Management Systems
in
Production Engineering

2025, Volume 33, Issue 2, pp. 258-267

Date of submission of the article to the Editor: 11/2024
Date of acceptance of the article by the Editor: 04/2025

DOI 10.2478/mspe-2025-0025

VIRTUAL MACHINING OF TOTAL KNEE REPLACEMENT PRODUCTS BASED ON FINITE ELEMENT ANALYSIS (FEA) AND RE-DESIGN OPTIMIZATION BY ISO 14243

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Abstract:
This study evaluates the performance of total knee replacement (TKR) components by examining the design, simulation, and machining processes involved. The purpose was to assess the suitability of computer-aided design (CAD) about established standards for total knee replacement (TKR) components, focusing on the femoral and tibial components. Finite element analysis (FEA) was conducted using Abaqus software to simulate stress and contact pressure on the components, specifically under ISO 14243-3 Standard loading conditions. The results revealed that stress concentrations and maximum contact pressure occurred at several points, with peak pressure observed on the lateral side of the femoral component. Based on these findings, the study included a redesign of the knee implant components, followed by re-validation using finite element analysis (FEA). The study also explored the machining process of the femoral component, highlighting the importance of using computer-aided manufacturing (CAM) software to ensure precision in producing complex geometries. CAM software simulations were used to verify tool paths and prevent manufacturing errors. These results underscore the importance of integrating CAD, FEA, and CAM processes to improve the design and production of TKR components.

Key words: total knee replacement, finite element analysis, computer-aided manufacturing, femoral, tibial, knee joint

INTRODUCTION

Many 60-year-old patients, particularly women, often undergo total knee replacement (TKR) surgery. This demographic is more prone to knee-related issues, such as osteoarthritis, which is a leading cause of joint degeneration. As the cartilage in the knee wears down, pain, stiffness, and reduced mobility become more prevalent, making TKR surgery a common solution to restore joint function and improve quality of life. Women, in particular, are more likely to experience knee osteoarthritis due to factors like hormonal changes, differences in joint alignment, and overall anatomy (Fig. 1B), which aims to replace the damaged knee joint with an artificial or prosthetic knee joint [1, 2]. In which the thigh bone (femur) to the shin bone (tibia) is linked. In its place, the smaller bone, in conjunction with the tibia (fibula) and the kneecap (patella), makes the knee joint (Fig. 1A). The knees support body weights daily, especially when standing, walking, running, and jumping [1].

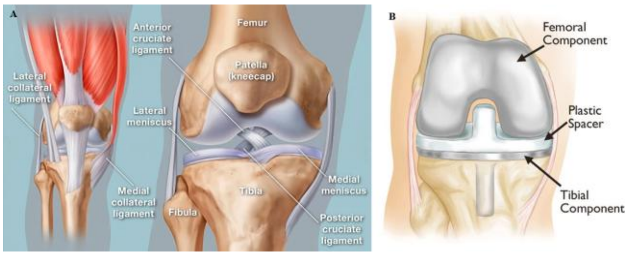

Fig. 1 Knee joint: A) Natural, B) Prosthesis
Source: [4, 5].

Total knee replacement (TKR) (Fig. 1B) as a knee joint replacement has become common, with a wide selection of products available on the market, including those offered by companies such as Simer, Depuy, or Stryker. In the Indonesian market, one type of total knee replacement (TKR) is widely used and is a product with specifications from the Depuy brand [1, 6].

Total knee replacement (TKR) products, despite their relatively low durability, continue to be available in the market, partly due to the absence of comprehensive regulatory standards. Current testing methods, such as those outlined in ISO 14243-3, assess these products under specific conditions to measure their strength and performance. While previous studies typically conducted static tests with single-point loading, this research adopts a more advanced approach by using finite element analysis (FEA). The FEA method applies ISO 14243-3 standard loads to simulate the dynamic forces and movements experienced during walking, providing a more realistic evaluation of TKR durability under human conditions [2].

This finite element analysis (FEA) study aims to evaluate the suitability of the computer-aided design (CAD) concept or drawing design with the referenced standard. The data was taken from a scanned model of Depuy's total knee replacement (TKR) at the Center For Biomechanics, Biomaterials, Biomechatronics (CBIOM3S), and Signal Processing [8, 9]. The modeling concept applied in this study refers to a framework that has been discussed in the literature, specifically by [3]. The study compares simulations using ISO standards, demonstrating the ability to predict wear rates on total knee replacement (TKR) focusing on ISO 14243-3 Standard loading. A free-body diagram is a simple graphical representation, showing the load distribution on an object. In the knee joint, a free-body diagram is used to show the position of the axial load, AP load, and IE rotation before running the simulation. The purpose is to provide a visual representation of the effect of the loads on the system. As shown in Fig. 2.

