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Al-Qadisiyah Journal for Engineering Sciences

Journal homepage: <https://qjes.qu.edu.iq>



Anatomical personalized plate implants (APPIs) are the best choice for the treatment of distal femur fracture

Mohammed Mizal Rashid 

Department of Mechanical Engineering, Collage of Engineering, University of Muthana, Iraq.

ARTICLE INFO

Article history:

Received 02 December 2022

Received in revised form 05 January 2023

Accepted 09 February 2023

Keywords:

Plate

Distal Femur

Specific Patient

Anatomical

Fixation

ABSTRACT

To fix a fractured distal femur, the typical approach involves the use of metal internal fixation plates along with supportive devices such as screws, pins, and wires. These plates are manufactured based on standard dimensions, which means they may not completely match the surface of the fractured distal femur for all patients, especially when the outer surface of the distal femur is complex and has intricate geometry. A complete mismatch, if it occurs, can lead to immediate and future problems. In order to avoid such issues, develop a faster recovery process for patients, and save time, effort, and money, this paper presents a new method. It focuses on designing and manufacturing a three-dimensional plate specifically tailored to perfectly match the external surface of the fractured distal femur for a specific patient. Modern technologies, such as additive manufacturing methods, are employed in the manufacturing process to ensure the production of an accurate plate dedicated to the fracture distal femur of each patient.

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1. Introduction

The technique of surgically implanting plates is used to facilitate the recovery of distal femur fractures by using nails and screws as fixing tools. Based on the location of the distal femur fracture fixation, the fixation method can be classified into two types. The first type is external fixation, where screws and pins are positioned inside the patient's body, while the remaining fixings are outside the body [1]. This approach allows for external control of the alignment of the distal femur fragments and the maintenance of this alignment during the healing period.

The second type of fixation technique used for the internal fixation of fractured distal femur involves placing all fixing tools such as plates, screws, and pins inside the patient's body [2 – 4]. In some cases of distal femurs fracture treatment, it may necessary to use external and internal fixation methods together. Through statistical analysis of practical applications in the field of fixing distal femur fractures, it was observed that the internal fixation process offers the potential for faster and more effective functional recovery compared to the external fixation method [1]. As a result, it is the most commonly employed approach today. The existing fixing devices (pre-

prepared), which are not designed and created for a specific patient, are manufactured and available in various dimensions and sizes to accommodate most cases of distal femur fractures.

Predetermined implants used for the recovery of distal femur fractures may not fully align with the surface of a fractured distal femur. This mismatch can result in problems during or after the implantation process due to the complex nature of the distal femur surface and the differences in surface shape, size, and geometry between the implant and the fractured distal femur.

In order to achieve improved healing and minimize complications arising from the mismatch between the implant and fractured distal femur during or after the implantation process, it is necessary to employ the custom personalized plate implant technique. Rather than bending a pre-prepared plate to conform to the surface of the fractured distal femur, this technique involves adapting the shape and engineering of the plate to fit the surface shape and anatomy of the patient's specific distal femur [4-6].

* Corresponding author.

E-mail address: mohammed.rashid@mu.edu.iq (Mohammed Mizal Rashid)



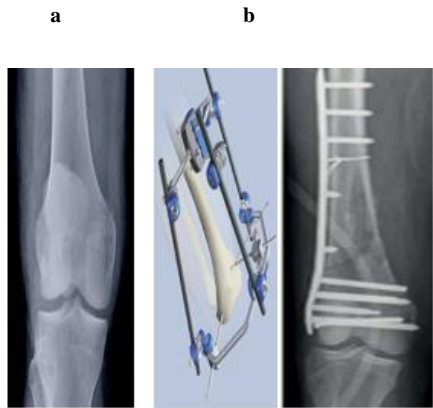


Figure 1. The application of traditional distal femur plates, a) distal femur fracture, b) external fixation, and c) internal fixation.

