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Advantages of customization of osseointegrated implants in transfemoral amputees: a comparative analysis of surgical planning

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Abstract

Background Commercially available osseointegrated devices for transfemoral amputees are limited in size and thus fail to meet the significant anatomical variability in the femoral medullary canal. This study aimed to develop a customized osseointegrated stem to better accommodate a variety of femoral anatomies in transfemoral amputees than off-the-shelf stems. Customization is expected to enhance cortical bone preservation and increase the stem-bone contact area, which are critical for the long-term stability and success of implants.

Methods A customized stem (OsteoCustom) was designed based on the statistical shape variability of the medullary canal. The implantability of the OsteoCustom stem was tested via 70 computed tomography (CT) images of human femurs and compared to that of a commercial device (OFI-C) for two different resection levels. The evaluations included the volume of cortical bone removed and the percentage of stem-bone contact area for both resection levels. Statistical significance was analyzed using paired and unpaired t tests.

Results The OsteoCustom stem could be virtually implanted in all 70 femurs, while the OFI-C was unsuitable in 19 cases due to insufficient cortical thickness after implantation, further emphasizing its adaptability to varying anatomical conditions. The OsteoCustom stem preserved a greater volume of cortical bone than did the OFI-C. In fact, 42% less bone was removed at the proximal resection level (3.15 cm^3 vs. 5.42 cm^3, $p \leq 0.0001$), and 33% less at the distal resection level (2.25 cm^3 vs. 3.39 cm^3, $p = 0.003$). The stem-bone contact area was also greater for the OsteoCustom stem, particularly at the distal resection level, showing a 20% increase in contact area (52.3% vs. 32.2%, $p = 0.002$) compared to that of the OFI-C.

Conclusions The OsteoCustom stem performed better than the commercial stem by preserving more cortical bone and achieving a greater stem–bone contact area, especially at distal resection levels where the shape of the medullary canal exhibits more inter-subject variability. Optimal fit in the distal region is of paramount importance for ensuring

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Betti *et al. Journal of Orthopaedic Surgery and Research*   (2024) 19:520

Page 2 of 15

the stability of osseointegrated implants. This study highlights the potential benefits of customized osseointegrated stems in accommodating a broader range of femoral anatomies, with enhanced fit in the medullary canal.

Keywords Osseointegrated femoral implants, Customized prostheses, Femur, Amputation, Bone stock, Bone volume removal, Stem–bone contact area, Personalization

Background

The use of osseointegrated prostheses for the treatment of lower limb amputations has been practiced since 1990 [1–3]. This solution provides a viable option for patients whose needs cannot be adequately addressed through traditional suspension sockets [4, 5], which are associated with issues such as skin irritation, discomfort, volume fluctuations, and a high rate of abandonment [6–8]. Osseointegrated prostheses establish a direct structural link between the external prostheses and the remaining living bone, showcasing related benefits, such as improved somatosensory feedback, an increase in hip joint range of motion, and a decrease in metabolic energy expenditure while ambulating [5, 9, 10].

The widespread adoption of osseointegrated transfemoral prostheses, however, has been hindered by concerns among clinicians about several possible complications, which include septic and aseptic causes of implant failure. The septic failure rates are a significant concern in clinical practice [11]. Nevertheless, there exist several aseptic complications, which affect a concerningly high fraction of patients. Aseptic complications include postoperative periprosthetic fractures and aseptic loosening [12, 13]. Periprosthetic fractures are reported to occur with an incidence between 4% and 44% [14–17]. This mode of failure is mainly related to the removal of cortical bone that occurs during the surgical procedure [18]. Excessive removal during surgery results in weakening of the bone structure, compromising the overall stability and integrity of the implant [13, 15, 19–21]. No general indication is available for osseointegrated femoral implants. However, the guidelines for one of the most common stems on the market (e.g. OPRA, [22]) recommend preserving at least 2 *mm* of cortical bone thickness. Therefore, careful consideration of cortical bone removal is essential to ensure optimal implant longevity and performance. It should also be considered that osseointegration implants are often placed after wearing the socket for many years, which has acted as an external brace and thus protected the weakened bone after surgery [17]. Concerning the second problem, aseptic loosening refers to the gradual separation of an implant from surrounding bone tissue without the presence of infections and is reported in 3–29% of cases [23]. This phenomenon occurs when there is insufficient osseointegration between the bone and the prosthesis, which depends on excessive relative movements at the bone-implant interface and inadequate contact area [24, 25]. This issue may arise both in

the short and long-term following the stem implantation [26–31]. To reduce the problems related to adverse bone remodeling caused by stress shielding, osseointegration should mainly occur near the level of bone resection (i.e., proximal to the femoral component of total hip replacement, distal to the stem for transfemoral amputees) to maintain physiological load transfer from the implant to the host bone as much as possible [32, 33]. Therefore, to reduce the risk of aseptic loosening, surgeons aim to achieve as much contact area as possible, especially at the implant-bone interface near the resection site [34–36].

To avoid possible fractures and mitigate aseptic loosening, it is crucial that the prosthesis design respects the anatomy of the femoral medullary canal while also considering its anatomical variability. Indeed, it has been demonstrated that there is significant inter-subject variability in various anatomical parameters (e.g., diameter and ellipticity of the canal, radius of curvature of the canal, and conicity) and that these variations also depend on the level of resection and on the residual canal segment [37, 38].

To date, however, osseointegrated off-the-shelf prostheses are manufactured in a limited number of sizes, where only the diameter and length of the implant vary, thus failing to consider the variability of the other anatomical parameters of the medullary canal [22, 39, 40]. Consequently, several inclusion criteria are in place, within which not all patients qualify. For instance, commercial osseointegrated prostheses such as OPRA, OPL, ILP, and BADAL X are typically available with a diameter ranging from 14 *mm* to 24 *mm* [22, 39, 40]. In addition, some of these prostheses (e.g. OPL, ILP, BADAL X) are manufactured with a fixed radius of curvature. These sizes do not cover the anatomical variability of the entire population [38], as the femoral canal may exhibit smaller/larger values and/or have different radii of curvature compared to those proposed by the current prostheses off the shelf. In addition, osseointegrated implantation is not advisable where canal reaming would result in excessively thin cortical bone remaining around the implant. Hence, it is imperative to evaluate whether customization would enhance the implant-bone fit-and-fill for this type of stem.

The aim of this study was to design a customized osseointegrated stem for transfemoral amputees capable of the following:

- Being suitable for a broader range of patient anatomies than the currently available commercial osseointegrated stems.
- Preserving a greater amount of cortical bone.
- Increasing the stem-bone contact area.