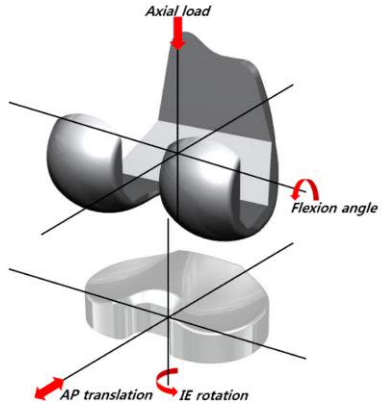

Fig. 2 Knee joint coordinates
Source: [4].

At the beginning of this research, the first step was to investigate previous studies that have explored total knee replacement (TKR) implant design. Several previous studies have implemented the Reverse Engineering method in the total knee replacement (TKR) implant design process. Such as research entitled "*Comparison of ISO 14243-1 to ASTM F3141 in terms of wearing knee prostheses*". The data collected was healthy and normal in terms of human gait angle. The typical gait system was a reference for decision-making [5]. Especially during the stance phase, where the soles of the feet are in direct contact with the floor. This system shows the contact between one foot on the floor and the ankle angle. It started with double support, then single support, and then returned to double support. Foot data is taken from a marker placed on a typical patient's leg, and this method facilitates performance evaluation of normal human walking, walking gait, and peak classification. As shown in Fig. 3 [6].

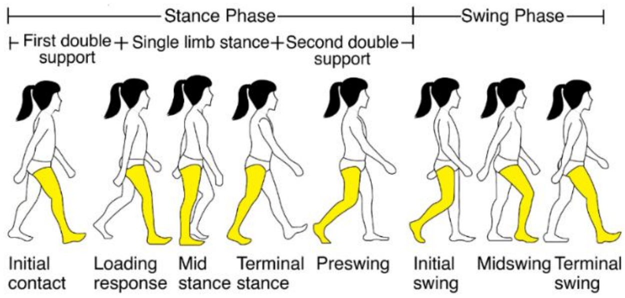

Fig. 3 Walking gait and Election Peak
Source: [6].

Focusing on load control according to ISO 14243-1, given its extended history, ISO 14243-1 is more common and established in the industry. FDA guidance documents and several multinational research organizations still recommend ISO 14243-1. It is based on decades of data [13, 14, 15].

Validation is performed by comparing the simulated data with the existing data in the Wang study, as has been commonly used in previous similar research or development projects. This research adopts a validation method that involves the best final results from the wang study [5]. The validation process is done by comparing the contact pressure between the model being validated and the reference model. After the comparison, the error or difference between the two will be displayed (Table 1). This study adopts a similar method to the previous study, specifically by using the type of present study (commercial Depuy), [5]. Boundary conditions, standards, load control, meshing method, and allocation determination.

Table 1
Validation Results

ISO PEAK	DEPUY Wang (MPa)	Result (MPa)	Difference	Deviations %
C	3.13	3.13	0.06	1.92
D	3.22	3.32	0.1	3.11

Source: [11].

However, this study did not involve ABAQUS Dynamic, using only the standard static method. Based on the literature study, the contact pressure value in the reference model (Wang study's) is shown in Fig. 4.