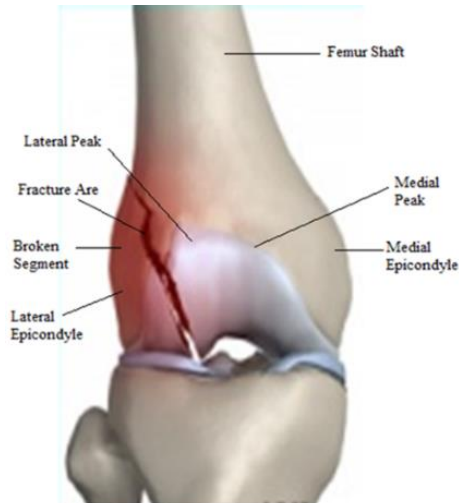


Figure 2. Shows the complex distal femoral surface, especially in the fracture area.

The application of the customized personalized plate implant (APPI) technology requires additional time for individual design and manufacturing for each patient, resulting in increased cost compared to pre-prepared plates [6]. In this research, we focus on distal femur fractures, which are known for their complex surface and geometry. These fractures commonly occur due to the location of the distal femur in the body, making it susceptible to fractures caused by falls, slips on hard surfaces, traffic accidents, and other reasons. Because of the difficulty of achieving a perfect match between the pre-prepared plate and the distal femur and its fragments, personalized plate implants are utilized to ensure a precise fit and accurate fixation during the implantation and recovery process [7-8]. The application of custom implants, created using CAD software based on the method of anatomical features (MAF), involves the creation of the geometric anatomical surface. The design and production of a parametric model of the personalized plate enable obtaining dimensions and surface that fit the any broken distal femur by changing the parametric values [6-8].

The APPIs are considered a basic model that can be changed on demand to match the surface dimensions of the broken distal femur for the defined patient and its manufacture by both traditional or additive manufacturing methods.

2. State of the art

This section provides the high level of review of the methods and tools applied in orthopedic fixation operations that have been subjected to fractures as follows:

2.1. Conventional internal fixation methods

The application of the traditional internal fixation methods must provide the following conditions to ensure the success of the broken distal femur fixation process:

- Ensuring the union of the distal femur fragments in the exact correct places that achieve the perfect match between the distal femur fragments and the distal femur.
- It does not impede movement in the joints and does not prevent the movement of muscle tissue.
- To provide a healthy and encouraging environment for the restoration of broken distal femurs [9].

The purpose of fixing the distal femur fragments internally is to prevent infections and diseases associated with distal femur fractures.

Achieving the appropriate stability between the broken distal femur and the tissue surrounding the fracture area, which leads to the process of nourishing the distal femur tissue by ensuring the flow of the appropriate amount of blood to the distal femur [9,10].

To achieve the goal of stabilizing broken distal femur fragments and ensuring their functional and mechanical stability, and creating the right environment for distal femur rebuilding without problems, surgeons resort to applying fixation methods that use the following fixing devices:

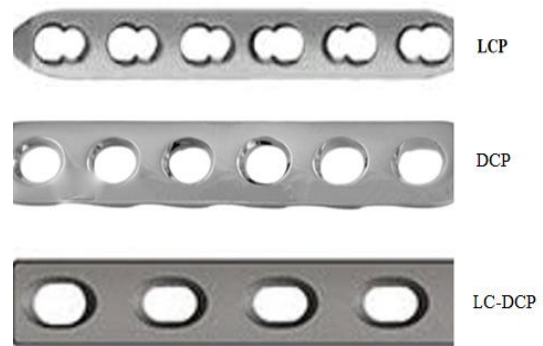


Figure 3. Diverse types of plates are utilized for the fixation of a broken distal femur.

2.2.1 Metal plates

Metal plates are one of the most common implants used in the process of fixing distal femur fractures. Compressive plates are prepared in different shapes and sizes such as Locking Compression Plates (LCP) and dynamic compression plates (DCP) to suit most pathological cases.