Materials and methods
Design of the customized stem
The customized stems (hereafter referred to as Osteo-Custom, Fig. 1) consisted of two main parts:

- A proximal portion, with customized diameter and radius of curvature of the canal. This part was designed to have a number of ribs as a function of the diameter. The tip – at the proximal end of this portion – consisted of a hemisphere with a diameter equal to the inner diameter of the stem, excluding the ribs. This portion was designed similarly to other commercially available models.
- A distal portion, customized to fit the shape of the medullary canal more precisely by adjusting the main anatomical parameters (e.g., diameter, conicity, ellipticity). The intra-extra rotation angle between the planes of curvature of the proximal portion was also customized. This portion terminated distally with the connector for the external components of the prosthesis (e.g., the abutment).

To customize the OsteoCustom stem for each femur examined in the present study (see below, in Sect. 2.3), the anatomical parameters were extracted by following an existing procedure, which was based on the reconstruction of the model at cross sections spaced by 10 mm [38]. The anatomical parameters were defined as follows:

- Each cross-section was first best fitted with a circumference, thus estimating the diameters at each cross section. The diameter of the proximal portion of the stem was calculated as the mean diameter of the medullary canal in the relevant proximal cross sections.
- Each cross-section was then best fitted with ellipses, thus identifying the centroid and estimating the major and minor axes at each cross section. The radius of curvature of the canal was computed by reconstructing the arc of the circle passing through the centroids of the canal along the entire length of the stem. It must be specified that the radius of curvature used in this study was the radius of curvature of the segment of medullary canal where the stem would be inserted, rather than the radius of curvature of the entire femur.
- The conicity was computed for the distal portion of the stem as the difference between the diameter in the most distal section and the minimum diameter within the segment considered (this often but not
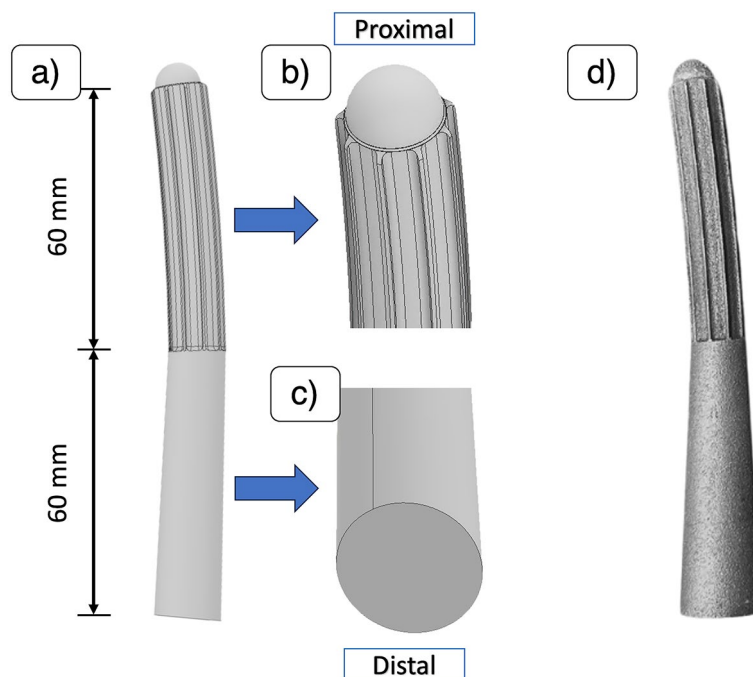
Fig. 1 Example of an OsteoCustom stem. (**a**) Overall view of the stem; (**b**) zoom on the proximal part, with ribs; (**c**) zoom on the distal part, to be connected with the abutment. (**d**) Example of a 3D-printed stem, with the external connection

Table 1 Range of variability and average values for the main anatomical parameters. The diameter is expressed as the mean diameter of the medullary canal. The radius of curvature of the canal was computed by reconstructing the arc of the circle passing through the centroids of the canal. The conicity is expressed as the difference between the diameter in the most distal section and the minimum diameter within the segment considered. The ellipticity is calculated as the difference between the major axis and the minor axis at the most distal section of the canal. More information is provided in [38]

	Diameter	Radius of curvature of the canal	Conicity	Ellipticity
Mean and range [mm]	15 [10–20]	863 [365–1300]	2 [1–7]	2 [1–5]
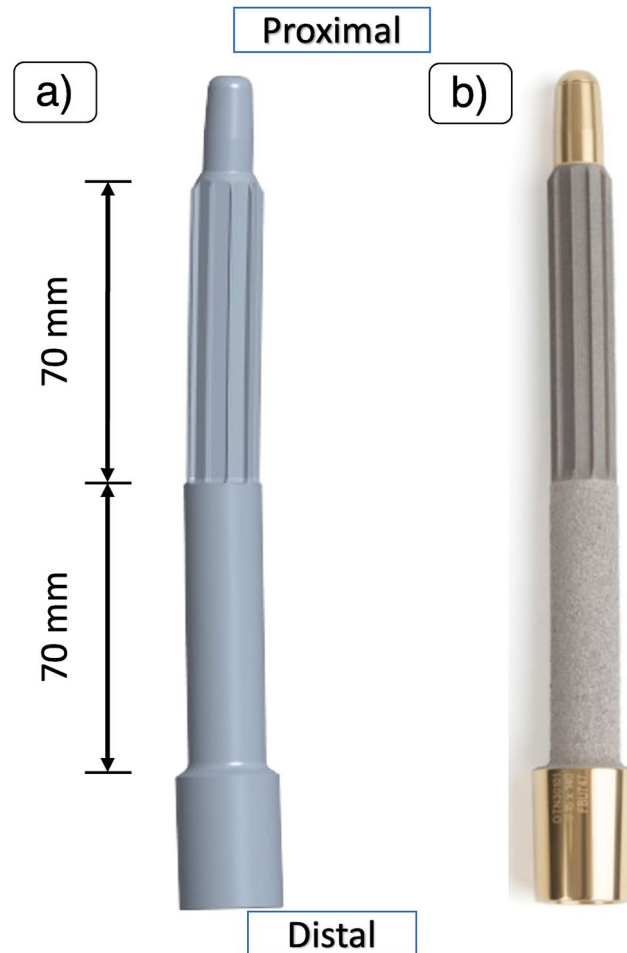
Fig. 2 Example of an OFI-C stem. (**a**) CAD of the stem without the distal connection to the abutment; (**b**) OFI-C stem on the market

always corresponded to the diameter in the most proximal cross section).

- The ellipticity was computed for the distal portion of the stem as the difference between the major axis and the minor axis at the most distal cross section of the canal.

The range of variability for these anatomical parameters to fit 95% of the population was derived from the statistical shape model (SSM) of the distal medullary canal of a large cohort of femurs [38] (Table 1). To reduce the risk of mechanical failure of the implant, the smallest diameter considered for the most distal section was 15 *mm* since smaller diameters were found to be a significant

predictor of mechanical failure [41]. This corresponds to the smallest size available for the OFI-C stem (see below).

The customized stems were designed using Autocad Inventor (vers. 23, *Autodesk*, San Francisco, CA, USA).