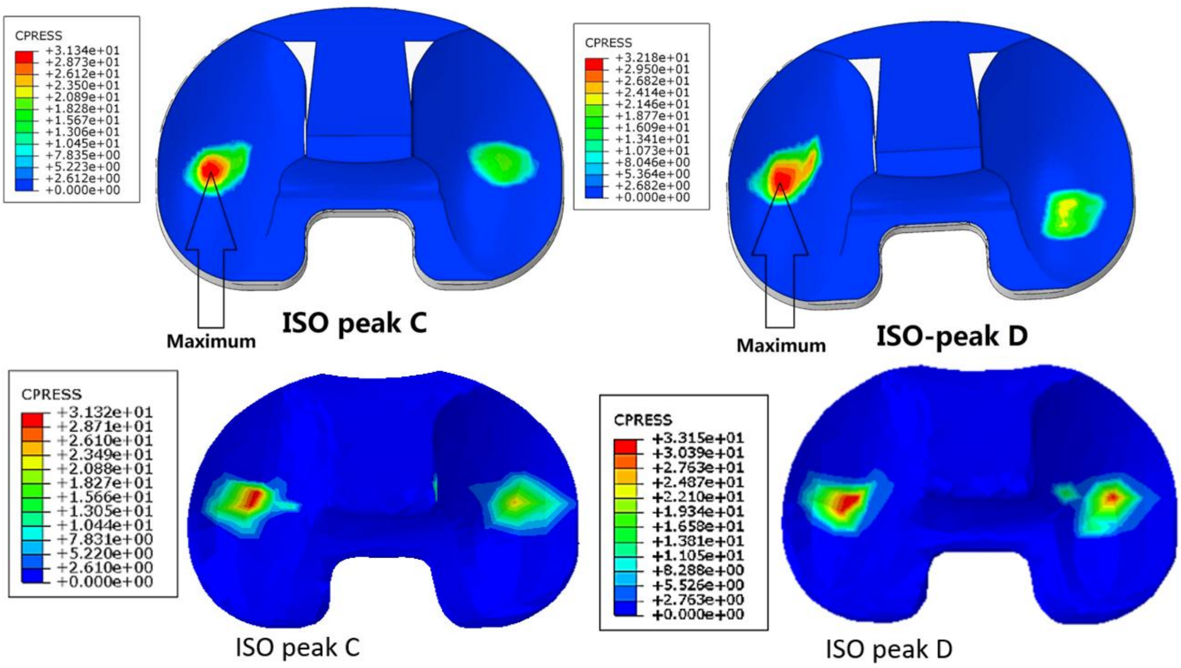

Fig. 4 The respective locations of the peaks of maximum contact stress: C and D
Source: [11].

MATERIAL AND METHODS

Finite element analysis (FEA) is used to simulate and analyze the mechanical behavior of knee prosthesis components before they are manufactured. Through FEA, the prosthesis design can be virtually tested to ensure that the components can withstand the loads received during daily activities without suffering structural failure. Once the prosthesis design is refined through FEA, computer-aided manufacturing (CAM) is used to transfer the digital design into physical form.

Finite Element Analysis Total Knee Replacement

FEA models of femoral and tibial components were simulated using Abaqus. The Depuy total knee replacement (TKR) model was scanned using Eiscan Pro 2x Plus [16]. Hen, the model image was updated by redrawing one plane using Solidworks 2024, which may affect the results of the FEA analysis process. The tibial insert was modeled as a deformable UHMWPE (Gur 1050) material. The insert contact regions were meshed using 8-noded hexahedron element C3D8R, and 10-noded tetrahedron element C3D10M was used for all other areas. The mechanical properties can be a guide to determine the material parameters required in the simulation, Table 2 shows the specifications of the materials used.

The boundary conditions are set following the ISO 14243-3 standard.

Table 2
Material Specifications

Material	Properties		
UHMWPE	Young's Modulus	522 MPa	Elastic
Gur 1050	Poisson Ratio	0,46	Properties
	Yield Stress	Plastic Strain	Plastic Properties
	10.8	0	
	12.5	0.075	
	15.5	0.1	
	16.2	0.125	
	17.7	0.175	
	18.1	0.2	
	18.5	0.225	
	18.5	0.25	
	19.5	0.275	
	20.5	0.3	
Titanium	Young's Modulus	105000 MPa	Elastic
	Poisson Ratio	0.37	Properties

Source: [17].

The axial loading axis is offset by Three of the loading curves (axial load, AP load, and IE torque). As shown in Fig. 5.

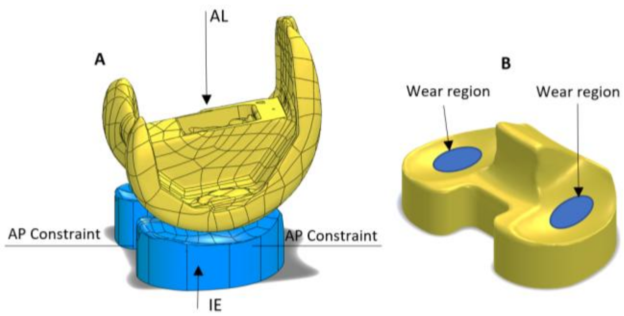

Fig. 5 FEA model; 5A (AL) Axial Load, (AP) Anterior-Posterior (IE) Internal External Rotation, B) Wear region

For the analysis of the total knee replacement (TKR) Depuy model, the optimal mesh size was 3.4 mm, which has been shown to provide an adequate level of accuracy. The mesh shape used in this simulation refers to the default provided by Abaqus, which uses tetrahedral elements. In the meshing process, optimal results are achieved when the meshing is close to the best or real value. Optimal convergence values characterize good meshing.