They are placed on the distal femur fragments after the process of matching these fragments with the broken distal femur and then fixing them using appropriate screws through oval-shaped holes and suitable preparations for fracture conditions and their degree of complexity [10 - 15]. To create an interstitial pressure to engage the screw in the position with which it is possible to ensure the highest possible stability between the distal femur fragments and the metal plate [12]. The (DCP) panel has some advantages that can be summarized as follows:

- It has an excellent ability to establish sufficient stability.
- It is considered one of the stable internal fixing devices.
- It provides the necessary functional requirements for the distal femur.
- Its use leads to a decreased docking rate.
- The use of DCP eliminates the need for external fixation.
- It can be directly fixed on the periosteum to form pressure on the distal femur to achieve the desired stability [15-17].
- It does not prevent the movement of the adjacent joints to the broken distal femur.

Sometimes a distal femur fracture occurs after removing the plate due to necrosis in the area of the screw tightening to the distal femur due to the lack of sufficient contact space between the plate and the shrapnel, so experts recommend not moving the plate only after at least 15 months have passed after the date of the installation process.

At that time, the DCP plate was updated and developed to create a new plate called the limited contact-dynamic compression plate (LC-DCP) or finite contact dynamic pressure plate. It was designed with symmetrical holes that provide dynamic pressure from both sides of the hole and with different densities [11 -15].

The application of this developed plate achieves many additional advantages:

- It reduces cortical pores by minimizing the interference of this plate with cortical perfusion.
- It minimizes surface contact with the periosteum in conjunction with DCP, thus reducing cortical osteonecrosis and osteoporosis.

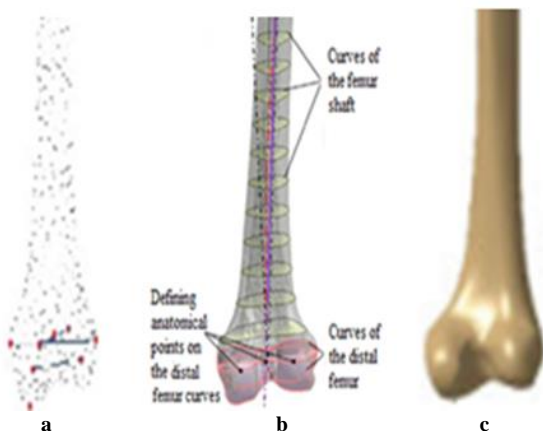


Figure 4. Showed procedures of the surface reconstruction of the distal femur, a) cloud points) b) spline curves, c) creation of the surface model

At present, the boards that perform the functions of both locking and non-locking are used as an alternative to the boards used so far, which were discussed in this research, like locking compressing plates (LCP). However, locked plating cannot completely replace traditional plating [16]. There is potential for an amalgamation of both lamination techniques, and it may be feasible to perform while it is possible [16-18].

When comparing LCP plates to DCP standard plates, we find that it is better in terms of enduring more loads and providing the best fixation [19]. Several factors have a significant impact on the course of treatment and its results (patient's general health status) like reduction quality, the characteristics of the injury, soft-tissue handling, and type of fixation. Depending on the anatomically predetermined plates, the DCP and LCP fixation methods can be determined, which eliminates or reduces the need to modify the plate (curvature) during implantation at the fracture site.

In this case, the LCP implant does not need to touch the entire surface of the distal femur, so precise determination is not required, especially when using screws for fixation, the LCP board acts like a stabilizer rod. It should be noted that some problems may appear when the distance between the distal femur and the plate is increased to an inappropriate distance [19-20]. Reconstruction plates like compression plates, in this case, have oval screw holes mentioned above, and they permit potentially limited compressing. The oval screw holes with deep notches are designed between the holes which enable them to contour (bent) into three planes to suit the distal femur complex surfaces. Reconstruction plates are available in stiffer pre-curved lengths and slightly thicker and straight [21]. There is an urgent need to design and manufacture distal femur reconstructive plates to provide the greatest degree of stability while ensuring blood flow to nourish the tissues during healing distal femur fracture, in other words, the fixation should be severe and harsh during the period of healing distal femur fracture, while it is less rigid during the period of the distal femur reformation [22].

