SUPPLEMENTARY MATERIAL

Methodological details and results

Appendix to the paper

Improved primary stability and load transfer of a customized osseointegrated transfemoral prosthesis compared to a commercial one

1. *Material and Methods: additional technical details*

1.1 Digital Image Correlation

A 3D digital image correlation system (Aramis Adjustable 12M, GOM, Braunschweig, Germany) was used to measure the relative displacement between the prosthesis (fiducial markers) and the host bone (speckle pattern) and the full-field strain distribution of the femur throughout the mechanical tests. Four cameras equipped with high quality 75 mm lenses (f 4.5, Titanar B, Schneider-Kreuznach, Germany) were used to acquire the images (12 MegaPixels 4096x3000 pixels, 8 bit). The distance between the specimens and the cameras was set to 1540 mm, with a field of view of 280 mm x 205 mm, obtaining a pixel size of 0.07 mm [1]. A high-contrast white-on-black speckle pattern was prepared on the bone surface before mechanical testing. The speckle pattern was created using matt white water-based paint (Q250201 Bianco Opaco, Chreon, Italy) thinned with 40% of water and sprayed using an airbrush air gun (nozzle 1.8mm). The distance between the specimens and the airbrush air gun was set to 1,000 mm, while the pressure was set to 1,000 kPa in order to obtain the desired dot size, following the same approach of [1]. The distribution of the speckle pattern and the dot size were estimated [1] with a dedicated script in Matlab (2021 Edition, MathWorks).

Additionally, the distal portion of the prosthesis, which protruded distally to the femur osteotomy, was equipped with a set of glossy, passive circular markers (type: 0.8 mm, GOM Aramis, Braunschweig, Germany) to track the prosthesis displacements.

Before each test, the DIC system was calibrated using a calibration target (Type CP40/200/101296, GOM Aramis, Braunschweig, Germany). This procedure allows to define the physical dimension of the measurement volume, the correction of the distortions due to lenses, and the compensation of the parallax effects [2]. An optimization of the DIC system was performed in order to find the best compromise between the need of reducing the measurement uncertainties, and the desire of obtaining a high measurement spatial resolution [1]. A facet size of 40 pixels and a grid spacing of 17 pixels were chosen, estimating a measurement spatial resolution of 2 mm.
DIC images were acquired with the following protocol:

- Acquisition of the first 10 cycles;
- Acquisition of the central 10 cycles (from the 45 to the 55 cycles);
- Acquisition of the last 10 cycles.

1.2 Assessment of the primary stability and load transfer from the DIC data

In order to assess the primary stability the spatial micromotion of the prosthesis with respect to the host bone was analyzed. In particular, the displacements (three components of rotations and three components of translation) between the prosthesis (tracked through the set of fiducial markers attached) and the proximal femurs (tracked through the surface speckle pattern) throughout the test were assessed. Then, the DIC measurements were post-processed with a script in MatLab (2021 Edition, MathWorks), which computed [1]:

- The permanent migrations, as the difference between the position of the stem inside the bone at the end of the test and at the beginning of the test (in the unloaded condition);
- The inducible micromotion, as the difference between the position of the stem inside the bone at the load peak (850N for the compression-flexion test, 10 Nm for the torsional test) and valley (150N for the compression-flexion test, 2 Nm for the torsional test) of each cycle throughout the test.

In order to assess the load transfer throughout the mechanical test, the full-filed distribution of the maximum ($\varepsilon 1$) and minimum ($\varepsilon 2$) principal strains at the peak load on the surface of the femur was evaluated. In particular, two region of interest (ROI) were selected and investigated:

- ROI 1, proximal, was centered on the stem tip and covered the femur from 10 mm proximal to 10 mm distal to the stem tip. The main concern of this region was the risk of strain concentrations.

- ROI 2, distal, covered the femur by 20 mm proximal from the osteotomy. The main concern of this region was the risk of strain shielding.

For each ROI, the median value of $\varepsilon 1$ and $\varepsilon 2$ was computed with a dedicated script in MatLab (2021 Edition, MathWorks). The median was chosen as it is a more robust estimator of the average trend, in case of noisy data containing outliers [3].