Commercial stem selected for comparison

To compare the customized stem with a gold standard, a commercial stem was used (OFI-C, Badal X, OTN Implants, Fig. 2). Such stem was selected for comparison as it is one of the most commonly utilized designs, among those employing a press-fit fixation, other than being the most similar to OsteoCustom in terms of design [42].

Collection of CT scans, canal segmentation, and extraction of anatomical parameters.

Table 2 Details about the study, with 'Age' referring to the subjects' age at the time of the CT scan

Number of subjects	Age [years]	Height [cm]	Weight [kg]
70 (36 Females, 34 Males)	55 ± 10	169 ± 11	76 ± 19

To detect a significant difference between the two types of stems, a power analysis ($\alpha = 0.05$, $\beta = 80\%$) was performed on the results while the procedure was carried out, including an increasing number of cases as needed [43]. This analysis indicated that 70 samples provided adequate statistical power both for bone volume removal and for the contact area. The CT scans of the lower limb were collected by combining data from two different databases:

- Twenty-two femur scans were obtained from the repository of ex vivo specimens from the Laboratory of Biomechanics at the University of Bologna. All of these previous studies received approval from the bioethics committee of the University of Bologna.
- Forty-eight scans from individuals chosen from the HipOp registry (Rizzoli Orthopedic Institute) were used, for which the data are partially available at [44]. Informed consent was obtained from all subjects participating in the study.

All CT scans had a pixel size within the range of 0.41 to 0.78 *mm*, and the slice thickness varied from 0.5 to 2 *mm*. The dataset was selected to satisfy the guidelines of osseointegrated prosthesis implantation (e.g., age<65 years old, BMI<30) [22, 40] and, more in general,

press-fit implantation (e.g. cementless hip prostheses) [45–47]. A similar mean age was chosen among followup studies on the literature [14, 26, 29, 42]. While these ranges of age and BMI are generally recommended and found in the literature, also subjects with higher BMI or older than 65 years are sometimes recruited for osseointegrated implantation. Additionally, a balanced representation of both men and women, encompassing a broad spectrum of age, height, and weight, was maintained throughout the data collection process (Table 2).

As each femur was positioned within its respective CT scan reference system, all femurs underwent initial realignment along their longitudinal axis using Mimics software (version 24.0, *Materialise NV*, Leuven, Belgium). This axis was defined as the line connecting the lateral edge of the piriformis fossa to the intercondylar notch [48]. Threshold-based segmentation was performed to isolate the entire femur [226–2999 HU] and the cortical bone [662–2999 HU] in the diaphyseal area. The shape of the medullary canal was then obtained from the Boolean subtraction of the previous masks.

Due to the specific length of the stem, at least 140 *mm* of residual canal is needed to provide the necessary space for implantation. Patients with a shorter femoral stump are not eligible for standard osseointegrated implantation [40]. In addition, to leave enough space for the external knee prosthesis, at least 150 *mm* are needed from the osteotomy to the intercondylar notch. Therefore, to include only the region of interest where an osseointegrated stem can be implanted, two extreme scenarios were simulated. Each canal was indeed cropped to
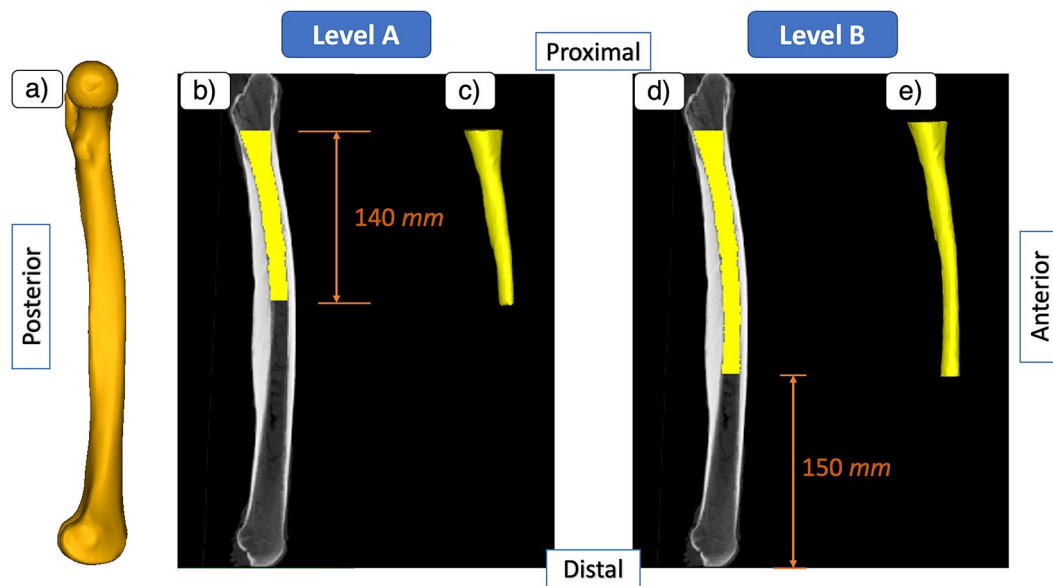
Fig. 3 (**a**) Sagittal view of a typical femur for reference; (**b**) Sagittal view of the canal considering the most proximal resection (level A, on the left, in yellow); (**c**) 3D view of the mask of the canal; (**d**) Sagittal view of the canal considering the most distal resection (level B, on the right, in yellow); and (**e**) 3D view of the mask of the canal for the same femur

simulate the two cases (Fig. 3), describing the range specified in [22, 40]:

- Resection level A, representing the most proximal possible osteotomy: 140 *mm* distal to the lesser trochanter.
- Resection level B, representing the most distal possible osteotomy: 150 *mm* proximal to the intercondylar notch.

The masks of the canals were then exported as triangulated surfaces. A total of 140 canal segments (70 for level A and 70 for level B) was therefore analyzed.

For both resection levels, the cross-section of the canal was then reconstructed every 10 *mm* and best-fitted with an ellipse, based on a validated procedure (Fig. 4) [38]. By measuring the major/minor axes and centroids, the anatomical parameters already cited in Sect. 2.1 were calculated for each mask (diameter, radius of curvature of the canal, conicity, and ellipticity).

Stem selection and preoperative planning

The customized OsteoCustom stems were designed based on the aforementioned anatomical parameters for both resection levels A and B for each of the 70 femurs examined. In parallel, the size of the commercial stem (OFI-C, Badal X, OTN Implants) was provisionally chosen based on the mean diameter of the medullary canal. Preliminarily, for both levels A and B, the two stems were virtually aligned on the same femur following the centroids of the canal. The actual preoperative planning was then carried out by two experienced surgeons, who

assessed whether the size chosen through the procedure for both prostheses (OsteoCustom and OFI-C) was appropriate. If the planned stems were considered too small/large, adjustments were made accordingly to correct the size. Adjustments of 1 *mm* were needed in 17 cases.