Several elements have been identified, including C3D8R, An 8-node linear brick element with reduced integration and hourglass control, and C3D10, A 10-node quadratic tetrahedron element. These element types are selected based on mesh control, which aims to control the desired mesh shape. While not all meshes can be formed as hexahedrons, almost all control meshes can be created as tetrahedrons. The C3D4 A 4-node linear tetrahedron comes from selecting the element type using linear geometry by simulation standards. Using a quadratic mesh will break the nodes into four dimensions, resulting in an insignificant simulation but giving results closer to the actual value [11].

This graph visualizes the AP (Anterior-Posterior) load by the knee joint simulation standard and is adopted by the Past Model as a standard reference in applying the test load. These loads play a crucial role in determining the direction and anterior-posterior movement that will affect the final result (Fig. 6A). The Axial Load graph obtains the highest value due to the presence of human body weight or load on the Z axis. The load has a positive value which causes a positive Z to form. The effect of this load has the highest impact on reducing the contact pressure value in the final result (Fig. 6B). The load graph on the Z roll can be interpreted as the torque in the simulation test. The torque in question is the torque with the minimum value but has a large share in the directional effect. The torque load itself shows the difference between gait cycles, be it clockwise (CW) or counterclockwise (CCW) (Fig. 6C).

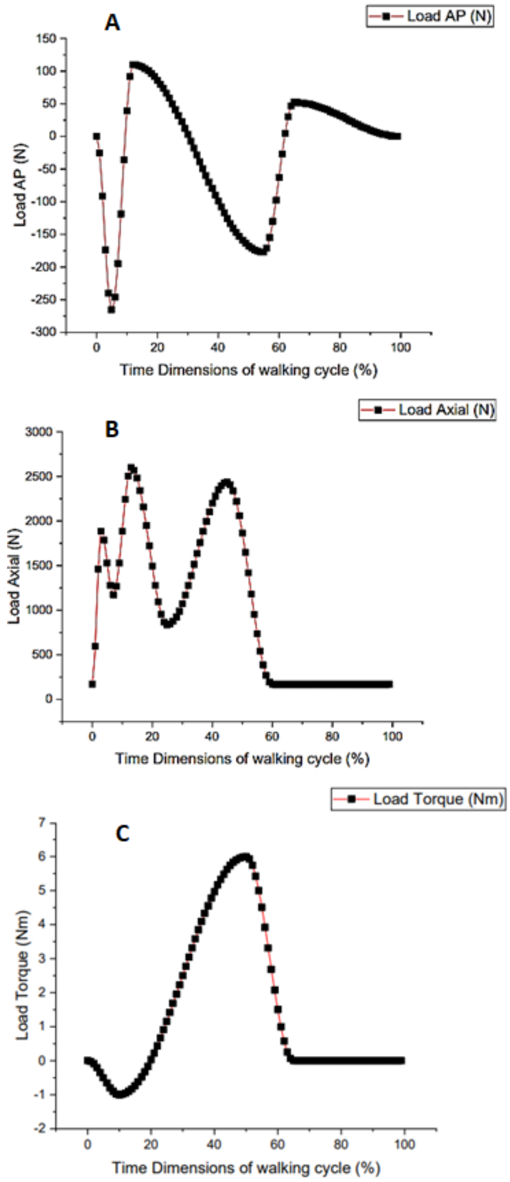

Fig. 6 Graph A) Anterior-Posterior (AP) Load, B) Axial Load, C) Internal External Rotation

Computer-Aided Manufacturing Total Knee Replacement

The design of the machining process of the femoral components of the total knee implant was re-designed and validated by finite element analysis (FEA), the focus was set on the machining process of the femoral component of the knee implant. The design of the machining process of this component, which includes complex geometrical shapes, is essential to be conducted on specialized computer-aided manufacturing (CAM) software. Machining of complex, "sculptured" surfaces is important in various industries such as automotive, aerospace, and optical components industry, as well as bioengineering. One of the main challenges concerning the machining of such surfaces is the reduction of machining time, as it is considerably difficult to achieve the required dimensional accuracy and surface quality. Apart from the use of cutting tools with special geometry, the machining strategy needs to be carefully planned to achieve the desired geometrical features, and suitable process parameters are required to be determined as well. Thus, all of these tasks need to be appropriately addressed by the use of CAM software to perform the machining process of the femoral component. CAM software is specialized to assist in various stages of product manufacturing. Using this type of software, details about the machining process, such as the definition of appropriate cutting tools for the machining process and their characteristics, the desired operations on the workpiece, process parameters during the various stages of the process, and machining strategies can be input at first. Then, a G-code can be generated concerning the type of CNC machine used, given that an appropriate post-processor exists. Furthermore, a simulation of the intended machining operations can be performed to verify that the machining will be performed safely and according to the desired goals or detect possible mistakes and perform the necessary adjustments.

