Wu et al. Journal of Orthopaedic Surgery and Research (2025) 20:294
https://doi.org/10.1186/s13018-025-05647-w

Journal of Orthopaedic Surgery and Research

RESEARCH Open Access

Robot milling system integrated design and finite element analysis of custom femoral prostheses

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Abstract
The long-term stability of cementless femoral prostheses is primarily affected by aseptic loosening, micromotion, and stress shielding, all of which are related to the force transfer of the prosthesis. These factors can compromise the osseointegration of the proximal prosthesis, leading to aseptic loosening within the femoral cavity. Due to the individual variability of the femur, the fit between the prosthesis and the femoral cavity during the design phase may differ from the fit achieved during the surgical procedure. Consequently, the force transfer of the prosthesis postoperatively may not align with the results obtained from finite element analysis conducted during the design phase, making it challenging to control the micromotion and stress shielding of the prosthesis. The design model of a custom femoral prosthesis is based on the CT reconstruction of the patient' femur. The fit of prosthesis within the femoral cavity during the design phase should match the fit during the surgical operation. Consequently, the results of finite element analysis conducted during the design phase can be used to control the force transfer of the prosthesis postoperatively. This approach helps to prevent improper micromotion and stress shielding of the proximal prosthesis, which can compromise the primary stability of the prosthesis within the femoral cavity, thereby facilitating the osseointegration of the proximal prosthesis.

This paper proposes a novel technology that combines the design, finite element analysis, and manufacturing of custom prostheses. Specifically, a CAD/CAM/robot integration method is used to fabricate these prostheses. This innovative technology not only enhances the control of force transfer in custom prostheses but also reduces design and manufacture time while lowering costs. In conclusion, the finite element analysis of the custom prosthesis effectively manages force transfer, and the milling errors associated with the custom prosthesis are less than 1 mm.

Keywords Custom prosthesis, Integration technology, Force transfer, Design and manufacture, Finite element analysis

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Introduction

Total hip arthroplasty (THA) is a widely performed surgical procedure for various hip disorders [1]. However, postoperative infections can lead to severe complications [2–4]. Consequently, precise placement of hip prostheses is crucial to prevent both short- and long-term complications [5]. Aseptic loosening is a significant cause of failure in THA [6–9]. Following the implantation of a cementless femoral prosthesis, the prosthesis transmits forces from the distal femur to the osseointegration area of the proximal prosthesis through micromotion. Subsequently, the osseointegration area conveys these forces to the proximal femur via deformation of the osseointegration interface. This indicates that the cementless femoral prosthesis relies on two mechanisms for force transfer: the relative motion between the prosthesis and the femoral cavity, and the deformation of the osseointegration area. If either micromotion or deformation of the osseointegration area occurs in isolation, it may compromise the stability of the prosthesis whthin the femoral cavity. However, when both mechanisms operate concurrently, the prosthesis can achieve long-term stability [10, 11]. After osseointegration occurs, the deformation of the osseointegration area allows a portion of the force exerted on the prosthesis to be transferred to both osseointegration area and the femoral cavity. Simultaneously, osseointegration stabilizes the prosthesis within the femoral cavity, maintaining a secure press-fit press-fit between the prosthesis and femoral cavity [12, 13]. A critical factor in preventing aseptic loosening of the prosthesis is a high level of fit between the prosthesis and the femoral cavity, as well as effective osseointegration of the proximal prosthesis.A tight fit of the prosthesis within femoral cavity can minimize subsidence and help preserve the integrity of the osseointegration at the proximal end of the prosthesis.

The prerequisite for achieving osseointegration with a proximal prosthesi is that the prosthesis must obtain primary stability [14, 15]. This means that the force transfer fron the prosthesis should not induce significant micromotion or stress shielding of the proximal prosthesis postoperatively. The force transfer characteristics of the prosthesis are influenced by its modulus, shape, and surface quality, as well as the fit of the prosthesis within the femoral cavity. Controlling the micromoton of the proximal prosthesis can be challenging [16]. If the force transfer results in excessive micromotion of the proximal prosthesis, it can adversely affect bony in growth in the osseointegration area [17, 18]. Conversely, if the force exerted on the prosthesis is not adequately transferred to the proximal femur, stress shielding will occur in the proximal femur. According to Wolff's law, the presence of stress shielding can lead to osteolysis in the proximal femur [19]. Both micromotion and stress shielding negatively impact the osseointegration, undermining the long-term stability of the prosthesis. In practice, even when the same type of prosthesis is used for different patients, the force transfer yield varying results, which in turn affects the ability of the prostheses to achieve osseointegration [20].

The finite element method (FEM) is an effective tool for analyzing the force transfer of prostheses during the design phase and for controlling force distribution on the femur [21, 22]. However, human femurs exhibit individual characteristics, which means that standard femoral prostheses often differ from the actual models used in surgical procedures. Consequently, the analytical results obtained from FEM during design phase may not accurately predict the force transfer of the prosthesis postoperatively. The custom femoral prosthesis model designed based on the computed tomography (CT) reconstruction of the patient's femur [23, 24]. This model corresponds to the prosthesis situated within the femoral cavity postoperatively. Consequently, the analytical results from FEM can be used to assess the force distribution in the femur. This force transfer mechanism enhances the primary stability of the prosthesis within the femoral cavity. Additionally, the custom prosthesis exhibits a high degree of fit within the femoral cavity, which further improves the force transfer capabilities of the prosthesis [25].

