# OSSEOINTEGRATED CURVED STEM PROVIDES GOOD IMPLANT STABILITY IN TRANSFEMORAL AMPUTEES

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## Introduction

The direct connection between the external prosthesis and the patient's bone makes osseointegrated prostheses for transfemoral amputees more advantageous than the socket prostheses, which are currently the *gold standard*. However, similarly to other uncemented prostheses, the osseointegrated ones are at risk of stress-shielding and aseptic loosening. How the implant influences the bone strain in specific regions of the femur was experimentally investigated only for straight-stemmed implants [1],[2].

In order to better match the physiological curve of the femoral canal, OTN implant offers a curved stem. However, the influence of the curved implant influences on femoral bone strain has not been investigated yet. Thus, the aim of the study was to evaluate the implant stability and the load transfer of OTN implant with Digital Image Correlation (DIC).

## Material and Methods

One human cadaveric femur was obtained through an ethically approved donation program. CT scans (slice thickness=0.6mm, in plane resolution=0.5mm) were performed to assess the dimension of the femoral canal and choose the correct size of the implant. An osteotomy was performed 200mm from the condyles. An OTN implant size 17 (Badal X$^{tm}$,OTN) was implanted after reaming the femoral canal to guarantee the optimal press-fit. The proximal femur was embedded into a metal pot, tilted as to load the femur like in the heel strike during gait. A speckle pattern was prepared on the surface of the femur for DIC measurements, while to track stem-bone micromotions, set of markers was placed on the distal end of the prosthesis.

Mechanical tests were performed using a uniaxial testing machine (Instron 8500, 10kN load cell). One hundred load cycles (80N-880N), corresponding to a bending moment of 30Nm at the osteotomy level, were delivered (Fig. 1a) [3]. A 4-cameras 3D-DIC system (Aramis Adjustable 12M, GOM, 10 fps, measurement spatial resolution 2mm) was used to measure the displacement and strain fields on the femur and prosthesis. A zero-strain analysis was performed to measure the DIC precision.

The maximum principal strains (ε1) were measured in two regions of interest: close to the osteotomy (ROI1) and close to the stem tip (ROI2) during the peak load of each cycle. The elastic micromotions were measured as the inducible displacement of the stem with respect to the bone within each cycle. The permanent migrations accumulated throughout the test were measured.

## Results

The random error was smaller than 100με. Maximum principal strains in ROI1 were smaller than those found close to the stem tip ROI2: 320±97με vs 1300±220με, respectively (Fig.1b). Inducible micromotions along the longitudinal axis were around 100µm and stable throughout the test. Permanent migration of 2µm was measured along the longitudinal axis.

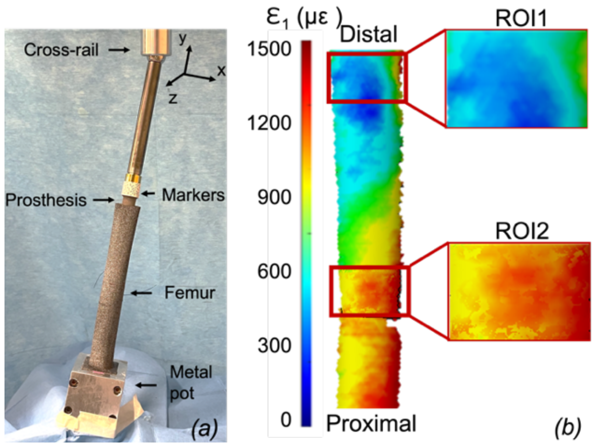


*Figure 1:(**a**) Experimental setup (front view, with the femur mounted upside-down). (**b**) Color map showing the distribution of maximum principal strains (ε1) on the femur, in RO1 and ROI2.*

## Discussion

The 3D strain distribution 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). The strain distribution obtained is comparable to those reported in a previous study of straight-stemmed implants [1]. The inducible micromotions and permanent migrations were both lower than the micromotions critically inducing fibrous tissue formation [4]. This suggests that this prosthesis reached a satisfactory press-fit condition and the primary stabilization. In order to generalize the findings, further mechanical *in vitro* tests will be carried out.

## References

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