2. Results: detailed strain distributions of the six pairs of femurs

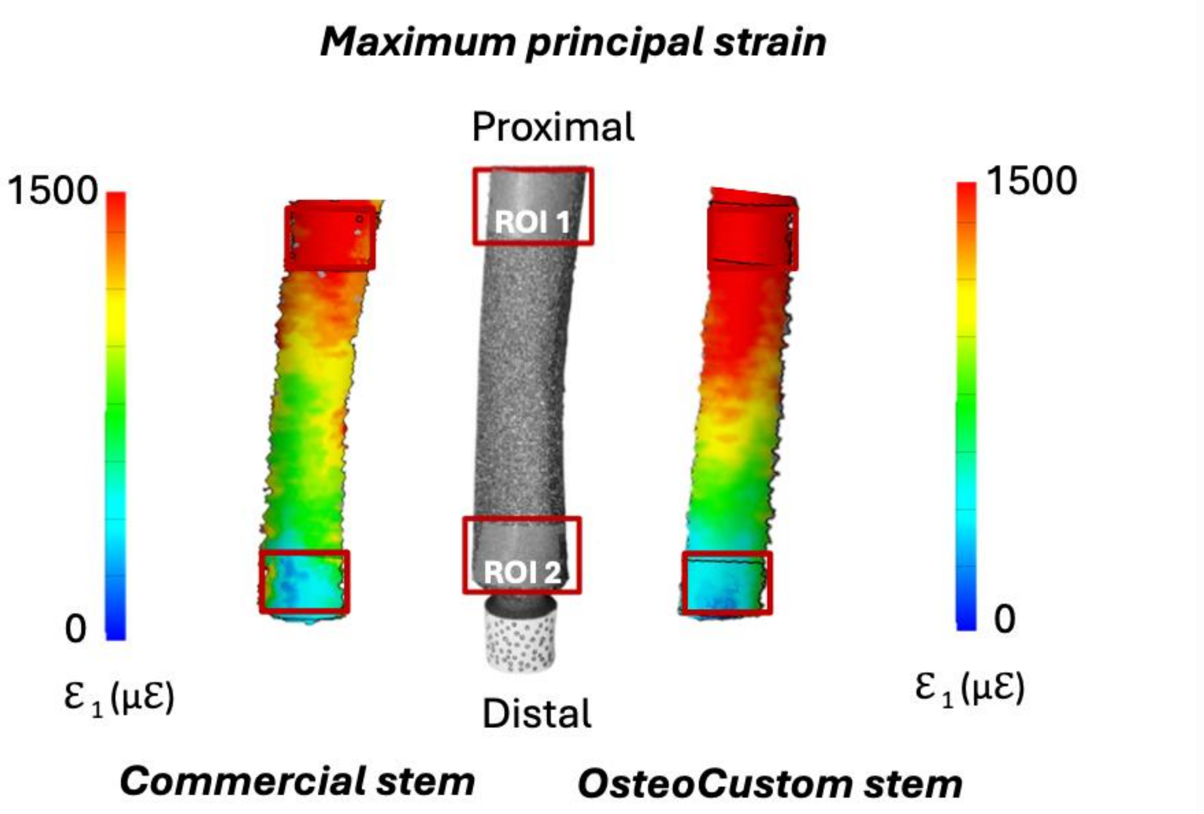

Fig. S-1: *The maximum principal strain of the commercial stem (on the left) and customized stem (on the right) are reported, #1*

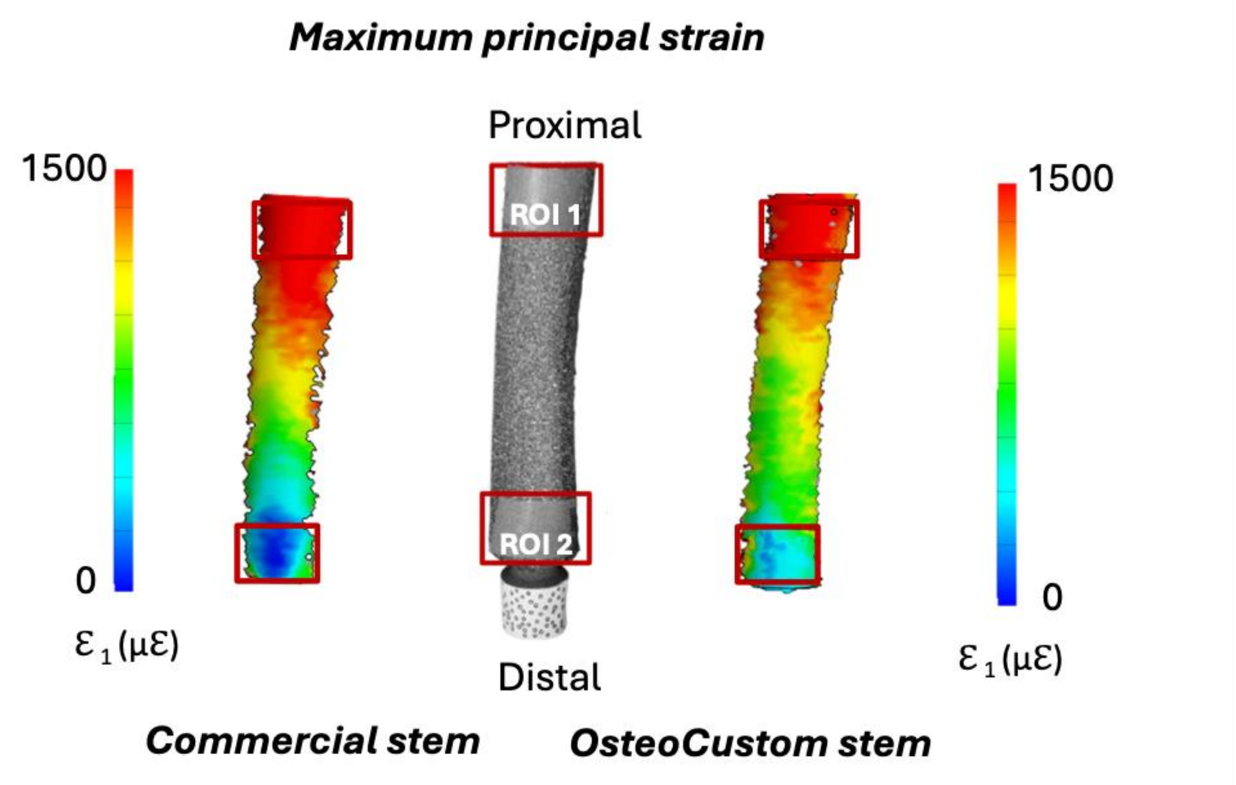

Fig. S-2: *The maximum principal strain of the commercial stem (on the left) and customized stem (on the right) are reported, #2*