Unlike the batch manufacturing of standard femoral prostheses, custom femoral prostheses are produced based on CT scans of the patient prior to the surgical operation. However, before a custom femoral prosthesis can be utilized in surgery, challenges such as high costs and lengthy manufacturing times must be addressed [26, 27]. This paper presents a novel integration method for the design and fabrication of custom prosthesis. The FEM is employed to evaluate force transfer and establish the primary stability of the prosthesis. Notably, CAD/CAM/robot technology is utilized for the milling of custom prosthesis. In comparison to CNC machining, robotic milling significantly reduces both manufacturing time and costs.

Materials and methods

Figure 1 illustrates the manufacturing process of a custom prosthesis, which consists of design, FEM analysis, and robotic milling.

Before designing the custom prosthesis, a 3D model of the femur is reconstructed based on the CT images of the patient's femur. Subsequently, a Boole operation is performed to obtain a 3D model of the femoral cavity, which will guide the design of the custom stem. The custom prosthesis consists of a sleeve and a stem; the sleeve can be designed according to the 3D model of the proximal femur.

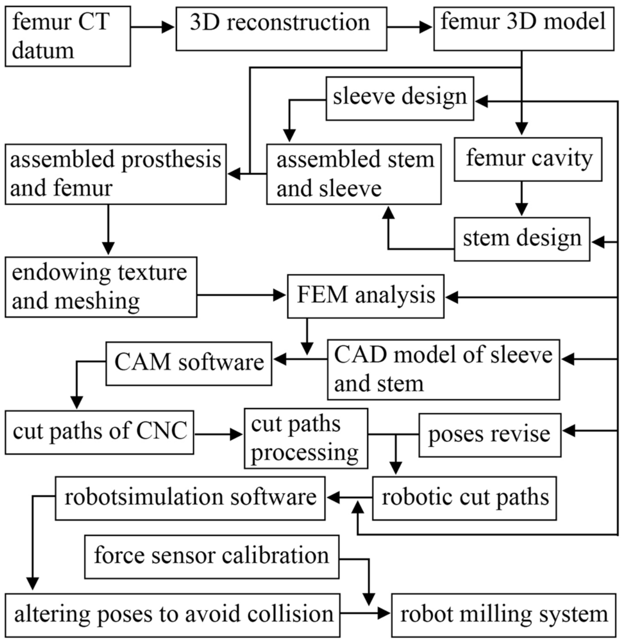


Fig. 1 Custom prosthesis integration system

The assembly process begins with the design of the sleeve and stem to create a custom prosthesis. This custom prosthesis is then combined with a 3D model of the femur to form a FEM analysis model. After applying texture to the prosthesis and dividing it into grids, the FEM software is used to analyze the force transfer characteristics of the prosthesis. When loads are applied to the prosthesis, the relationships between the force transfer of the prosthesis and its geometric parameters, as well as the relationship between the force transfer and the contact area between the prosthesis and the femoral cavity, can be determined. Based on these relationship, the geometric parameters of sleeve and stem can be optimized, thereby enhancing the primary stability of the prosthesis and promoting osseointegration of the proximal prosthesis.

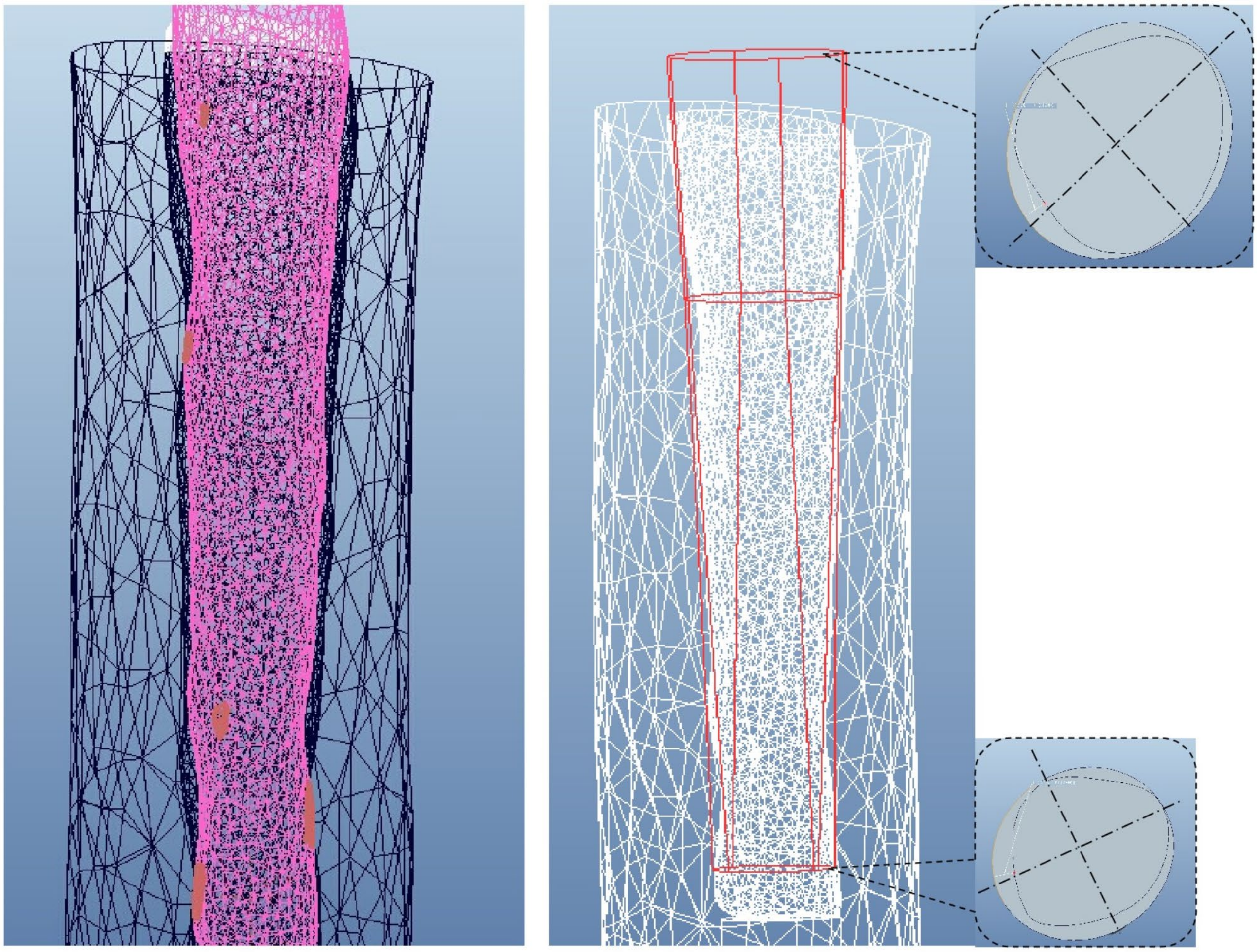
After completing the design of the sleeve and stem, the CAD models of both components are imported into the CAM software to automatically generate the cutting paths. The CAM software processes these cutting paths to create the milling paths for the robot. By applying geometric constraints between the cutter and the CAD models of the sleeve and stem, the poses of the milling paths can be adjusted. When the robot's milling paths are simulated in the fabrication software, any potential collisions between the cutter and the CAD models of the sleeve and stem can be identified. Once the poses of the robot's milling paths are revised, these collisions can be avoided.

