IMPLANT STABILITY AND LOAD TRANSFER OF OSSEOINTEGRATED TRANSFEMORAL PROSTHESIS

Giulia Galteri (1), **M. Palanca** (1), **V. Betti** (1), **K. Morellato** (2), **E. Gruppioni** (2), **L. Cristofolini** (1)

1. *Dept of Industrial Engineering, Alma Mater Studiorum - University of Bologna, Bologna, IT*
2. *Centro Protesi INAIL, Vigorso di Budrio, Bologna, IT*

Introduction

Osseointegrated prostheses for transfemoral amputees provide a direct connection between the external prosthesis and the patient's bone, providing many advantages over the *gold standard* socket prostheses. However, similar to other uncemented prostheses, the risk of stress-shielding and implant instability may occur. The influence of implant stiffness on femoral bone strain at selected locations of the femur was experimental investigated for some straight-stemmed implants [1],[2]. The OTN implant has a curved stem matching the physiological curve of the femoral canal, but the influence of the implant on femoral bone strain has not been investigated. Thus, the aim of the study was to evaluate the mechanical stability of OTN implant with Digital Image Correlation (DIC).

Material and Methods

One human cadaveric femur was obtained through an ethically approved donation program. Osteotomy was performed 200 mm from the condyles. The proximal femur was embedded into a metal pot. The dimension of the femoral canal was measured at the isthmus level (ellipse 17x14 mm) from CT images (slice thickness=0.6 mm, in plane resolution=0.5mm). An OTN implant size 17 (Badal X^{tm},OTN) was implanted after reaming the femoral canal to guarantee the optimal press-fit. Tests were performed with a uniaxial testing machine (Instron 8500, 10kN load cell). One hundred load cycles (80N-880N), corresponding to 30Nm at the osteotomy level, were delivered in the direction corresponding to the heel strike during gait (Fig. 1a) [3]. The full-field displacements and strains were measured throughout the test by a 4-cameras 3D-DIC system (Aramis Adjustable 12M, GOM, 10 fps, measurement spatial resolution 2 mm). A high-contrast speckle pattern (white-on-black) was prepared on the surface of the femur for strain measurements, while to track stem-bone micromotions, set of markers was placed on the distal end of the prosthesis. A zero-strain analysis was performed to measure the random error. The maximum principal strains ($\varepsilon 1$) were measured in regions of interest near the osteotomy (ROI1) and near the stem tip (ROI2) during the peak load of each cycle. The elastic micromotions were measured as the inducible stem displacement within each cycle. The permanent migrations accumulated throughout the test were measured.

Results

The random error was smaller than 100 με. Smaller deformations were found near the osteotomy (median±SD of ROI1: ε_1=320±97 με, Fig.1b). Larger deformations were found distally (median±SD of ROI2: ε_1=1300±220 με). Inducible micromotions along the longitudinal axis were around 100 μm and stable throughout the test. Permanent migrations along the longitudinal axis were 2 μm.

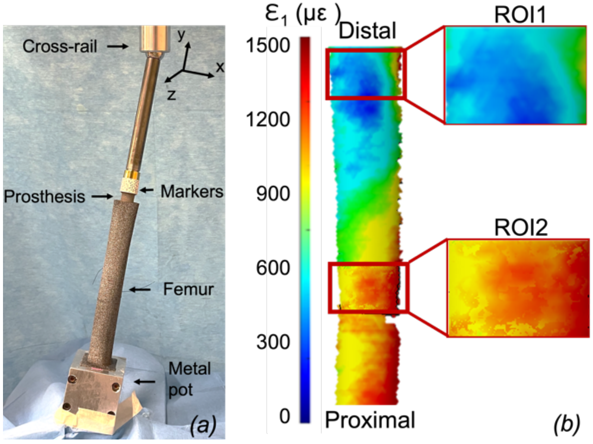

*Figure 1:(**a**) Experimental setup (front view). (**b**) Color map showing the distribution of maximum principal strains ($\varepsilon 1$) on the femur, in RO1 and ROI2.*

Discussion

The DIC full-field measurements showed how the insertion of the OTN implant leads to a high strain shielding at the distal region of the femur and a strain concentration proximally (at the stem tip level). This strain distribution is comparable to those reported in a previous study of straight-stemmed implants [1]. The inducible micromotions and permanent migrations were lower than micromotions inducing fibrous tissue formation [4]. This suggests that satisfactory press-fit condition and the primary stabilization have been reached throughout the test. Further mechanical *in vitro* tests will be carried out to increase the number of specimens.

References

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