The basic challenge that exists in the present work is that because the outer and inner surfaces of the femoral component contain sculptured surfaces, mounting the workpiece on the machining center bed is difficult to perform. For that reason, it is considered more appropriate to perform the machining process in two separate phases; during the first phase, it is intended to create the internal surface of the femoral component and during the second phase, the workpiece will be reverted, and then, machining of the outer surface will occur. Thus, in the CAM software, different coordinate systems will be defined for the two stages as well as different Stock and Target materials. During the first phase of machining, the emphasis is set on the creation of the inner surfaces. This phase constitutes the main material removal phase and the cutting tools will remove material up to a specific height until the second phase takes place. For the first phase, four cutting tools, both flat and ball end, will be employed, as can be also seen in Table 3.

Table 3
Characteristics of the cutting tools employed in the present work

No	Type	Diameter (mm)	Material
1	Flat End	4	Carbide
2	Ballnose	4	Carbide

It is important to note that, in the early stages of the machining process, tools with flat ends and a larger diameter are preferred to remove large bulk of material quickly (area clearance stage) without requirements for high accuracy of produced shape.

However, at the final stages of the machining process, cutting tools with smaller diameters and ball ends are selected to render appropriately the final sculptured surface according to the desired dimensional and geometrical requirements (finishing stage). The cubic workpiece material, which was chosen is stainless steel 316L (Fig. 7), which is appropriate for the femoral component [18, 19, 20].

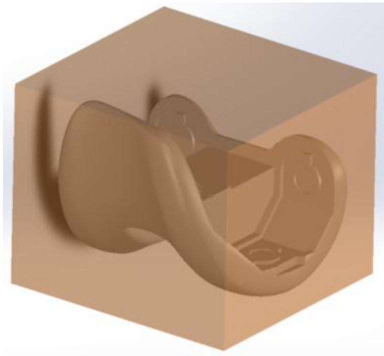

Fig 7 The cubic workpiece/stock material

This process was repeated two times with different at various zones of the TKR during the finishing stage, to investigate the effect of process parameters on surface quality. The process parameters that were employed for the machining of the TKR during the finishing stage are presented in Table 4.

Table 4
Machining parameters for femoral component

No	Machining Process	Cutting Tool (mm)	Cutting Method	Out-Tolerance
1	Area clearance	Flat End Ø 4	Climb	0,1
2	Area clearance	Ballnose Ø 4	Climb	0,1

To create the desired shape of the inner surface of the femoral component, the 4 mm diameter cutting tool was first employed to reduce the initial height of the workpiece at several passes, as seen in Figure 8.

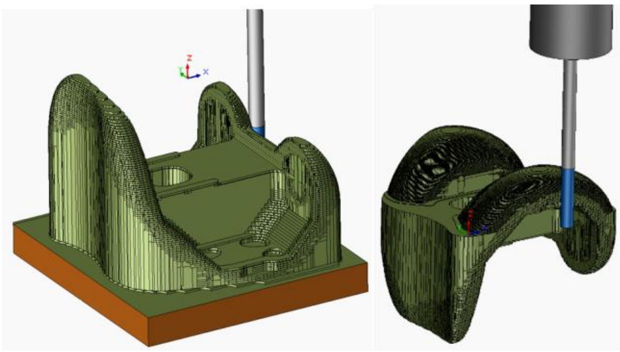

Fig. 8 Snapshots from the simulation of the machining stage

Afterward, a cavity was formed in the region where the inner surfaces of the implant will later be created. Using the same cutting tool, a contour cutting process was also performed to create the front and back sculptured surfaces. As shown in Fig 8.

During the second phase of the machining process, the workpiece is mounted on the machine the workpiece is mounted on the machine tool bed after it is reverted, by sing a specially designed platform, as can be seen in Fig. 9.