Before the sleeve and stem are milled, the robotic milling system must be calibrated. If this calibration is not performed, errors may occur when the milling paths generated by the CAM software are mapped into the robotic milling system. Calibration ensures that the transition matrics between the robotic unit and the CAD model, as well as the robotic unit and the cutter in the simulation software, align with the transition matrics between the robotic unit and the part, and between the robotic unit and the cutter in the robotic milling system.

The RoboDoc robotic system is used for the automatic mill of the femoral cavity in THA. The milling paths for the robot are generated using the OrthoDoc plan software. Before these milling paths can be employed by the RoboDoc robotic system, it is essential to calibrate the transition matrix among the robot, the CT machine, and the femur. The calibration method for the RoboDoc robotic system involved hammering three metal nails into the femur. Subsequently, a force-sensing probe, which is fixed at the end of the robot, is used to contact the nails, allowing for the determination of the transition matrices [28, 29]. In this paper, we utilize the geometric structure of the contact wheel of the robotic milling system, along with the calibration tools and the force-sensing probe, to calibrate the transition matrices of the robotic milling system. Following this, in the CAM software, the position and orientation of the units are adjusted to ensure that the transition matrix in the CAM software matches the transition matrix of robotic milling system.

Results

Femur specimens are provided by Nanjing Medical University (Nanjing, China), while CT scans of these femur specimens are conducted at the 82nd Hospital of the People's Liberation Army (Huai'an, China). The layer distance of the scans is 0.9 mm, and the resolution is 512×512 pixels. The CT scan data are imported into Mimics software (Materialise Company, Austria) to reconstruct a 3D model of the femur. The Hounsfield unit (HU), which expresses the gray level of CT images, is set to [−726, 2800] to simultaneously reconstruct the 3D models of cancellous bone. When the "Fill" command from the "Tools" menu is executed, a 3D solid model of the pig femur is obtained. Following the Boolean operation between the 3D femur and the 3D solid model, the 3D model of the femoral cavity can be generated. The surface of the 3D femoral cavity features as a concave area and cannot directly serve as the 3D model for the stem, as illustrated in Fig. 2 (a). Ellipses are employed to align the upper and lower cross-sections of 3D femoral cavity. Once the positions of the upper and lower ellipses are fixed, the "Stretching" command in Pro-E software (Parametric Technology Company, USA) can be used to create the shape of the stem, which is situated in the distal fitting area of the prosthesis and the femoral cavity, as shown in Fig. 2 (b). The same method is applied to derive the shape of the stem located between the distal fitting



(a) (b)

Fig. 2 3D model of the femur cavity and the stem

area and the Morse conical surface of the stem. The proximal stem corresponds to the Morse conical surface that fits into the Morse cone hole of the sleeve, as depicted in Fig. 3 (b). It is well established that the neck of the femur diverges from the axis of femoral cavity. To ensure that the force transfer of the prosthesis is comparable to that of a normal femur, the anatomical femoral prosthesis adopts a contoured shape. The custom prosthesis features a straight stem, with an 8 mm divergence between the neck of the femur and the axis of the femoral cavity, which is designed to maintain the tip of the prosthesis at the center of the femoral head. This divergent design of the neck allows the sleeve to fit the metaphysis of the femur effectively. The sleeve of the custom prosthesis is designed based on the anatomical shape of sleeve is similar to that of the S-ROM prosthesis, as illustrated in Fig. 3 (b).