To evaluate whether a customized stem would allow the inclusion of more cases, the canals were categorized into two groups:

- Group 1: canals in which a commercially available size of the OFI-C stem preserved at least 2 *mm* of cortical bone around the stem (as per the guidelines for osseointegrated prostheses [22]).
- Group 2: canals where the insertion of the commercial prosthesis did not meet these criteria. In these canals, implantation of the customized stem was tested.

Measurement of bone volume removal

The volume of cortical bone removed was calculated as the difference between the volume before and after the insertion (Fig. 5) using a script in Python (version 3.11, Python Software Foundation). This volume was calculated for both stems and both resection levels (Vol_A and Vol_B) for all femurs.
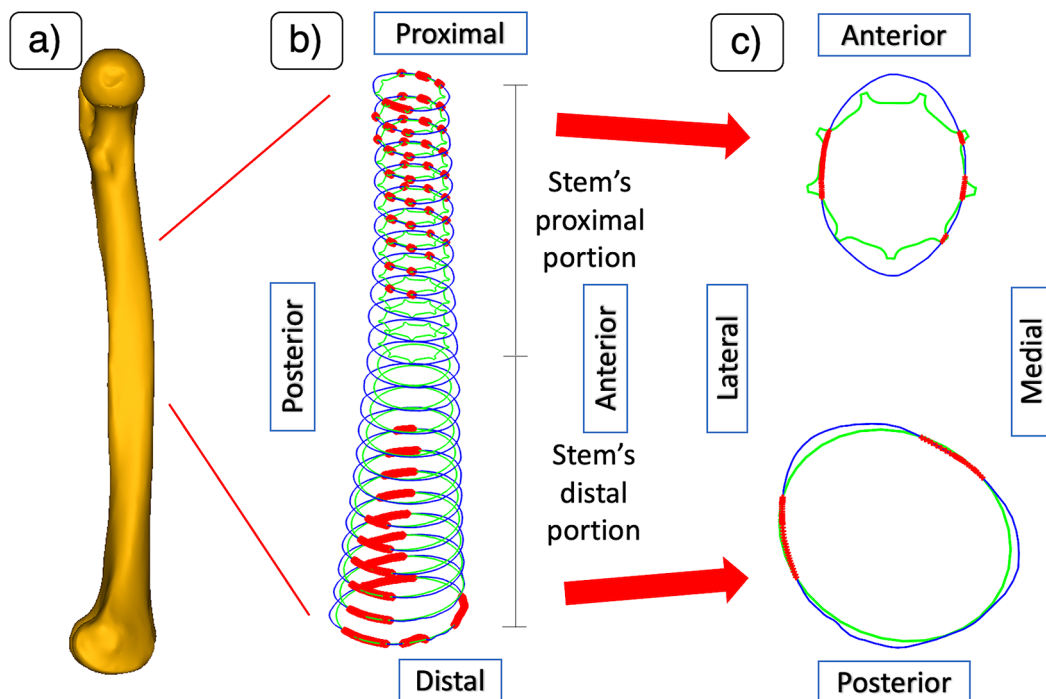
Measurement of the stem-bone contact area

To measure the contact area ($Area$) between the stem and the canal, their surfaces were reconstructed as a series of points every 5 *mm* (Fig. 6). The intersection
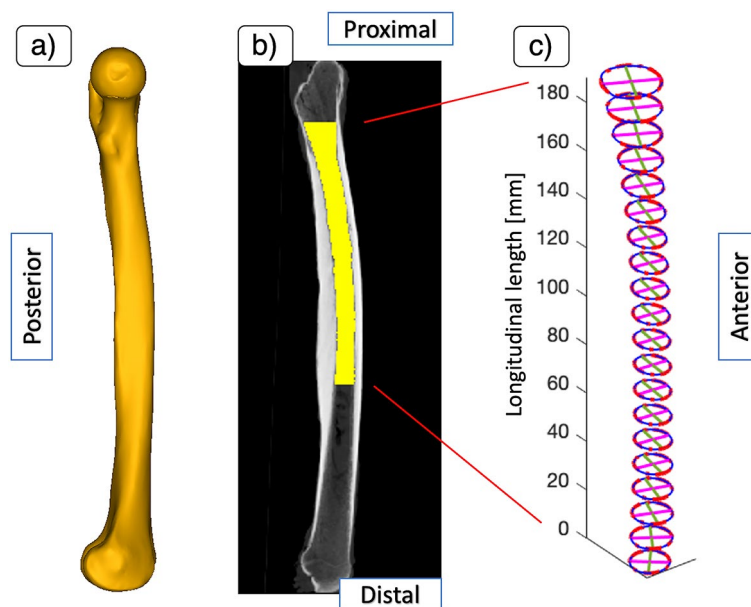
Fig. 4 (**a**) Sagittal view of a typical femur for reference; (**b**) Sagittal view of the canal; (**c**) Visual representation of the canal (in blue) reconstructed every 10 mm and best-fit with an ellipse (in red), with the major axes in pink and the minor axes in green
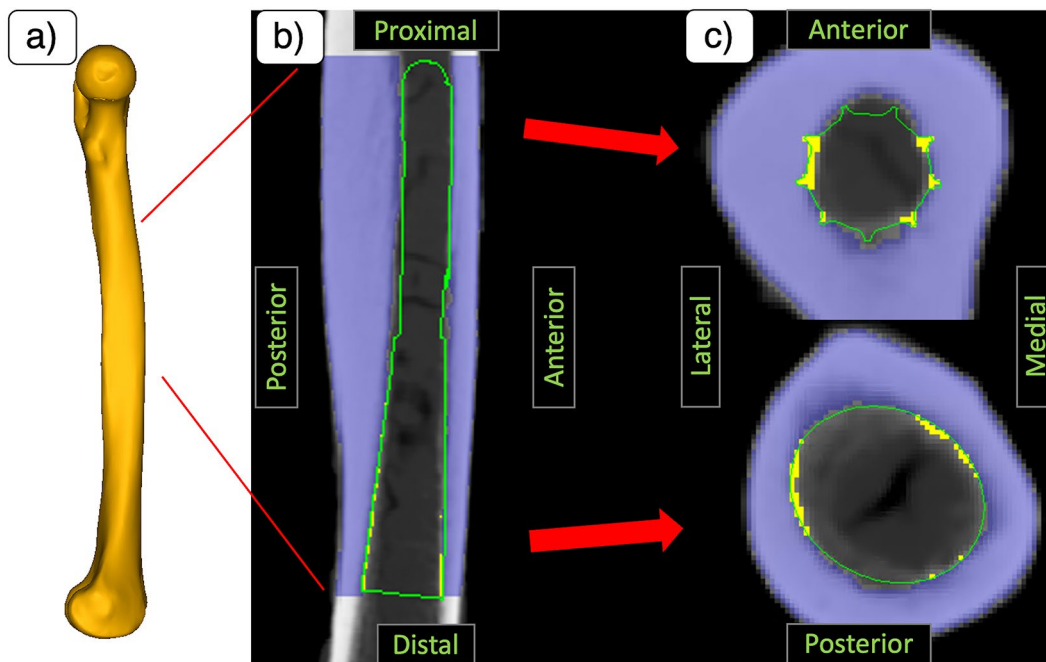
Fig. 5 Evaluation of bone volume removal in the canal. (**a**) Sagittal view of the femur, for reference; (**b**) Sagittal view of an example of an OsteoCustom stem virtually inserted in a femoral canal; (**c**) Axial view of proximal (top) and distal slices (bottom) with the volume of the cortical shell before (yellow + blue) and after (blue) the stem insertion (green)