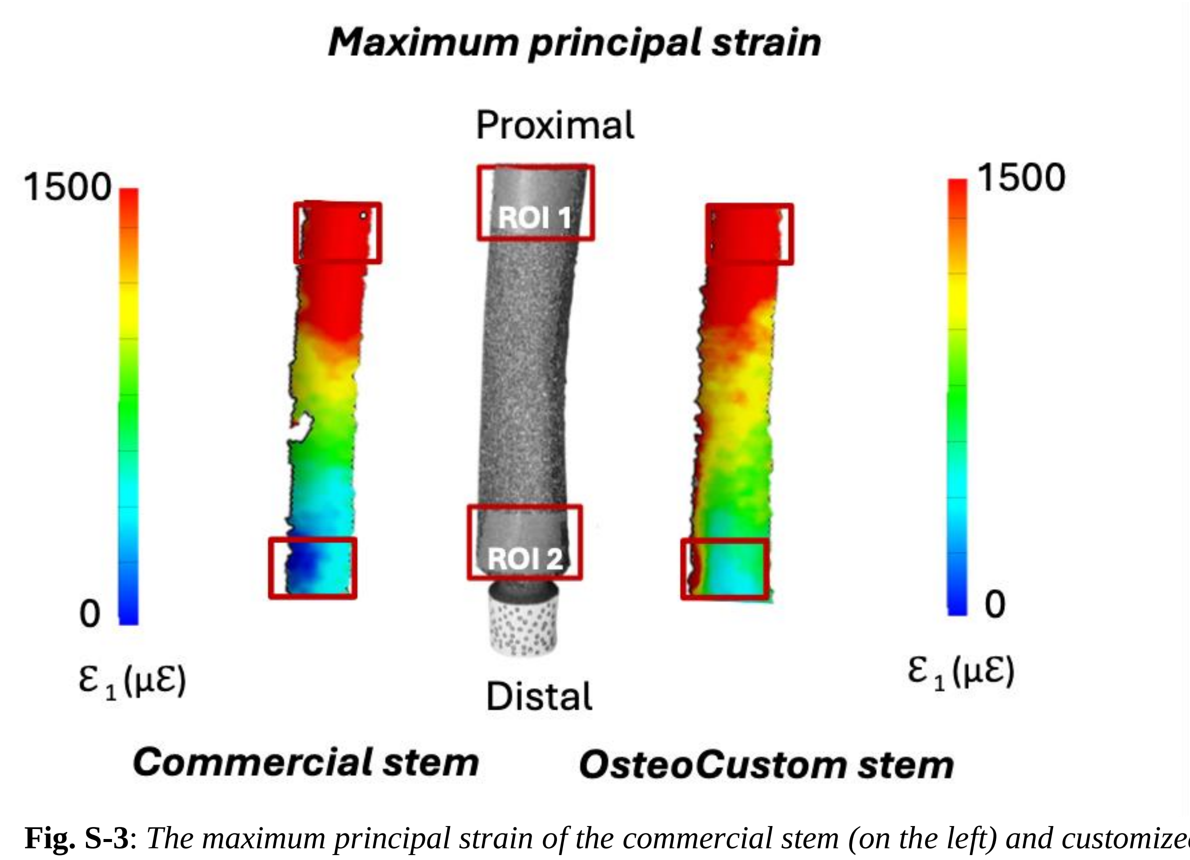

Fig. S-3: *The maximum principal strain of the commercial stem (on the left) and customized stem (on the right) are reported, #3*