The 3D models of the femur and custom prosthesis are imported into Pro-E software for assembly. Once assembled, the models of the femur and prosthesis are imported into ANSYS Workbench software (ANSYS Inc., USA) to apply textures and create mesh grids. The modulus of elasticity for the femur is 2×10^{10} Pa, while the modulus of elasticity for the custom prosthesis is 11×10^{10} Pa.

The loads applied to the prosthesis in the finite element model consist of bending forces and pressure, which are exerted at the tip of the prosthesis. When the prosthesis is inserted into the femoral cavity, the distal stem aligns with the diaphysis of the femur, while the sleeve fits with the metaphysis of the femur. The length of the stem that engages with the femoral cavity is 50 mm, and the middle section of the stem does not make contact with the femoral cavity. During the recovery period following THA, osseointegration of the proximal prosthesis occures; therefore, the forces on prosthesis must be controlled to prevent excessive micromotion could adversely affect osseointegration. Figure 4 (a) illustrates the force distribution on the femur. When a force of 480 N is applied to the prosthesis, the force is transmitted to the tip of

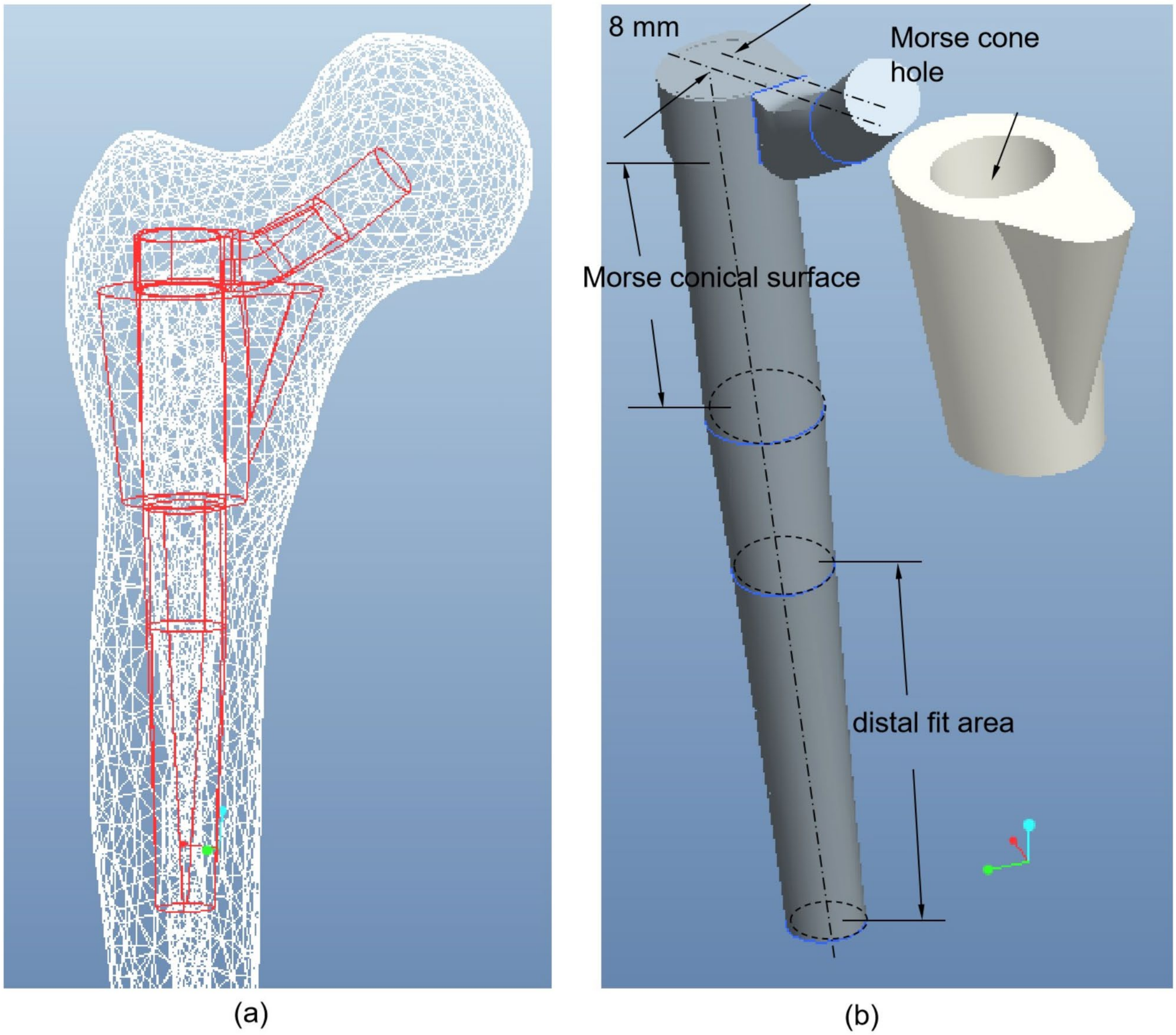


Fig. 3 Designed model of custom prosthesis

femur, as shown in the local view of Fig. 4 (a). If the force on the prosthesis increases beyond this point, significant micromotion will occur in the proximal femur, resulting in relative motion between the prosthesis and the femoral cavity. This will compromise the press-fit status of the prosthesis and hinder the formation of osseointegration in the proximal region. Thus, in Fig. 4 (a), the condition for primary stability of the prosthesis is that the force does not exceed 480 N. In Fig. 4 (b), the fit length of the distal stem is reduced to 25 mm. When a force of 350 N is applied to the prosthesis, the force is again transferred to the tip of femur. Therefore, in Fig. 4 (b), the condition for primary stability of the prosthesis is that the force does not exceed 350 N. From the analysis of Fig. 4, it is evident that as the fit length of distal stem decreases, the force on the prosthesis is more readily transferred to the proximal femur. Consequently, we can effectively control the force transfer of the prosthesis by adjusting the fit length of the distal stem. Additionally, we can modify the shape of the stem and sleeve to further influence the force transfer characteristics of the custom prosthesis.