3. The application of the anatomical features method

The application of MAF to create different distal femur models (in this paper, the human distal femur) gives high geometric accuracy. In this research, MAF was applied to develop the distal femur model in order to obtain more geometric accuracy for the purpose of employing it in the process of designing and manufacturing a custom plate for distal femur reconstruction [23-26]. Because of the complexity of the distal femur surface and the need for an accurate geometric representation for creating the required plate, the application of the MAF method ensures meeting these requirements. This is achieved through cloud point and spline curve techniques, which determine the relevant points to create the required surface. These points are then connected on the curves to design a plate that exactly matches the fracture area of the personalized patient's femur fracture, as shown in Fig.4.

The application of the MAF helps in creating geometric models of the distal femur surface by utilizing Referential Geometrical Entities (RGEs) that are specific to each distal femur. RGEs illustrate the basis for the reconstruction of distal femur geometry, and they (axes, planes, lines, points) were created in consideration of the anatomical entities and landmarks. The application of MAF to create distal femur models gives good geometrical accuracy and presents a new technique for the description of basic distal femur geometry based on anatomical landmarks. In this paper, a 3D surface model of the distal femur was created and employed to determine personalized plate implant (PPI) geometry. The geometrical accuracy of the distal femur surface model was improved to reach the best potential accuracy of the (APPis) model, this was performed by utilizing more curves and additional points on the input digitized model acquired from the CT scan. Models have been created by using CATIA V5 R21 software, see Fig.4.

4. Deviation analysis

In this research, input data based on a polygonal model with its deviations was adopted, because most of the points of this model belong to the internal structure of the distal femur. We note by comparing the deflection analysis of the previously constructed surface model and the newly created surface model that 75% of the points analyzed for deviation were less than 1 mm apart.

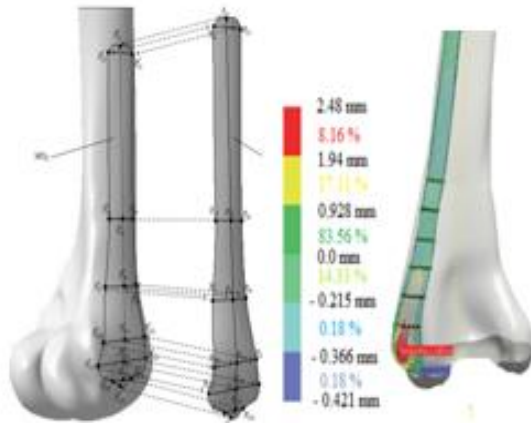


Figure 5. Deviation analysis between the distal femur surface and the plate contact surface.

The analysis of deviations is a) an analysis of deviation between the created surfaces, b) an analysis of deviation between the previously created surface and input polygonal model, and c) an analysis of deviation between the newly created surfaces and input polygonal model. It also appeared that areas with sharp (large) curves have a large deviation value, which may reach 2.48 mm. This means that to create an accurate geometric model, it is necessary to increase the number of additional curves [27,28].

5. The geometric model of the distal femur plate

The aim of this paper is to propose and develop a new procedure for designing and constructing a custom plate for the rebuilding of the distal femur fracture. A reconstructive plate can be applied for the purpose of stabilizing the fractured distal femur on both the lateral and medial sides. The plate can be easily bent around the epicondyle of the distal femur on the medial side, and it can also be placed laterally and posteriorly on the distal femur [28,29]. In order to complete the process of healing the fractured distal femur quickly and hygienically, it is necessary to improve the process of adaptation of the plate to the fractured femur. Therefore, the new method presented in this research was developed, where additive manufacturing techniques can be used to produce this model of the customized plate.