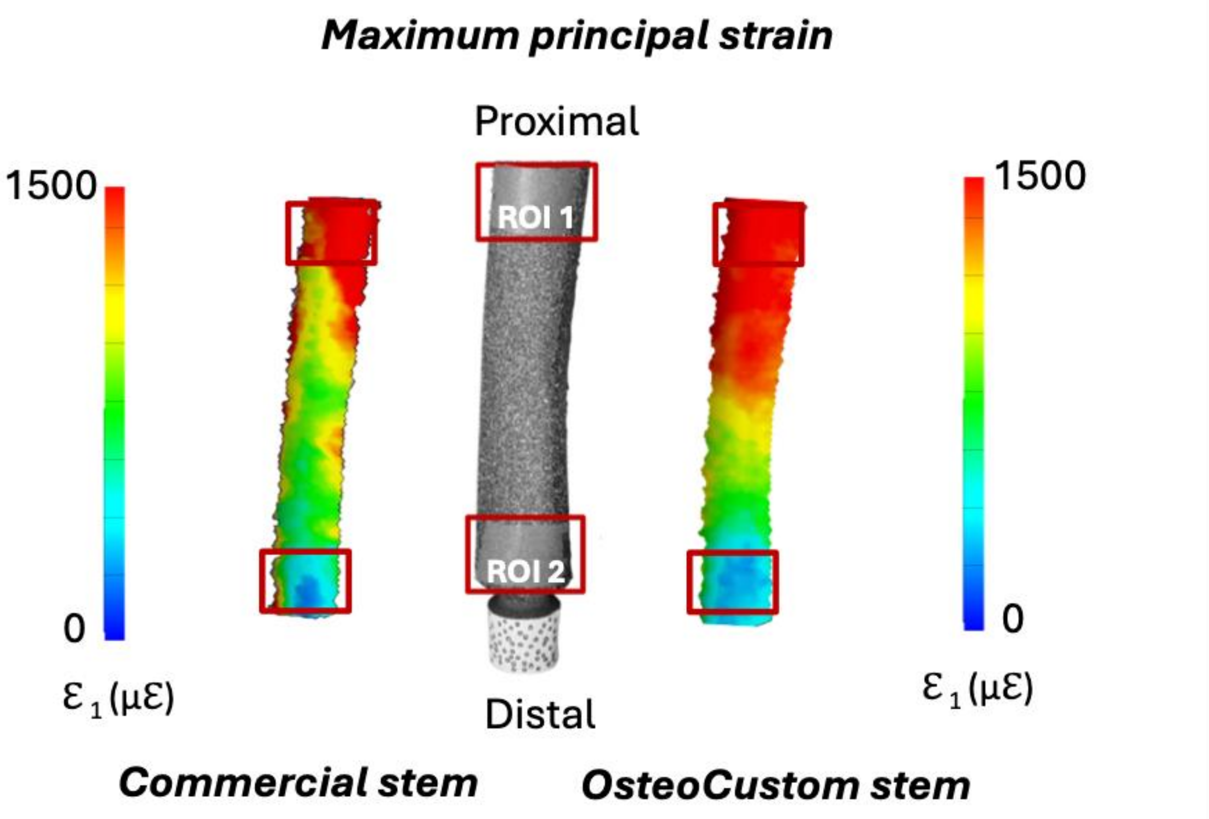

Fig. S-4: *The maximum principal strain of the commercial stem (on the left) and customized stem (on the right) are reported, #4*

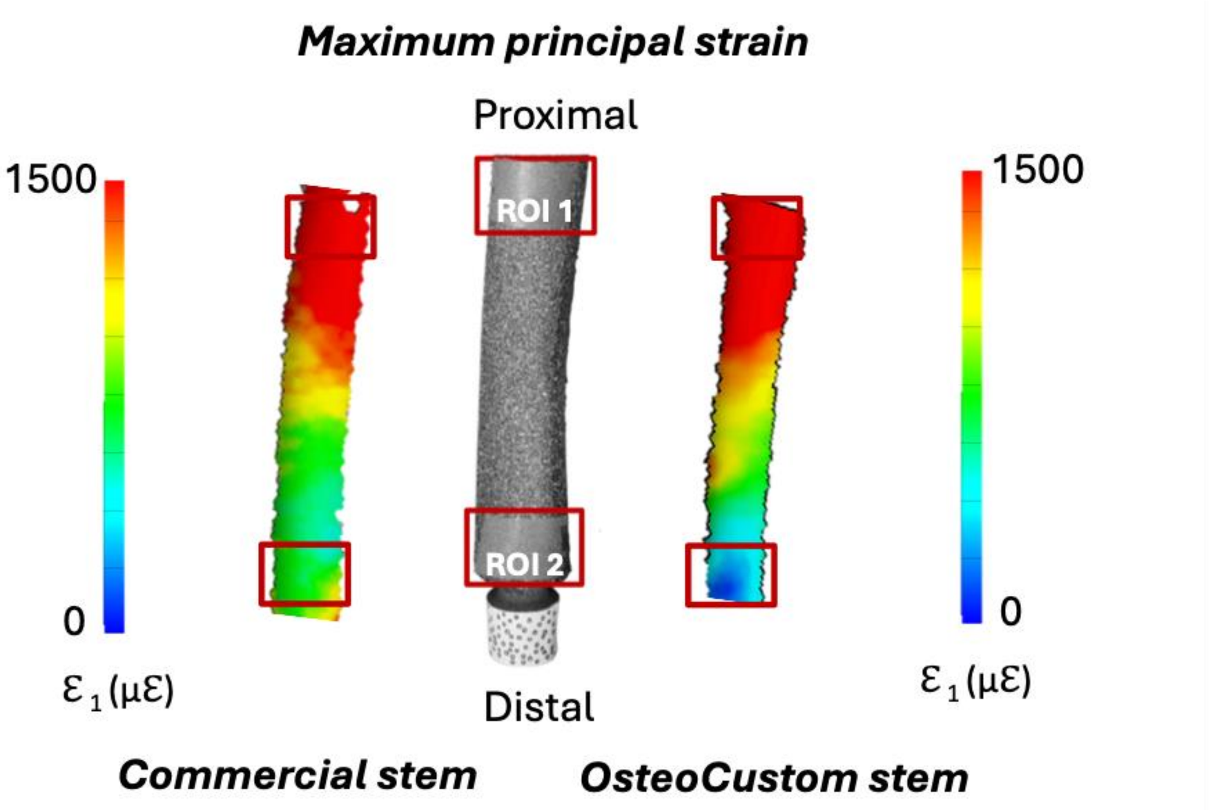

Fig. S-5: *The maximum principal strain of the commercial stem (on the left) and customized stem (on the right) are reported, #5*