When the CAD model of the stem is imported into the CNC machining software ArtCAM (Delcam Company, England), the cutting paths can be generated automatically. In Fig. 5 (a), the CNC cutting paths are displayed on the surface of the stem as produced by ArtCAM software, with the cutting path being parallel to one another. ONCE the cutting paths are imported into the robotic simulation software RobotStudio (ABB Company, Sweden), the base coordinate system of the cutting paths is adjusted, and the paths are transformed into the robot's base coordinate system to create the milling paths for the

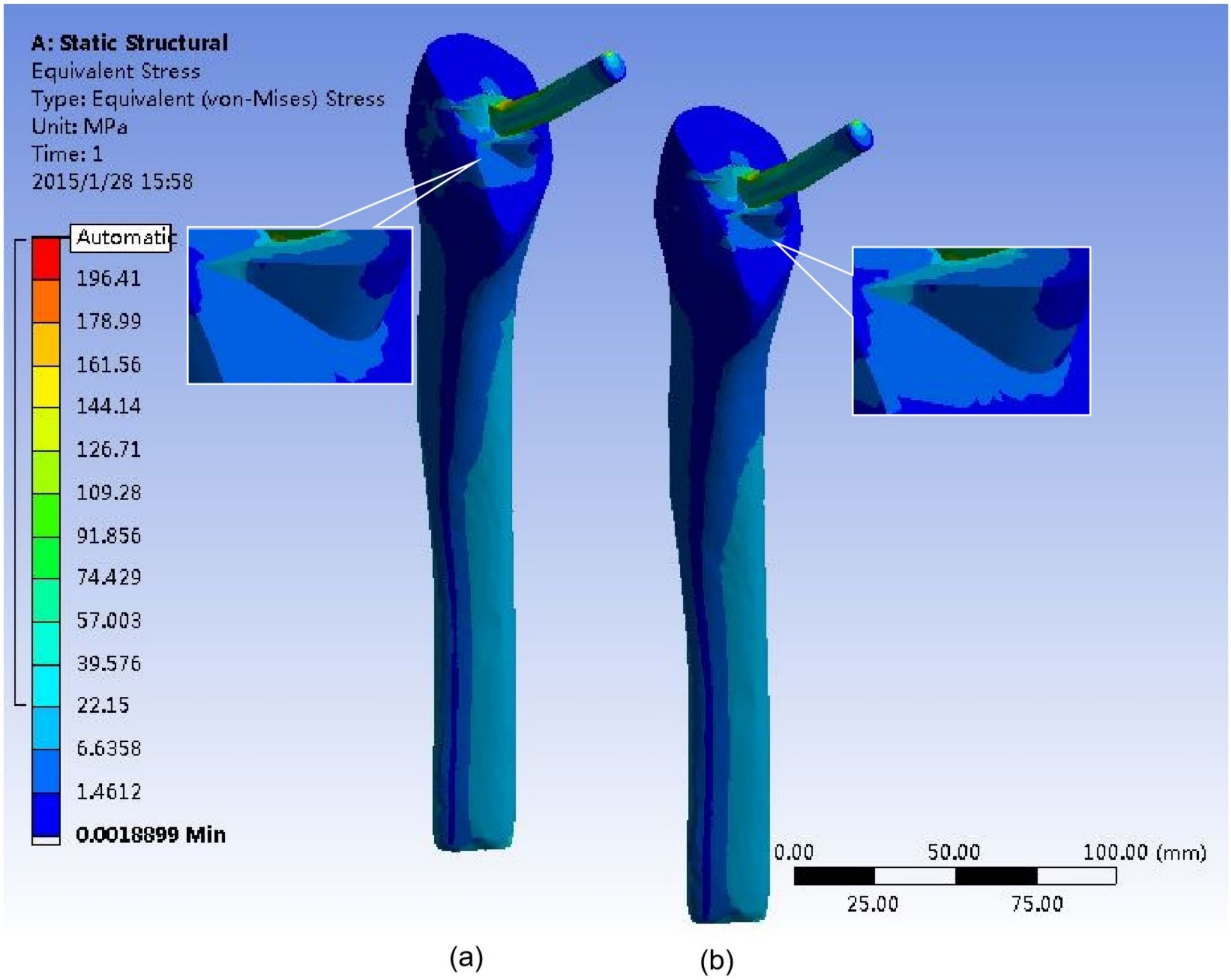


Fig. 4 The force transfer of different fit area

robot. Subsequently, the base coordinate system of the milling paths is aligned with the end coordinate system of the robot. In order to mill the prosthesis accurately, the milling path poses must be perpendicular to the surface of the CAD model. Three adjacent points along the milling path can define a plane, and geometric methods can easily calculate the normal vector of this plane. This normal vector serves as the pose for a point on the cutting path, as illustrated in Fig. 5 (b). The normal vectors of the milling path are oriented vertically to the surface of the CAD model of the stem. In Fig. 5 (c), RobotStudio software is used to simulate the milling procedure of the stem, ensuring that there is no collision between the CAD model of the stem and the contact wheels. Once the robot's milling paths have been simulated, they can be imported into the robot's controller to mill the stem, as shown in Fig. 5 (d). A copper bar with a diameter of 30 mm is secured at the end of the robot.As the robot mills the copper bar according to the defined milling paths, the shape of the stem is effectively replicated onto the copper bar. The fabrication method for the sleeve is the same as that for the stem.

