, in vitro studies are usually carried based on ideal implantation, and tend to focus on the dependence of stress distribution or stability on the prosthetic design under ideal conditions, rather than on the surgical parameters. In some case the effect of surgical factors was explored such as the stem insertion depth (e.g. Harman et al., 1995), of stem fit (e.g. Jasty et al., 1994), of intra-operative fractures (e.g. Monti et al., 2001). However, these factors were addressed one at a time and in a deterministic way. Indeed, to the authors' knowledge, no in vitro study has been carried out so far addressing the effect of the variability of all such parameters simultaneously. As implant failure occurs in few cases out of a large population, a simulation of the clinical variability is needed so as to estimate and compare the probability of failure of different prostheses.

The present study aims to estimate the effect of the inter-subject variability of weight, height, bone quality, and presence of interface gaps on the primary stability of a particular anatomical cementless stem during stair climbing. It was decided not to simulate mere surgical errors, but to keep the focus only on the intrinsic scatter of such variables.

2. Materials and methods

The study was conducted on an anatomical cementless stem, widely used in our clinical department as well as in many others (AncaFit, Cremascoli-Wright, Milano, Italy) (Toni et al., 2001). The implant (Fig. 1) is being monitored by the RIPO outcomes register (Stea et al., 2002) where it exhibits after 5 years from its introduction a survivorship of $98.9 \pm 0.9\%$ (95% CI). This stem has thoroughly been investigated in vitro and numerically (Cristofolini and Viceconti, 1999; Monti et al., 1999; Baleani et al., 2000; Viceconti et al., 2000, 2001a).

Fig. 1. Solid model of the AncaFit anatomical stem assembled with a 28-mm ball-head and a straight modular neck.

In order to answer the research question, the finite element model of an anatomically normal human femur implanted with an anatomical cementless stem, was modified to represent in a parametric form:

- the mechanical properties of the bone tissue,
- the presence and extent of gaps at the bone–implant interface,
- the patient body weight, and
- the size of the host femur.

Also, the stem model was parametrically scaled so that in each femur size the prosthesis remained correctly sized and aligned with the axis of the medullary canal.

For each of these parameters, we defined a realistic and clinically relevant statistical distribution, whose