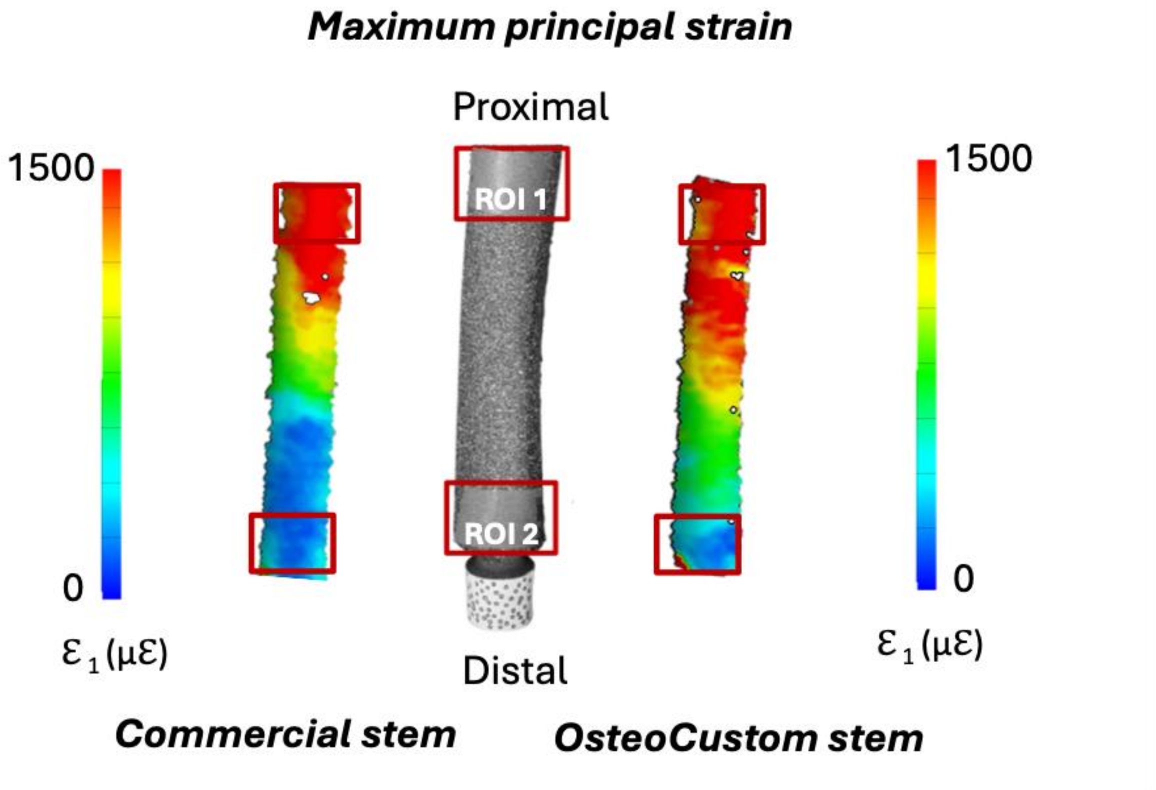

Fig. S-6: *The maximum principal strain of the commercial stem (on the left) and customized stem (on the right) are reported, #6*

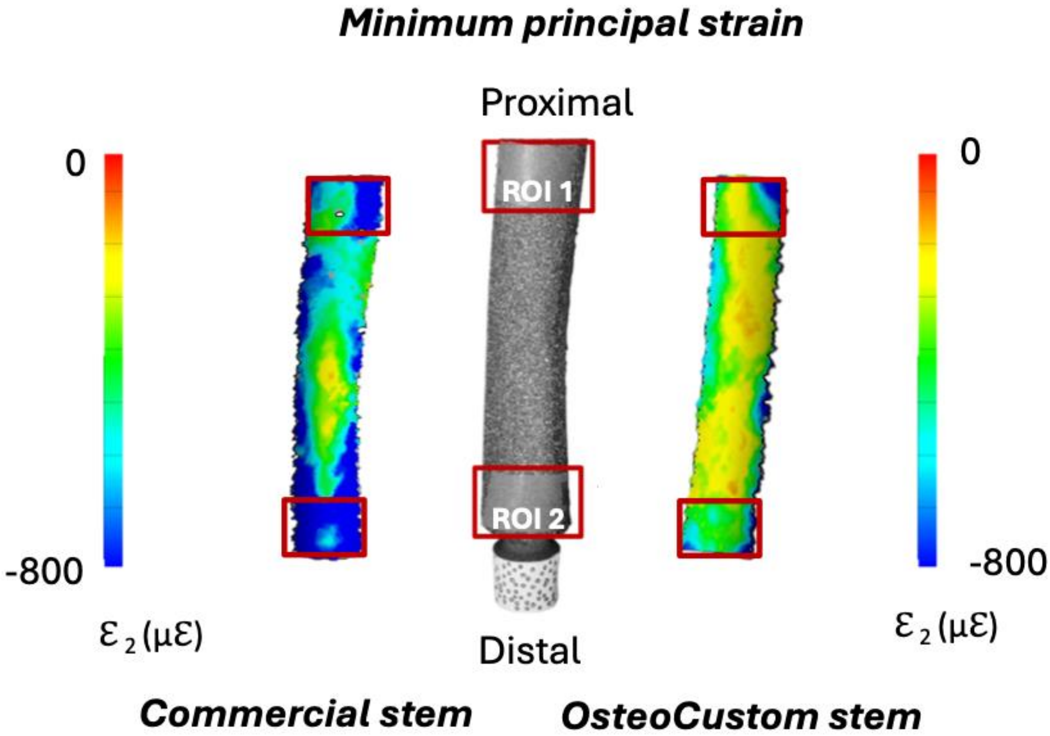

Fig. S-7: *The minimum principal strain of the commercial stem (on the left) and customized stem (on the right) are reported, #1*