In Fig. 5 (d), robotic belt milling technology is employed to fabricate the custom prosthesis. This system consists of a motor and several contact wheels. The belt, which is covered with a substantial number of abrasive grains, is driven by the motor and wraps around the contact wheels. During the milling process, numerous "cutters" formed by the abrasive grains rapidly shape the custom prosthesis.

The sleeve of a custom prosthesis can be batch-manufactured in advance; therefore, this paper focuses solely on testing the milling of the stem. Figure 6 (a) illustrates the distal stem that is milled by the robotic belt milling system. In Fig. 6 (b), a measurement probe with a precision of 0.01 mm is employed to measure the dimensions of cross-sections of the stem. These dimensions will be compared with the dimensions of the cross-sections of the femoral cavity at the same positions to identify any errors in robotic milling. The dimensions of the femoral

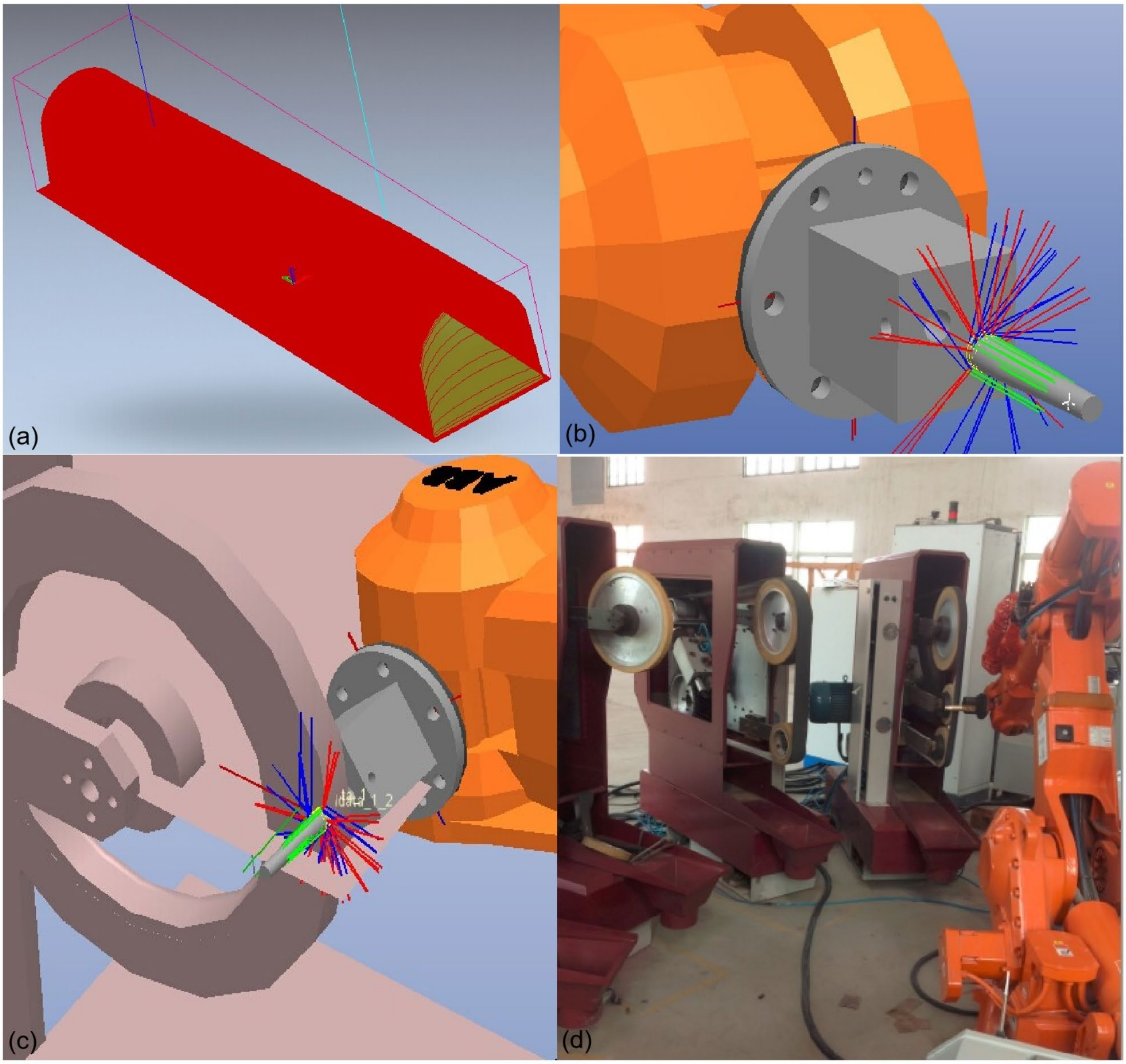


Fig. 5 Cut paths producing and robot milling

cavity cross-sections are obtained from the CAD model of the femur. Two-cross sections of the stem were measured, with a distance of 25 mm between them, and the measurement points for each cross-section of the stem totaled 72. Figure 7 (a) illustratess the dimension of the first cross-section of the stem, which is compare to the dimensions of the first cross-section of the femoral cavity. The errors between the stem and the femoral cavity are shown in Fig. 7 (b). The mean error is 0.2905 mm, the maximum error is 0.6248 mm, the minimum error is -0.0383 mm, and the variance is 0.025. Figure 7 (c) presents the dimensions of the second cross-section of the stem, compared to the dimensions of the second cross-section of the femoral cavity. The errors between the stem and the femoral cavity are displayed in Fig. 7 (d), with a mean error of 0.2536 mm, a maximum error of 0.5715 mm, a minimum error of -0.0144 mm, and a variance of 0.0196.