Fig. 6 Evaluation of the stem-bone contact area in the canal. (**a**) Sagittal view of the femur, for reference; (**b**) 3D representation of the contact area (in red) between the stem (in green) and the canal (in blue); (**c**) An example of the contact area calculated for the proximal (top) and distal (bottom) portions of the stem
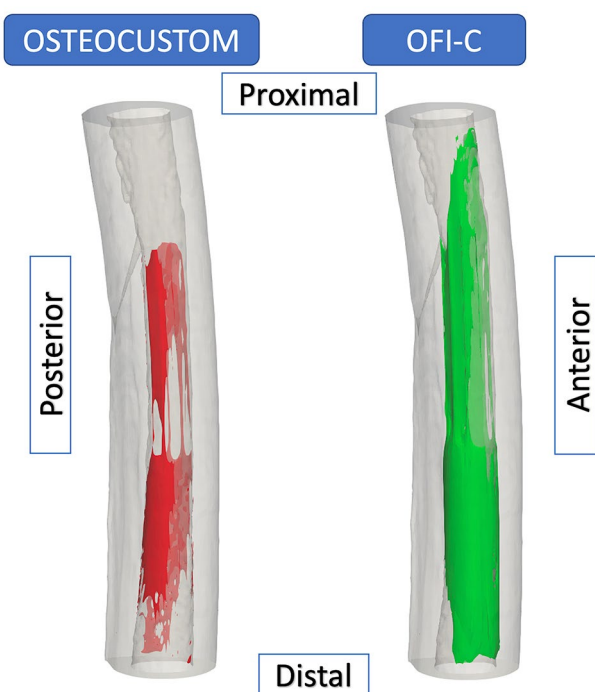
between the stem and the canal was quantified as the percentage of points where the canal was inside the stem volume over the total number of points of the canal at each cross section. The contact area was calculated for the proximal and distal portions of the stem separately. These values were then compared between the two stems for both resection levels ($Area_{prox,\ A}$, $Area_{dist,A}$, $Area_{prox,\ B}$, $Area_{dist,B}$) for all femurs.

Statistical analysis

Continuous variables were verified for normality using the Shapiro−Wilk test. Since all the variables were found to be normal, parametric statistical tests were chosen. Paired T-tests were performed to compare:

- The cortical bone removed to implant the OsteoCustom and OFI-C stems for both resection levels A (Vol_A) and B (Vol_B). These evaluations were performed for both Groups 1 and 2.
- The contact areas of the OsteoCustom and OFI-C stems in the proximal and distal portions of the stem for resection levels A ($Area_{prox,\ A}$ and $Area_{dist,\ A}$, respectively) and B ($Area_{prox,\ B}$ and $Area_{dist,\ B}$, respectively). These evaluations were performed for both Groups 1 and 2, but the results for Group 2 are reported in the Supplementary Materials for brevity.

To assess whether similar results would be achieved by implanting the OsteoCustom stem in medullary canals that are not eligible for implantation with the OFI-C, the contact area for the OsteoCustom stem was compared between Group 1 and Group 2 with an unpaired t test.

A two-tailed *p* value ≤ 0.05 was considered to be statistically significant. All the data were analyzed using GraphPad Prism (version 10, GraphPad Software, La Jolla, CA, USA).

Results

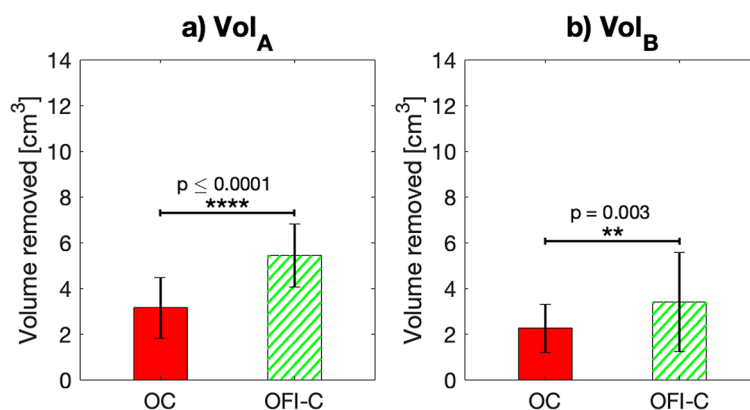### Canals assigned to Group 1 and Group 2

Among the 70 medullary canals analyzed, 51 retained at least 2 *mm* of cortical bone thickness after the virtual insertion of an OFI-C stem, both for resection levels A and B (and were thus assigned to Group 1), while 19 did not meet this criterion (thus categorized as Group 2). For most of the cases who fell under Group 2, the diameter of the medullary canal was less than 12 *mm* ($\sim 70\%$ of the cases). For each of Group 1 and Group 2 cases, it was possible to design an OsteoCustom stem capable of meeting the criteria outlined by osseointegrated prosthesis guidelines. In case of canals with a diameter smaller than 15 *mm* in the isthmus, the proximal part of the OsteoCustom stem was designed with a diameter from 12 *mm* to 15 *mm*. By adjusting the parameters of conicity and ellipticity, a diameter of at least 15 *mm* was achieved in the distal section.

### Comparison of bone volume removal for the OsteoCustom and OFI-C

From a visual comparison of the bone volume removed, it was already clear that implantation with the OsteoCustom stem spared more cortical bone tissue than implantation with the OFI-C in the same canal (Fig. 7). For Group 1, a significantly lower volume of cortical bone needed to be removed to implant the OsteoCustom stem (3.15 *cm³* on average) than for the OFI-C (5.42 *cm³*) for resection level A ($p \leq 0.0001$). Similarly, less cortical bone needed to be removed to implant the OsteoCustom stem (2.25 *cm³*) than to implant the OFI-C (3.39 *cm³*) for resection level B ($p = 0.003$, Fig. 8).

Although, in principle, the OFI-C was not recommended for the medullary canals in Group 2 due to excessively thin remaining cortical bone, a comparison of the theoretical results that would be obtained is reported to highlight the different volumes of bone to be removed. In this group, significantly less cortical bone needed to be removed for the OsteoCustom group than for the OFI-C group for both resection level A (2.67 *cm³* vs. 7.37 *cm³*, $p \leq 0.0001$) and level B (2.11 *cm³* vs. 7.28 *cm³*, $p \leq 0.0001$, Fig. 9).