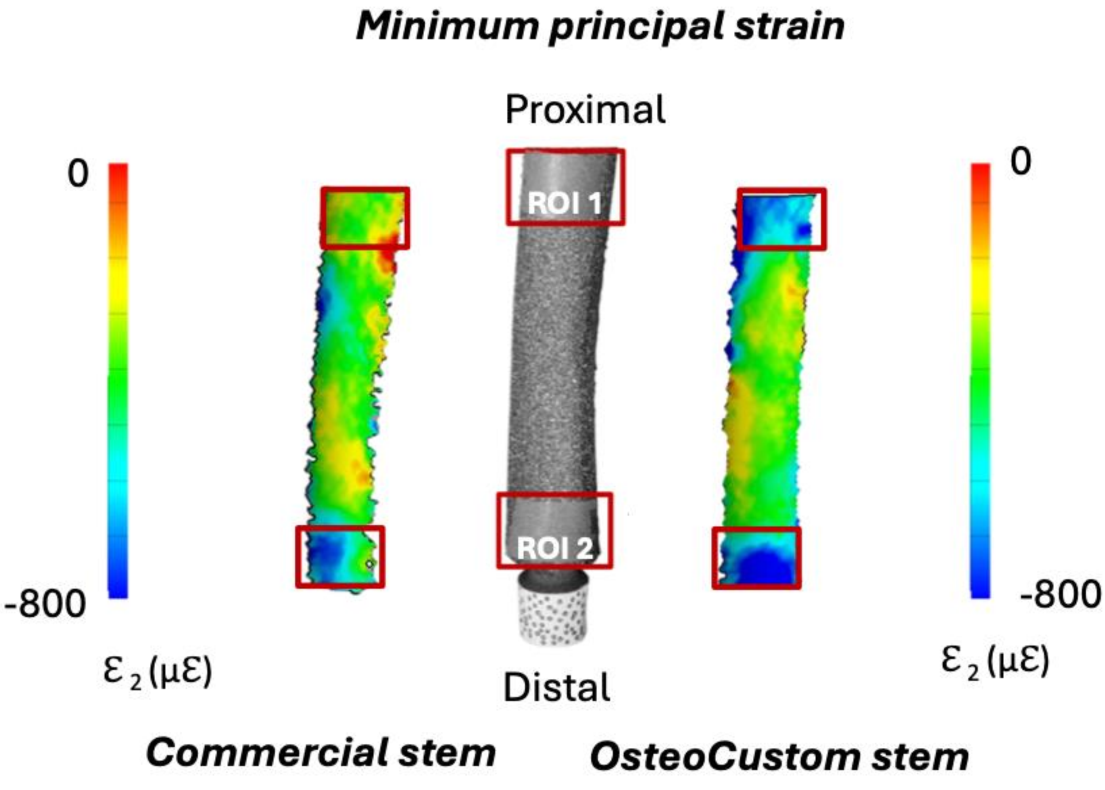

Fig. S-8: *The minimum principal strain of the commercial stem (on the left) and customized stem (on the right) are reported, #2*

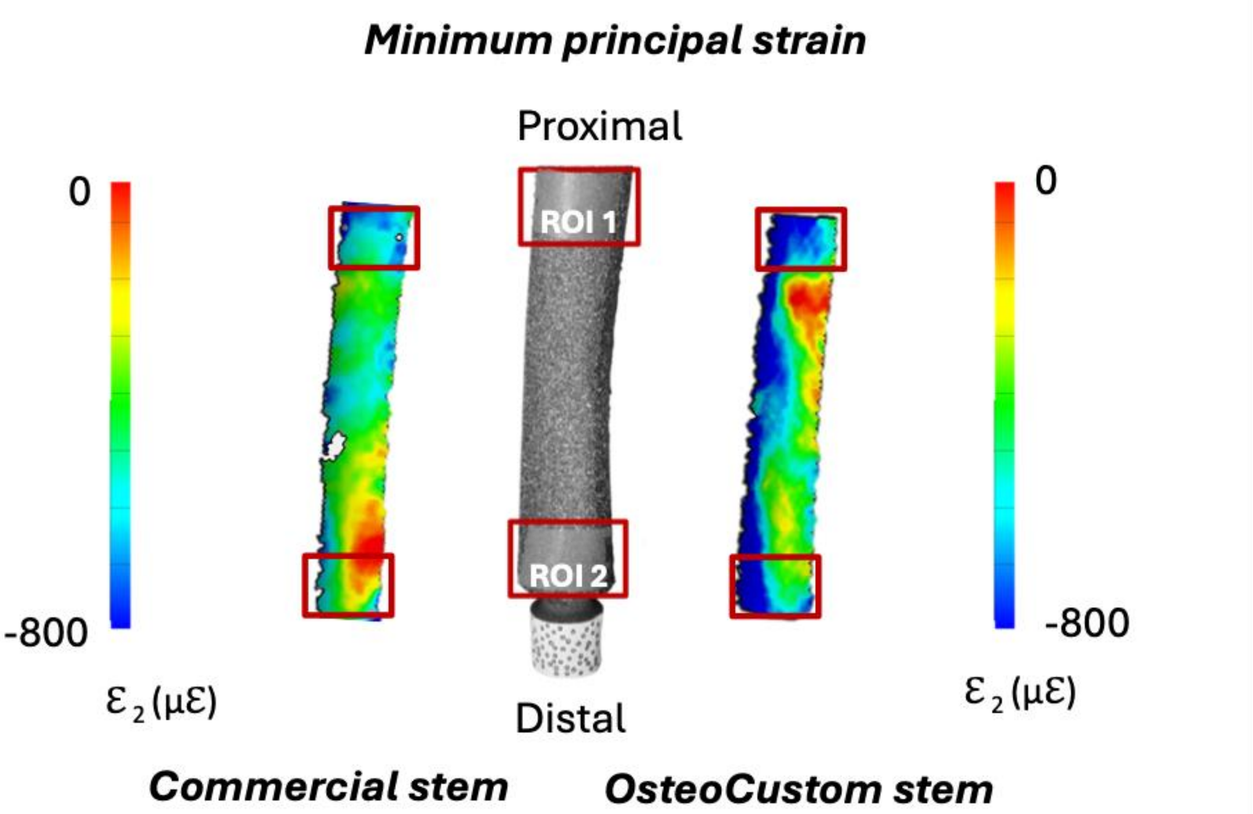

Fig. S-9: *The minimum principal strain of the commercial stem (on the left) and customized stem (on the right) are reported, #3*