In Fig. 6 (a), the cut tracks on the surface of the stem are visible. When the distance between adjacent milling paths increases, the cut tracks become more pronounced, leading to significant errors in robotic belt milling. However, this also results in a reduced milling duration for the stem. If a longer machining period for the stem is acceptable, the distance between adjacent milling paths should be minimized to enhance the precision of the robotic belt milling. Additionally, when the final layer of the stem is milled, the cutting depth also affects milling precision;

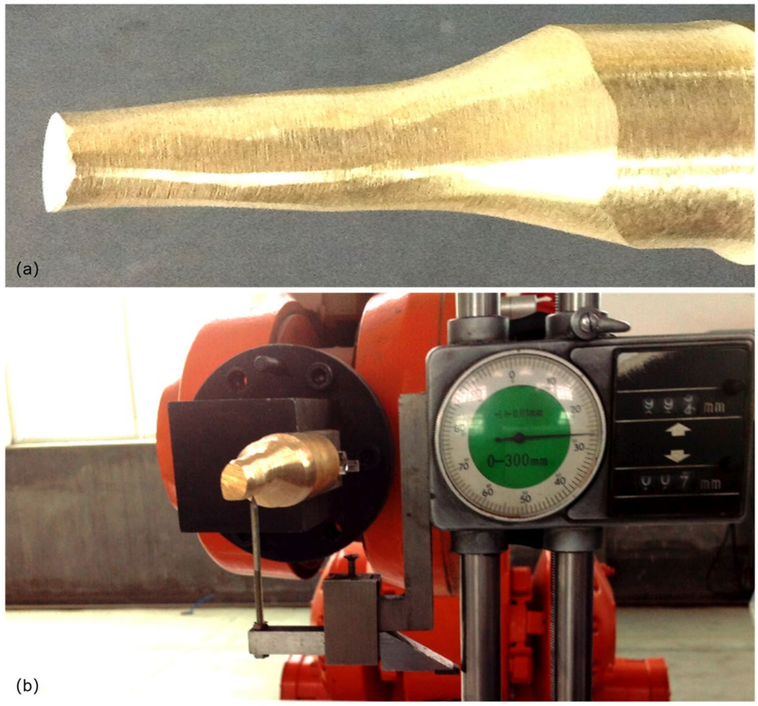


Fig. 6 The milled stem and the measurement of errors

shallower cutting depths tend to produce smaller errors. After milling the stem, the robotic belt system can further refine the surface using a belt embedded with fine abrasive grains.

Discussion

The long-term stability of cementless femoral prostheses depends on the osseointegration of the proximal prosthesis and its fit within the femoral cavity. A key condition for successful osseointegration is the primary stability of the prosthesis. The transfer of forces through the prosthesis significantly impacts its primary stability. When forces applied to the prosthesis are transmitted to the proximal femur and result in excessive micromotion, the prosthesis may lose its primary stability, preventing the formation of osseointegration. Conversely, if the forces on the prosthesis are not adequately transferred to the proximal femur, stress shielding may occur, leading to osteolysis and, similarly, hindering the osseointegration of the proximal prosthesis [30].

It is essential to accurately construct the fitting model of the prosthesis and femoral cavity to effectively control force transfer. The force exerted on the prosthesis should be transmitted to the proximal femur without causing significant micromotion of the proximal prosthesis [31]. Due to the individual variations in femoral anatomy, the fitting model of the prosthesis and femoral cavity during the design phase differs from that observed postoperatively. Consequently, the FEM analysis results obtained during the design phase can not be used to mange the force transfer of the prosthesis after surgery.

The custom prosthesis model is designed based on a 3D reconstruction of the patient's CT images. The fit of the custom prosthesis model and the femoral cavity during the design phase is identical to the fit observed postoperatively. This consistency allows the FEM analysis results from the design phase to be utilized in managing the force transfer of the prosthesis after surgery. This ensures that the forces exerted on the prosthesis are effectively transmitted to the proximal femur, minimizing the risk of significant micromotion. Consequently, this primary stability of the prosthesis fosters osseointegration with the proximal femur, leading to long-term stability of the implant [32].

The standard femoral prosthesis is produced using a batch manufacturing method, which is selected during the surgical operation. This method helps reduce the cost of the prosthesis. In contrast, custom prostheses are manufactured in real-time as single units, resulting in higher costs and longer production times compared to standard femoral prostheses. To reduce costs and shorten manufacturing period, new fabrication technologies must be researched.