In future research, additional tests will be conducted on multiple models to demonstrate their potential applicability in distal femur reconstruction within the field of orthopedic surgery. The MAF is employed to create a geometric plate model by using the spline curves to build a surface model of the distal femur. These surface models are then utilized to generate a parametric model for the plate, with the arc serving as one of the adjustable parameters that determines the width of the plate [29-31].

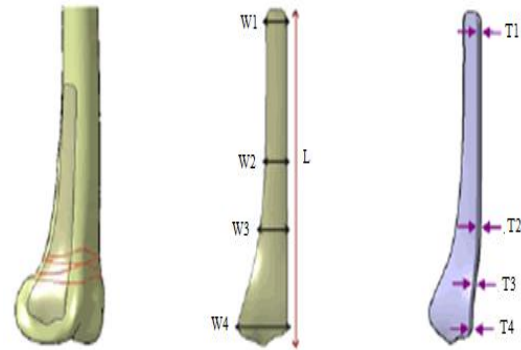


Figure 6. The creation of the geometrical model surface of the distal femur plate.

The middle curve, width, and thickness parameters (T1,...,T4) as well as width values (W1, ..., W4) are important for controlling the geometry and dimensions of the plate, tailored to meet the specific needs of each patient. It is important to ensure that all design limitations are maintained, allowing the plate to function effectively within this environment and bear all the influences (stresses) from the surrounding tissue. These parameters are shown in Fig. 6 and Table 1.

Table 1. The measured parameter values for the specific patient.

W1 [mm]	W2 [mm]	W3 [mm]	W4 [mm]
23	25	28.7	39.1
T1 [mm]	T2 [mm]	T3 [mm]	T4 [mm]
3.20	3.50	2.80	3.10

The patient-specific parameter values presented in Table 1 were used to create a surface model of the plate that would contact the patient's distal femur surface. The intersection with the distal femur surface is minimal and occurs only at the end of the curved part, ensuring that the surface of the plate maintains an appropriate distance from the distal femur surface. Deviation analysis between the plate contact surface and the surface model of the distal femur is shown in Fig. 6. It can be observed that the maximum deviation of 2.48 mm occurs in the outer region of the plate surface, particularly closer to the edges. The deflection should closely match the outer surface of the distal femur, with deviation values ranging from -0.421 to 2.48. This ensures compliance with the requirements for the plate contact surface. Regarding the specific requirements, the analysis ensures that parameters were sufficient to define the shape of the fastener surface. The surgeon can manipulate the plate, implementing additional curvature (with a much smaller degree), and move and rotate it to adapt and conform to the distal femur during a real surgical intervention. The solid model of the reconstruction plate was created by the application of the thick surface feature in CATIA (thickness was defined as 2.48mm), and it is presented in Fig. 7.



Figure 7. Creation of the solid model of the distal femur plate.

Simulation results for the distal femur defect, which was reconstructed with a solid distal femur plate, are presented. The magnitude and location of the stresses are indicated for: (a) distal femur model von Mises stress, and (b) distal femur plate von Mises stress. The stresses are within the permissible limits, enabling the plate to be implanted within this environment alongside the surrounding tissues without any problems or failure during or after the transplantation process. These results are shown in **Fig. 8**.

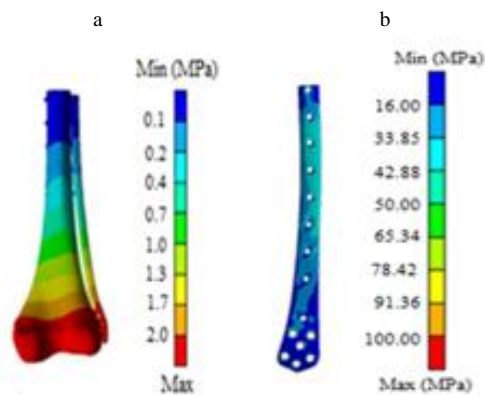


Figure 8. The von Mises stress testing: (a) distal femur model: (b) distal femur plate.