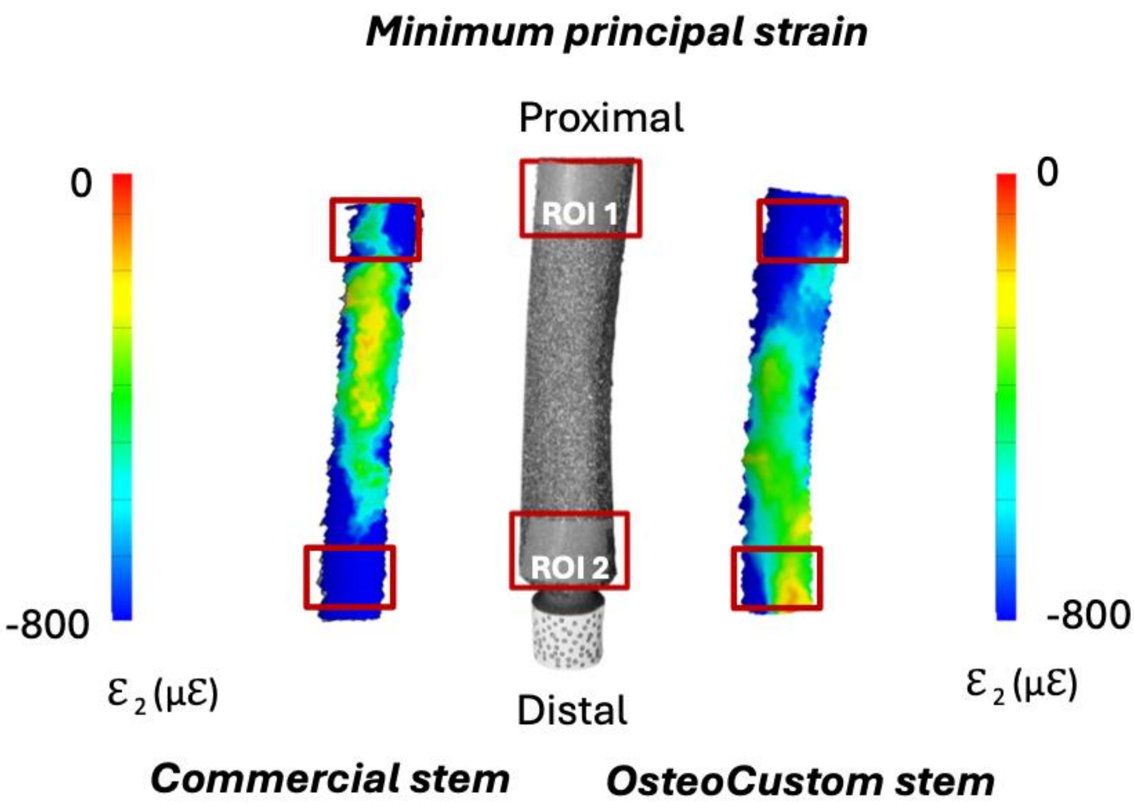

Fig. S-10: *The minimum principal strain of the commercial stem (on the left) and customized stem (on the right) are reported, #4*