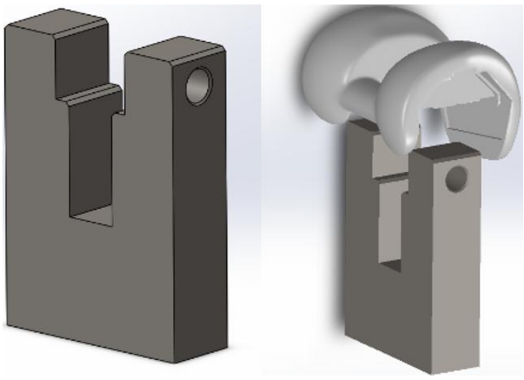

Fig. 9 The platform for mounting the workpiece on the machining

The use of this platform is required as it is impossible to fix otherwise the workpiece appropriately on the machine tool. To ensure the stability of fixation of the implant, it is required that the internal surfaces of the workpiece are properly aligned on the platform surfaces, parallel to the machining center bed. After the implant is mounted on the platform and fixation is properly performed by one screw, the platform is clamped on a chuck. Bed after it is reverted, by using a specially designed platform, as can be seen in Fig. 9. The use of this platform is required as it is impossible to fix otherwise the workpiece appropriately on the machine tool. To ensure the stability of fixation of the implant, it is required that the internal surfaces of the workpiece are properly aligned on the platform surfaces, parallel to the machining center bed. After the implant is mounted on the platform and fixation is properly performed by one screw, the platform is clamped on a chuck. Fig. 9. Views of the workpiece after the first machining stage.

RESULT AND DISCUSSION

ISO 14243-3 standard load simulation results FEA simulations focused on Contact Pressure, Static conditions, and only on the tibial insert component. The analysis was performed using Abaqus software, and the output was obtained in the form of maximum contact pressure and von Mises stress values. The contact pressure simulation was loaded using ISO 14243-3 Standard Load and used a mesh size of 3.4 mm. With this, the simulation results with each value at each angle (cycle %) can be identified.

Fig. 10A shows the results of the contact pressure value described through a graph, then from the graph, a conclusion can be drawn. The graph data taken is a set of data from simulation results from the first cycle to the last gait cycle, and then the data is processed using several examples of results. Fig. 10B shows the results of von Mises stress values described through graphs, then from these graphs, conclusions can be drawn. The graph data taken is a data set from taking simulation results from the first cycle to the last gait cycle, then the data is processed using several examples of results such as Wang's research.

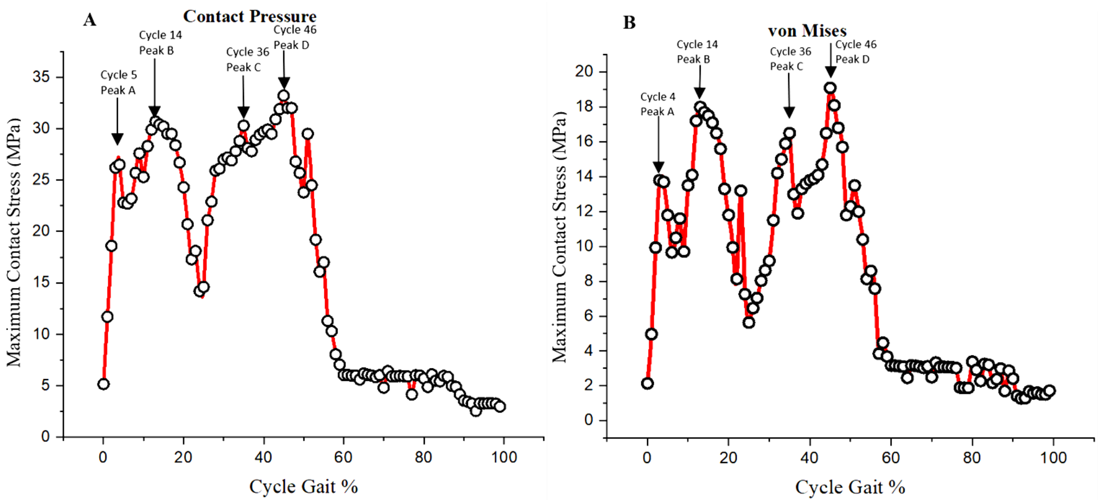

Fig. 10 A) Results Graph of Contact Pressure Value B) Results Graph of von Mises Stress Value