Fig. 7 Example of visual comparison of the cortical bone removed by OsteoCustom (red) and OFI-C (green) in the same medullary canal

Fig. 8 Group 1: volume of cortical bone removed by OsteoCustom (OC, in red) and OFI-C (in green) for (**a**) resection level A (Vol_A) and (**b**) level B (Vol_B)
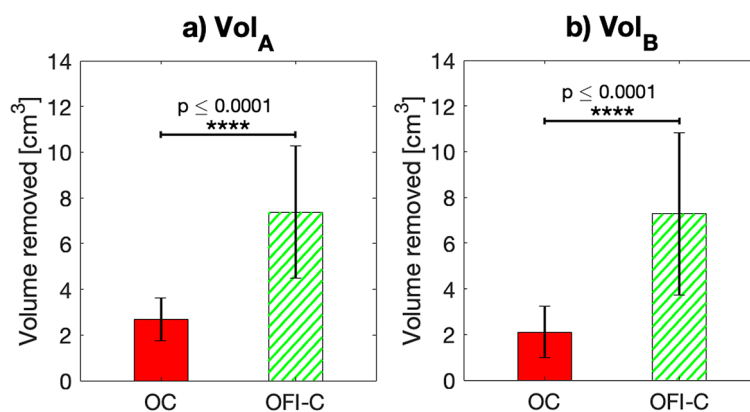
Fig. 9 Group 2: volume of cortical bone removed by the OsteoCustom (OC, in red) and OFI-C (in green) stems for (**a**) resection level A (Vol_A) and (**b**) level B (Vol_B)

Comparison of the stem-bone contact areas of the OsteoCustom and OFI-C stems

For Group 1 (which met the indications for both implantation with OsteoCustom and OFI-C), a slightly greater percentage of the stem-bone contact area was observed for the OsteoCustom stem than for the OFI-C stem for resection level A, both in the proximal portion of the stem (OsteoCustom: 8.7% vs. OFI-C: 6.7%, $p = 0.05$) and in the distal portion (OsteoCustom: 77.0% vs. OFI-C: 72.7%, $p = 0.03$, Fig. 10). A significantly greater percentage of contact area was observed for resection level B, both in the proximal portion (OsteoCustom: 27.3% vs. OFI-C: 15.8%, $p = 0.001$) and in the distal portion (OsteoCustom: 52.3% vs. OFI-C: 32.2%, $p = 0.002$).

The results for Group 2 (where according to the guidelines [22], the OFI-C should not be implanted due to excessively thin remaining cortical bone) are not detailed here for brevity but are reported in the Supplementary Material.

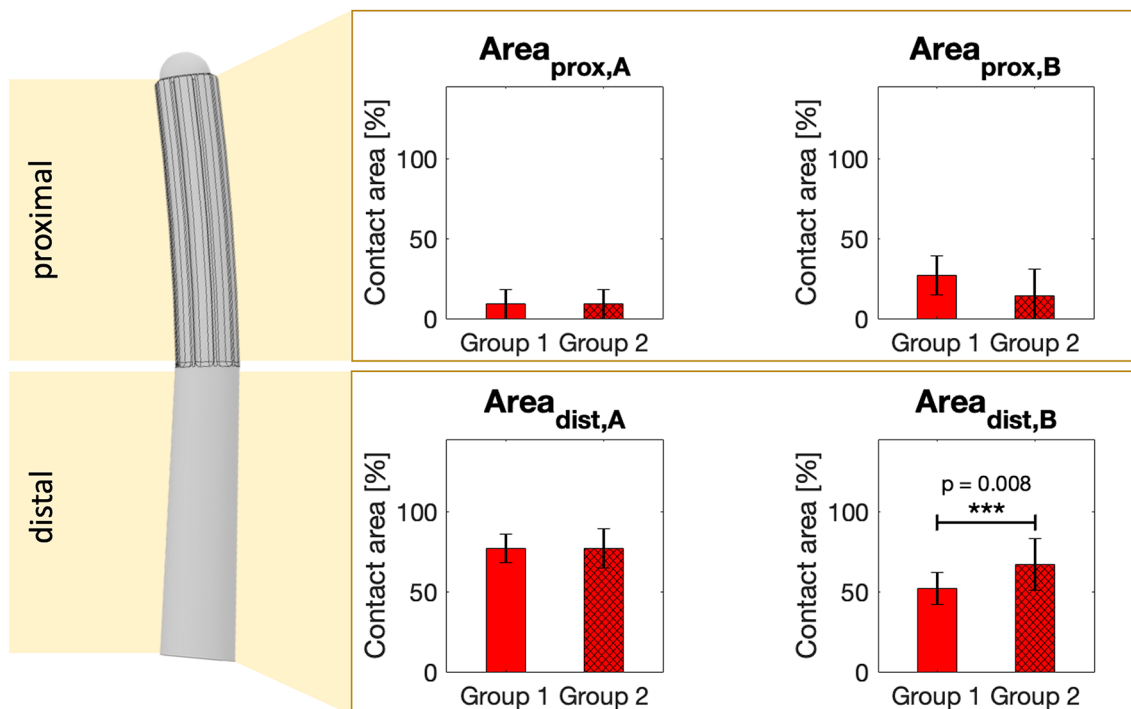For resection level A, the contact area achieved with the OsteoCustom stem for Group 2 was comparable to that for Group 1, both in the proximal portion of the stem (Group 1: 8.7% vs. Group 2: 9.1%, $p = 0.7$) and in the distal portion (Group 1: 77.0% vs. Group 2: 77.1%, $p = 0.7$, Fig. 11). For resection level B, a smaller contact area was achieved for Group 2 in the proximal portion of the stem (Group 1: 27.3% vs. Group 2: 12.1%, $p = 0.6$). Conversely, for the distal stem portion of resection level B, a significantly greater contact area was achieved for Group 2 (Group 1: 52.3% vs. Group 2: 67.2%, $p = 0.008$).