The robot has six degrees of freedom; however, its price is only one-sixth that of a CNC machine with the same degree of freedom. Unlike the CNC machine, the robotic system can grind parts. The robotic belt milling process employs multiple "cutters" to simultaneously cut the part,

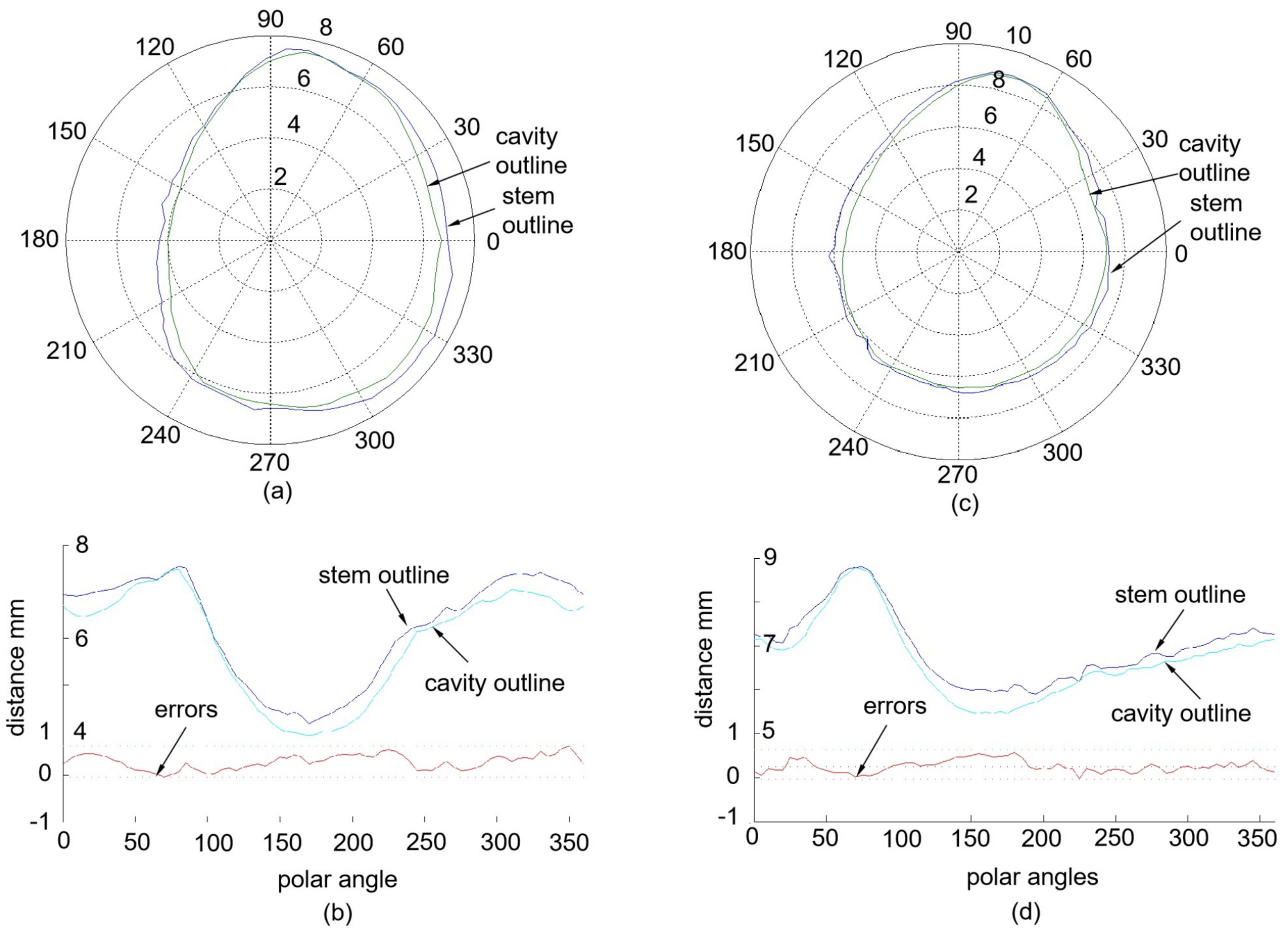


Fig. 7 Milling errors analysis of custom stem

whereas the CNC machine utilizes a single cutter. As a result, robotic machining offers lower costs and shorter machining cycles compared to CNC machining.

It has been confirmed that the osseointegration of a proximal femoral prosthesis can occur when the gap between the prosthesis and the femoral cavity is less than 1 mm. The accuracy of robotic belt milling is typically 0.2 mm, making it more advantageous than CNC machining in terms of cost and the fabrication period for custom femoral prostheses.

It is well-established that the integrated CAD/CAM method of CNC machining is designed to manufacture products quickly. However, there is currently not commercial CAM software available for generating machining paths for robotic applications. In this paper, we present a method for producing milling paths for robots based on existing CAM software used in CNC machining. This integration system for custom prostheses combines design, FEM analysis, and the manufacturing process, which not only shorten the design and production time but also effectively controls the force transfer of the prosthesis. To further reduce the fabrication time of custom prostheses, in this paper, we propose a modular design approach. The sleeve of the custom prosthesis can be fabricated in advance, while the stem that fits with the sleeve is produced in real-time.

Acknowledgements

The authors express their deepest gratitude and thanks to the Collaborative Innovation Center of High-End Equipment Manufacturing in FuJian for their assistance with the robot belt milling system presented in this paper.

Author contributions

Qi Wu guided by Pengju Yue, performed the literature search and wrote the preliminary manuscript, Siyu Yin, Wang Liu, Zhenjie Li, Renjie He completed the modeling.All authors reviewed the manuscript.

Funding

None.

Data availability

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

Declarations

Competing interests

The authors declare no competing interests.

Received: 8 January 2025 / Accepted: 24 February 2025
Published online: 18 March 2025

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