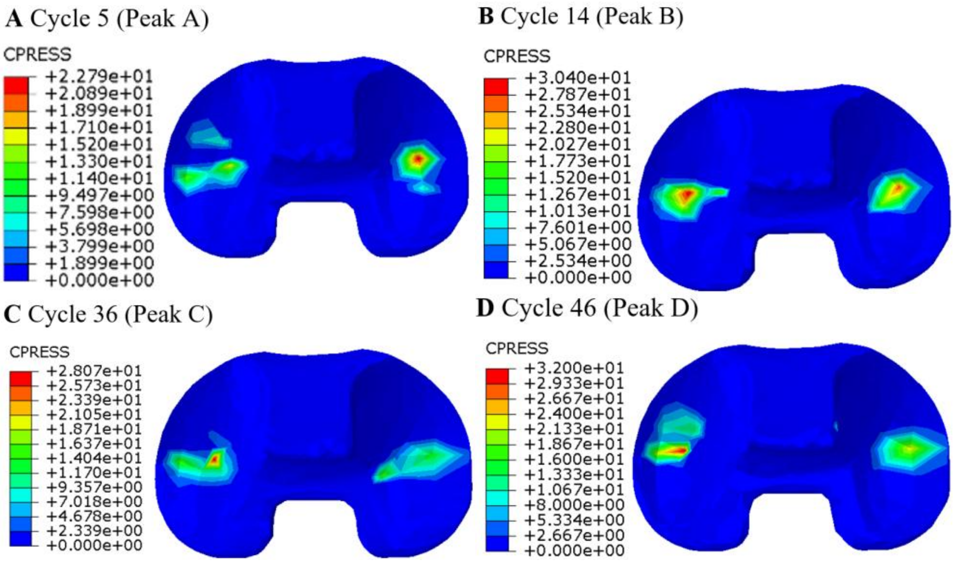

Fig. 11 The respective locations of the peaks of maximum contact Pressure: A, B, C, and D

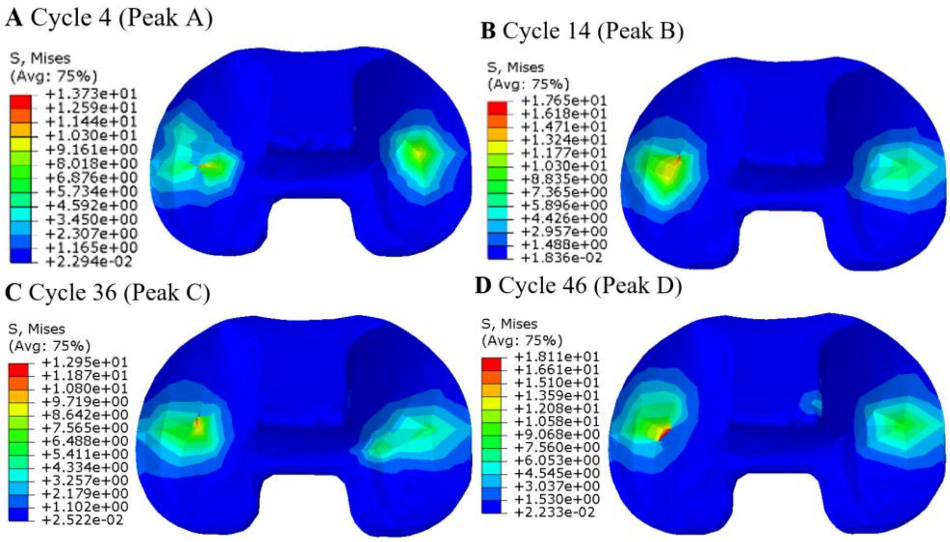

Fig. 12 The respective locations of the peaks of maximum von Mises stress: A, B, C, and D

The simulation results show that the contact pressure occurs in stress concentration at several points, and peak A (Fig. 11A) appears on the lateral side of the tibial component. Furthermore, peak B (Fig. 11B) occurs in the medial and lateral parts. At point peak C (Fig. 11C), the concentration tends to be invisible, and at peak D (Fig. 11D), no stress concentration is detected. The results of the contact pressure simulation align with the loading carried out, where at Peak D (Fig. 11D), there is no stress concentration due to a more even load on the input load system.

In von Mises, there is no stress concentration in some simulation results, and this is in line with the consistency of the loading carried out with the same standard as a reflection of ISO 14243-3, where the axial force, medial-lateral force, and Anterior-posterior force are continuous with the simulation results. As shown in Fig. 12.

Once the design is finalized, CAM software takes the 3D model from CAD and generates instructions for computer numerically controlled (CNC) machines. These instructions control the cutting tools to precisely machine the implant components from materials like Stainless Steel 316L. CAM software can also simulate the machining process itself, ensuring there are no tool collisions or gouging during manufacturing.

The simulation provides a visual representation of how the material is being removed layer by layer, ensuring that the final geometry of the TKR matches the CAD design specifications. It verifies that all features (e.g., holes, contours, surfaces) are being machined without overcutting or undercutting. For complex geometries like TKR, this is crucial to prevent defects in the final part. CAM software predicts the surface finish of the knee joint based on cutting parameters and tool selection. This is especially important for TKR, as smooth surfaces are needed to reduce friction in the joint. The simulation can help identify whether additional polishing or finishing steps are required to achieve the desired surface quality. As shown in Fig. 13.