Fig. 9 shows the shape of the final product of the plate designed for fixing distal femur fractures. It was manufactured using one of the additive manufacturing methods to suit a specific pathological condition. Stress tests were conducted on the plate, and it was placed on the fracture area to fix the distal femoral segments.



Figure 9. The final product of the plate fixed the distal femur fracture.

6. Discussion

The desired goal of the personal distal femur plate design is to improve the fixation and stability of the complex fracture of the distal femur and improve the mechanical environment surrounding the plate after the completion of the implant process, as well as to expedite the anatomical restoration process. Because of the difference between distal femur fractures in terms of the type of fracture, the severity of the trauma, and the shape of the distal femur, it may lead to the emergence of problems that can be avoided by strengthening the mechanical structure of the plate and the appropriate matching between the distal femur and the plate. This is done by reconstructing the original surface of the broken distal femur and designing the plate that matches it individually. The models that were built on the basis of CT scans represent the structure and typical shape of the distal femur but remain far from the accurate detailed representation of the surface of the individual distal femur. The manual splicing of the distal femur segments has become impractical due to the lengthy process and the associated difficulties arising from the lack of available information about the normal anatomical structure of the fractured distal femur. Expertise was employed to meet this challenge by using the anatomical landmarks technique to create the complex model. On the basis of this original reference model, the fractured segments of the distal femur were aligned with the corresponding original anatomical position after using a rigid recording of distinct and specific points in the reference model. Based on the paper's results, individual surfaces can be created automatically and accurately.

In previous studies, modifying the anatomical distal femur plates for use with other complex personal distal femur fractures is very difficult and requires more effort and time. To overcome this problem, mapping marks were created between distal femur plate parameters and distal femur parameters on the basis of the corresponding characteristic points. The appropriate plate model is selected to fix the fractured distal femur, and then the individual distal femur parameters will guide the deformation of the model automatically so that it is accomplished in less time and effort. The paper shows focus on the standard distal femur plate design applied to treat individual complex distal femur fractures and emphasizes the need for further study to overcome many problems and limitations.

7. Conclusion

In this paper, a new method has been applied to design a custom 3D anatomical plate for the treatment of distal femur fracture. The design process takes into account the specific features, determinants and requirements of surgical treatment. The 3D anatomical plate is quickly designed and constructed to precisely fit the fractured distal femur. It also allows for intuitive modifications using semantic features parameters, ensuring compliance with the surgical requirements for distal femur fracture treatment. In addition to all this, this method enhances the design efficiency and quality of the personalized anatomical distal femur plate through stable fixation of the fractured distal femur and the possibility of intuitive adjustment by orthopedic surgeons. The geometry, shape, and length of the materials that are used to stabilize the distal femurs, which were presented in this research, such as nails, screws, plates, and wires, have a significant impact on the surgical intervention process and the period and quality of distal femur healing and gaining healing. Also, they are considered necessary equipment used for orthopedics. The improvement of plate design led to the remarkable stability of the fracture, decreasing distal femur recovery time and improving functional properties of the distal femur

and joints. The morphological and geometrical characteristics of the geometric model were completely acceptable according to the results obtained through the application of this new method that was described in this research and which is dedicated to creating a geometric model of the distal femur reconstruction plate. The engineering model of this plate can be manufactured by applying additive manufacturing techniques. Future research, based on the parameters of the feature, should focus on the enhancing strength of the plate and on improving the distribution of loads and internal pressure in order to improve the mechanical performance of the anatomical plate intended for the reconstruction of the distal femur fracture.

The paper focuses on the standard distal femur plate design applied to treat individual complex fractures and emphasizes the need for further study to overcome many problems and limitations. Additionally, many distal femur samples will be added for the purpose of determining the type and number of parameters that determine the structure of the desired contact surface between the plate and distal femur.

Authors' contribution

All authors contributed equally to the preparation of this article.

Declaration of competing interest

The authors declare no conflicts of interest.

Funding source

This study didn't receive any specific funds.

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