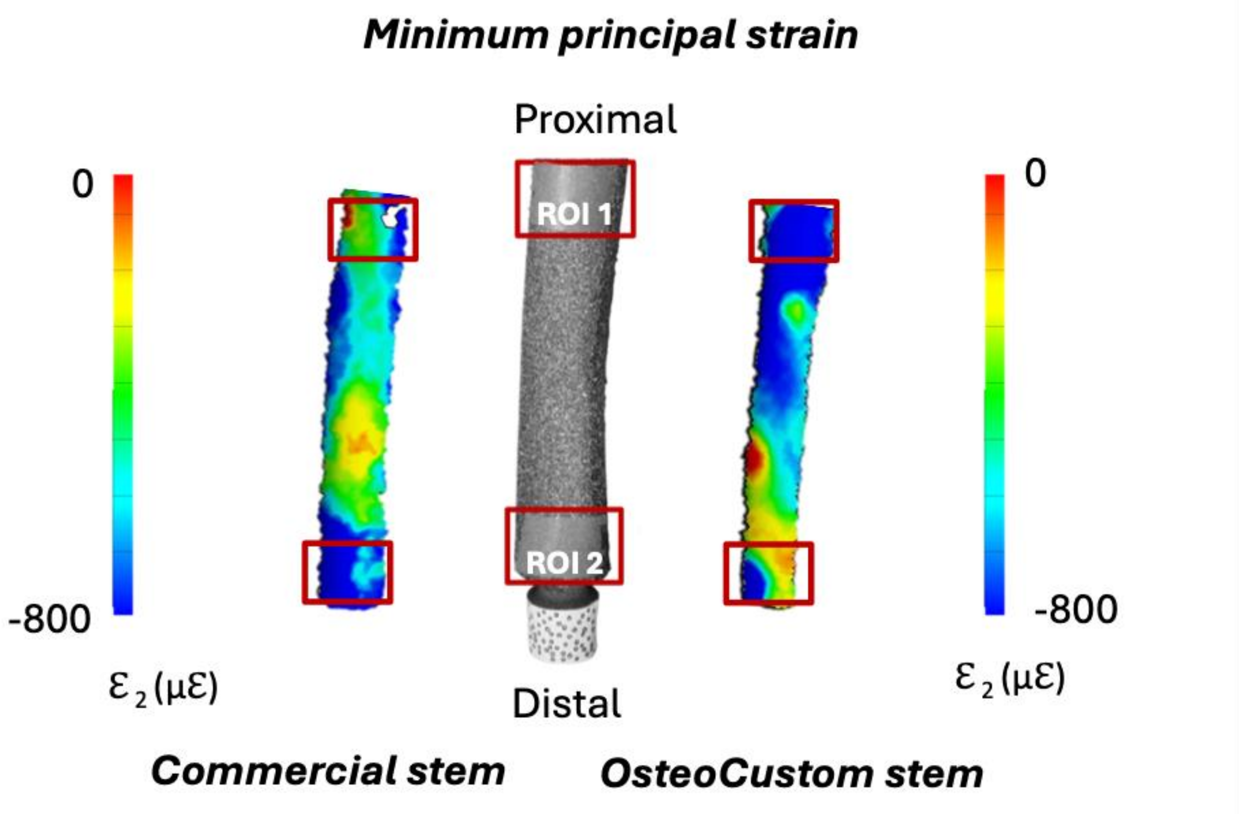

Fig. S-11: *The minimum principal strain of the commercial stem (on the left) and customized stem (on the right) are reported, #5*

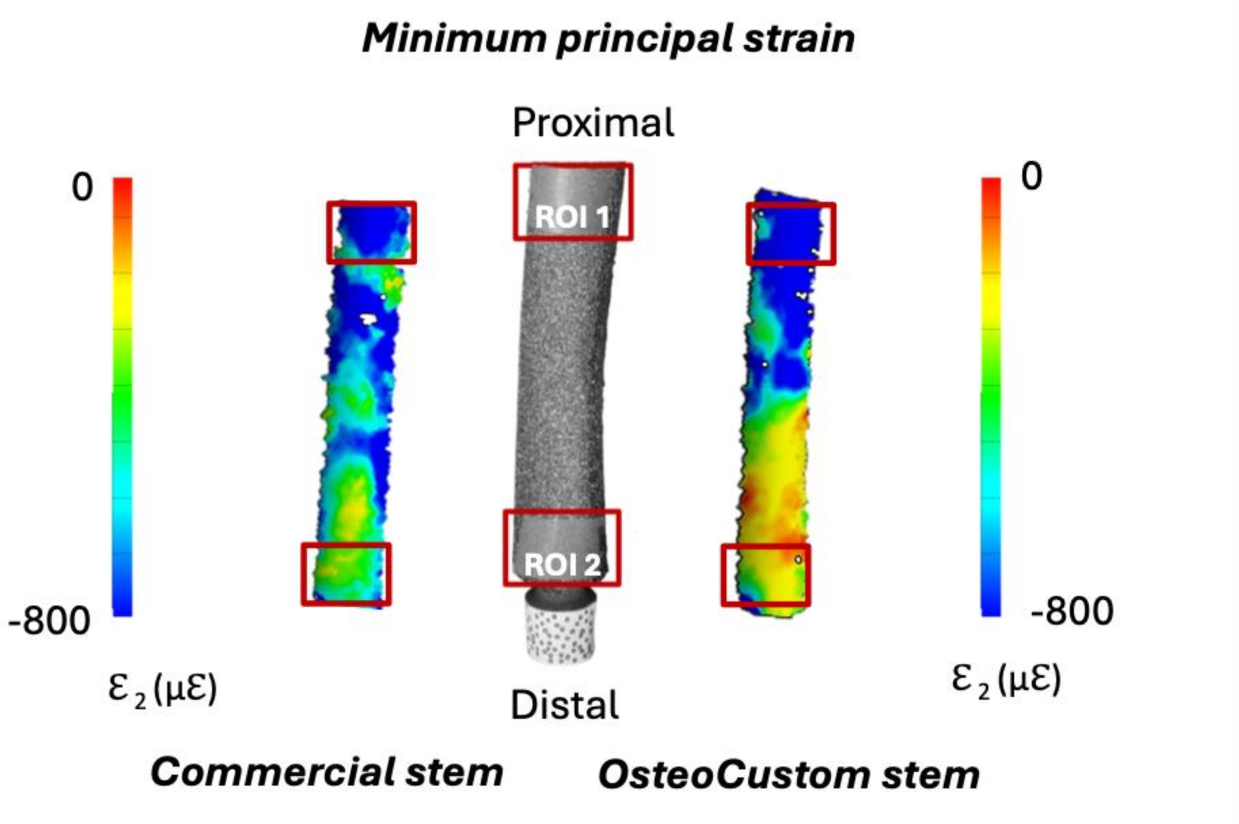

Fig. S-12: *The minimum principal strain of the commercial stem (on the left) and customized stem (on the right) are reported, #6*

Fig. S-9: *The maximum principal strain (on the left) and minimum principal strain (on the right) are reported for the customized stem, specimen #4*

Fig. S-10: *The maximum principal strain (on the left) and minimum principal strain (on the right) are reported for the customized stem, specimen #5*

References

[1] G. Galteri *et al.*, “Reliable in vitro method for the evaluation of the primary stability and load transfer of transfemoral prostheses for osseointegrated implantation,” *Front. Bioeng. Biotechnol.*, vol. 12, Mar. 2024, doi: 10.3389/fbioe.2024.1360208.

[2] M. Palanca, G. Tozzi, and L. Cristofolini, “The use of digital image correlation in the biomechanical area: a review,” *Int. Biomech.*, vol. 3, no. 1, pp. 1–21, Jan. 2016, doi: 10.1080/23335432.2015.1117395.

[3] D. C. Montgomery, *Introduction to Statistical Quality Control*, 6th ed. Wiley, 2009.