The absence of extensive standards for total knee replacement (TKR) products poses a substantial challenge. Utilizing ISO 14243-3 for simulation offers a solid foundation for assessing implant performance under practical conditions. Finite element analysis (FEA) facilitates a thorough examination of stress distributions and contact pressures,which is essential for guaranteeing the implants' durability and functionality. The study's results on stress concentration points deliver critical information for advancing future design enhancements.

Fig. 13 Result of the simulation of the machining stage

Research conducted by Wang in 2018 and Bauer in 2021 elucidated that the simulation process utilized ISO 14243-3 for kinematic analysis and wear assessment. Notably, this study did not include wear calculations due to the negligible damage caused by wear, which can be disregarded when its impact is minimal. Furthermore, Parkin 2018 indicated that the finite element analysis (FEA) simulation concentrated exclusively on contact pressure and contact area, thereby providing a representative illustration of the simulation. Additionally, factors related to the machining process were simulated to identify the optimal procedures, that influence the smoothness and geometry of the knee joint, ultimately ensuring the best outcomes in each process [21, 22].

Angelos stated in 2018 that the machining process is divided into five sections, each with varying degrees of roughness. However, only two processes are presented: the initial machining process using an endmill and the finishing process using a ball nose mill, with the final finishing process achieving relatively good roughness. Kumbhalkar in 2011, conducted a toolpath simulation using a 4-axis CNC, whereas the current study used a 3-axis CNC with jig components. In both previous studies, the resulting contour and geometry did not accurately resemble the final implant product. The use of different cutting tools and strategies to achieve precise shapes and dimensions underscores the necessity for meticulous planning in the manufacturing process [23, 24].

The next plan of research in the FEA analysis is to perform a wear simulation to assess whether the wear significantly affects the outcomes of the machining process. By simulating wear patterns, the study aims to understand how material degradation may influence the overall performance and longevity of the TKR implant. Once the wear simulation is complete, the actual machining process can be carried out using a 3-axis CNC machine. This step will help evaluate whether the optimized procedures identified in the simulation translate effectively to the physical manufacturing process, ensuring that the machining process adheres to the design and performance standards.

CONCLUSION

The results of this study indicate that knee kinematics, simulated according to ISO 14243-3, particularly for the Depuy Wang and Depuy models, closely replicate the natural human gait. Both ISO 14243-1 and ISO 14243-3 standards show consistent trends in the contact area, total contact forces, and contact stress, which align with the axial load inputs. Notably, the maximum contact pressure and von Mises stress were observed consistently on the medial side of the tibia in both standards. However, it is essential to note that the location of peak contact stress did not always coincide with the region of maximum contact pressure, highlighting the complex nature of wear patterns and stress distribution in TKR implants under dynamic loading conditions.

Additionally, following the FEA and identifying the point of maximum contact pressure in the knee joint, it was confirmed that this pressure did not exceed the yield stress of the UHMWPE material. This ensured that the stresses on the tibial component remained within the material's yield limit, validating the potential for subsequent processing. In this particular case, the processing was simulated through a virtual machining approach.

This paper presents the integrated approach of computer-aided design and computer-aided manufacturing for the design and manufacture of the femoral component of knee prosthesis. The system implemented is from surgeon requirements to the completion of manufacturing. Solid modeling, rapid prototypes, and virtual machining are used in the system to establish the interface between conception, design, and manufacture. The CAD/CAM techniques are applied to fulfill the design of complicated surface and multi-axis NC machining. The NC programs are verified through solid cutting simulation and virtual cutting. The results are useful for the development of the femoral component.

ETHICS APPROVAL ON HEALTH RESEARCH

*The Health Research Ethics Committee, National Research and Innovation Agency (NRIA) informs that the research title *__Development of Artificial Knee Joint Products (Total Knee Arthroplasty) for the Needs of Indonesian People__* has been reviewed by the Health Research Ethics Committee, National Research and Innovation Agency, with No: 123/KE. 03/SK/11/2023 on Jakarta, 30 November 2023 by Chair of the Health Research Ethics Committee NRIA (Prof. Dr. Rustika, SKM., M.Si).*

ACKNOWLEDGMENT

The authors thank the Indonesia Endowment Fund for Education Agency and the National Research and Innovation Agency, for research funding under RIIM grants of numbers: 156/IV/KS/11/2023 and 353/LPPM/UWH/XI/2023.

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