Discussion

This study focused on the development of a customized stem, OsteoCustom, designed to meet a wider spectrum of anatomies than existing commercially available stems while maintaining greater cortical bone volume preservation and a greater stem–bone contact area. To achieve this goal, a customized stem was designed based on the anatomical parameters of the femoral medullary canal. The parameters on which the design of the OsteoCustom stem was based had been evaluated in a previous study, where the mean and variability range were calculated [38]. To the best of authors' knowledge, no previous studies computed the conicity and ellipticity of the
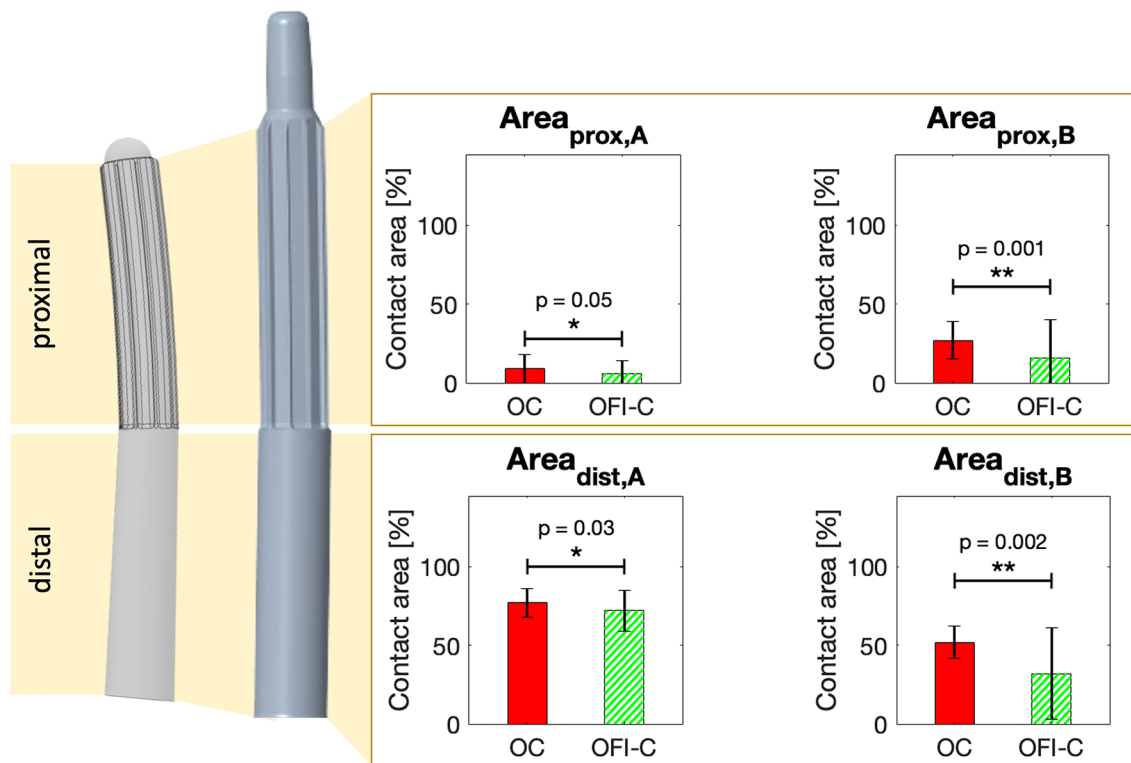
Fig. 10 Group 1: The stem-bone contact area of the OsteoCustom (OC, in red) and OFI-C (in green, crossed lines) stems in the proximal and distal portions for resection levels A and B

Fig. 11 The stem-bone contact area of the OsteoCustom stem for Group 1 (in red) and Group 2 (in red, crossed lines) in the proximal and distal portions for resection levels A and B

femoral medullary canal. Concerning the canal diameter, the results were in line with the literature. Indeed, a minimum diameter of 9–10 *mm* was found for the isthmus [49, 50], and an average value of 13–14 *mm* was reported for the canal diameter [51, 52]. Concerning the radius of curvature, the mean value and the range in [38] were smaller than those reported for commercially available osseointegrated stems (e.g., OPL, ILP and BADAL-X [53]). These numbers were also smaller when compared to studies that calculated the radius of curvature of the femoral canal as the femoral bow in the sagittal plane (689 – 1885 mm) [54, 55]. However, such values are comparable to the radius of curvature reported in other studies where a similar methodology was applied, and in particular the one considering only the proximal femur [56, 57].

This study focused on 70 CT scans in which a customized stem was designed for two resection levels and was compared to a commercial stem (OFI-C).

Out of the 70 femurs examined, 19 were not suitable for implantation of the commercial stem OFI-C (Group 2), since less than 2 *mm* of cortical bone thickness remained after virtual implantation both in level A and B. This was due to several reasons, such as the combination of very narrow femoral canals with the constant radius of curvature of the OFI-C stem. This issue arose for both the most proximal and distal resection levels. Therefore, shortening the femur above the isthmus to bypass the narrower canal sections would still not enable to implant the OFI-C stem.

In contrast, it was possible to implant the OsteoCustom stem in these femurs while preserving at least 2 *mm* of cortical bone thickness. The ability to adjust the conicity and ellipticity in the distal portion of the stem allowed designing stems thinner than 15 *mm* in the proximal portion (e.g., between 12 *mm* and 15 *mm*). Indeed, this approach ensured that the distal portion always maintained a diameter of at least 15 *mm* to prevent the risk of stem breakage [58].

This outcome highlighted the potential benefits of the OsteoCustom prosthesis, which is capable of accommodating a wider range of femoral anatomies than the current standard.

In comparison with a commercially available stem (OFI-C), qualitative and quantitative differences were observed both for the volume of cortical bone removed and the stem-bone contact area between the stem and the canal.

When both the OFI-C and the OsteoCustom stem could be implanted (Group 1), the OsteoCustom stem implantation reduced the amount of cortical bone removed by 42% compared to that of the commercial stem at the more proximal resection level (3.15 *cm^3* vs. 5.42 *cm^3*). Similarly, compared with the OFI-C, the

OsteoCustom stem spared 33% of the cortical bone at the distal resection level (2.25 *cm^3* vs. 3.39 *cm^3*, Fig. 8). These values represent the absolute amounts of bone removed for the two prostheses. Even if these amounts of bone removed are scaled, by normalizing with respect to the stem length, there would still be roughly one third bone sparing using OsteoCustom compared to OFI-C for the proximal resection level. Similarly, for the distal resection level the OsteoCustom would spare nearly one fourth of the bone that would be removed for implanting the OFI-C.

Regarding the contact area, the OsteoCustom stem achieved 8.7% and 77.0% of the contact area in the proximal and distal portions, respectively, of the most proximal resection level (Level A). These numbers were slightly greater than those found for the OFI-C stem. A more significant increase was instead observed at the most distal resection (level B). Particularly, in the distal portion of the stem, a 20% increase in the contact area was noted between the OsteoCustom and OFI-C stems (52.3% vs. 32.2%). These results highlighted the improved fit-and-fill granted by a customized stem compared to a commercial stem, especially at the most distal resection level. This outcome was not unexpected, considering that the statistical shape model of the femoral medullary canal demonstrated that certain anatomical parameters (e.g., conicity) were more pronounced in the distal part of the medullary canal, whereas the proximal part exhibited a more regular geometry [38]. Therefore, the customization of the stem that accounts for these anatomical parameters (e.g., conicity, ellipticity, and others, as described in Sect. 2.1) enabled better matching with the subject-specific anatomy, especially at the distal resection level. Unfortunately, a direct comparison with literature data was not possible, as to the best of the authors' knowledge, this is the first study evaluating the benefits of customizing osseointegrated stems for transfemoral amputees. In the field of hip replacement, numerical studies have been performed to estimate the contact area needed to achieve long-term secondary stability of cementless hip stems: a contact area of 72 $\pm$ 8% was needed for osseointegration [59]. These numbers are comparable to those achieved for the most proximal resection level in this study (level A) but greater than those found at the most distal resection level (level B). However, the present findings are in agreement with in vivo and ex vivo observations in cementless hip implants, where generally 50–55% of the contact area was found in stable implants (approximately 75% under the most favorable conditions) [60–62]. The findings for the OsteoCustom stem seem very promising, as a greater contact area facilitates better osseointegration, leading to improved implant stability [63]. Indeed, an increase in the stem-bone contact area of 23% already showed several benefits in cementless hip stems [64, 65].

For completeness, the implantation of the OFI-C stem was also simulated in the subset of patients for whom implantation of the OFI-C stem was not advisable (Group 2). In this group, the OsteoCustom stem achieved less contact area than did the OFI-C stem (Fig. S1 – Supplementary Materials). However, in such group, the potential benefit of the OsteoCustom stem with respect to the OFI-C was even more relevant regarding the volume of cortical bone removed, with almost 5 cm^3 of spared cortical bone for both resection levels. The large amount of bone removed in part can explain why the OFI-C stem achieved a larger contact area than did the OsteoCustom stem in Group 2. Such massive cortical bone removal, particularly considering that - for Group 2 - there would not have been even 2 *mm* of cortical bone remaining around the stem, would have strongly discouraged surgeons from implanting the OFI-C stem. In a study on the effect of cortical thickness on stress and strain on osseointegrated prostheses, Thesleff et al. reported that an increase in cortical thickness from 2 *mm* to 5 *mm* reduced the stress in the host bone from 100 MPa to 43 MPa, with a significant decrease in the risk of periprosthetic fractures [20]. Hence, in scenarios where 2 *mm* would not be preserved if a commercial stem was implanted, the customization of the OsteoCustom stem would facilitate the avoidance of extensive cortical bone removal, thus allowing for the inclusion of these 19 cases from Group 2 as viable candidates for osseointegrated implants. This suggests that while commercial implants would be unsuitable for approximately 30% of the anatomies, implant customization would make nearly all patients eligible from an anatomical point of view for osseointegrated implantation.

To assess whether the customized stem would yield similar results in the anatomies that were not eligible for the commercial stem (Group 2) as in the anatomies that were eligible for the commercial stem (Group 1), the contact areas achieved with the OsteoCustom stem were compared between the two groups. A similar contact area was found for the most proximal resection level, both for the proximal and for the distal portions of the OsteoCustom stem. For the most distal resection level, however, a greater contact area was found in Group 1 than in Group 2 in the most proximal portion of the stem. This is explained by the fact that more ribs are present in the stems designed for the femurs of Group 1, as they have a larger canal diameter compared to Group 2. Conversely, in the most distal portion, a significantly larger contact area was achieved in Group 2 than in Group 1. As the stem diameter was at least 15 *mm* to prevent the risk of stem breakage [41, 58], in Group 2, which had a narrower canal, more bone was removed, resulting in an increased contact area.

The results of this study could have a significant impact on the design of osseointegrated stems, particularly on how customization is related to the optimization of bone removal and on improving fit-and-fill. Indeed, preserving more bone stock can be beneficial if an osseointegrated implant needs revision, as it helps prevent further weakening of the bone [66].

This study presents some limitations. First, the study focused on a limited number of subjects (*n*=70). This sample size was comparable to that in a study on the statistical shape modeling of the distal femoral medullary canal [38]. Indeed, the power analysis confirmed that this number of subjects was adequate to detect statistically significant differences between the two stems. Another limitation relies on the study population included for this study. First of all, patients older than 65 years were excluded since aging generally leads to a deterioration in bone quality [67] and in the majority of the studies reported an average patient age below 50 years [26, 29, 68]. However, in some follow-up studies, patients older than 70 years old were included [69]. Similarly, patients with a BMI>30 were excluded following the guidelines for press-fit implants [40]. Furthermore, to the best of authors' knowledge, most follow-up studies on osseointegrated prostheses have focused on patients with a BMI<30 [70–72]. However, other studies have found that BMI is not associated with an increased risk of aseptic or overall failure [69].

Furthermore, this work focused primarily on the immediate outcomes of stem design customization, such as cortical bone preservation and stem-bone contact area. However, the long-term performance and durability of the customized stem, including factors such as implant stability, were not directly assessed here. However, the indicators measured in the present study are good predictors of the fit-and-fill of the implant, which is a key factor for short- and long-term success. The promising results obtained from the methodology developed in this article led to further preclinical validation of the OsteoCustom concept, for which biomechanical tests are currently underway to assess implant stability following a validated procedure [23].

Another limitation relies on how the comparative analysis is performed. Indeed, while the study compared the customized stem (OsteoCustom) with a commercially available stem (OFI-C), it is essential to acknowledge that other prosthetic designs exist on the market, not only press-fit stems such as the one developed in the study (e.g., OPL stem [39]) but also threaded implants, which are screwed inside the medullary canal (e.g., OPRA [73]). Among these stems, the one with the most similar geometry to the OsteoCustom was chosen for comparison. However, commercial designs appear to be more or less similar in terms of geometry: these stems indeed have a

constant cross-section and curvature, with a diameter in the range of 14–25 *mm* [53]. No significant changes are anticipated if the design of other stems is included in the study.

Throughout this study, it was possible to explore whether customization could have a potential benefit in terms of bone volume removal and stem-bone contact area. Given the good results obtained, one of the next steps will be a health technology assessment to evaluate several aspects, as the potential costs associated with possible implant mobilization, the expected reduction in the number of mobilized implants with OsteoCustom, and the potential increase in the number of patients treated with OsteoCustom. Throughout such analysis, it will be possible to understand if the customization process of osseointegrated stem would be advantageous in economic terms, therefore whether it is worthwhile to commercialize customized prostheses.

It must also be acknowledged that this study evaluated the advantages of a customized stem in terms of anatomical fit-and-fill. More pre-clinical work is needed to confirm if this would translate to an actual advantage in terms of implant stability or load transfer. In parallel, our group has developed a biomechanical test on ex vivo specimens to measure implant stability and load transfer [23].

Conclusions

This study aimed to develop a customized osseointegrated prosthesis stem (OsteoCustom) to address the main limitations of the existing commercial designs. According to anatomical data from femoral medullary canals, the OsteoCustom stem demonstrated superior cortical bone preservation and increased contact area compared to a commercial stem (OFI-C). Notably, the use of an OsteoCustom stem offered a viable solution for patients for whom the OFI-C failed to meet the cortical bone thickness criteria. The promising results from this study represent a crucial step in exploring the potential benefits of customized osseointegrated prostheses in terms of fit-and-fill.

Abbreviations

CT   Computed Tomography
HU   Hounsfield Unit
BMI   Body Mass Index
OC   OsteoCustom
SSM   Statistical Shape Modeling

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13018-024-04944-0.

Supplementary Material 1

Data availability
The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Declarations

Competing interests
The authors declare no competing interests.

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