Design and Simulation of a Foot Prosthetic Testing Machine Compliant with ISO 10328 Standard

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***Abstract*—The lack of proper testing equipment makes it difficult for Indonesia to produce high-quality prosthetic feet that meet national and international standards. Following the ISO 10328 Structural Testing of Lower Limb Prostheses, this study aims to design and enhance a testing machine for prosthetic feet using SolidWorks and ANSYS. The machine, constructed from AISI 1020, SS 201, and AA 6061 materials, underwent a finite element analysis to assess deformation, stress, and safety factors under a maximum load of 322 kg, incrementally applied at a rate of 161 N/s. Results revealed deformation values of 0.16751 mm, 0.16043 mm, and 0.43303 mm, along with safety factors of 2.1439, 2.0921, and 1.8741, respectively. Material selection considerations and von Mises stress simulations led to the choice of AISI 1020. To address localized stress, design optimization introduced a collar, enhancing the safety factor from 2.1439 to 3.225. This comprehensive approach to testing equipment design and optimization is vital for ensuring the reliability and conformity of domestically produced prosthetic feet in the Indonesian market.**

***Keywords*—foot prosthetic test machine, finite element analysis, ISO 10328**

I. Introduction

The development of prosthetic limb devices has played a crucial role in enabling individuals with below-knee amputations to perform their daily activities. The prosthetic legs commonly found in the Southeast Asian market are primarily imported and are known for their high quality, modern technology, and practical characteristics [1]. The production of transtibial prosthetics, particularly in Indonesia, is predominantly conducted on a small-scale industrial basis [2–5]. This sector often lacks adherence to ideal biomedical design principles, with a greater emphasis placed on cosmetic considerations rather than product standards.

According to the findings of the Indonesian Population Profile Survey, individuals with disabilities face more significant difficulties in carrying out daily tasks compared to individuals without impairments. According to a 2015 survey, it was found that 3.76% of Indonesia's entire population faced mobility challenges, precisely difficulties with walking. This finding suggests a significant market demand for transtibial prosthetic products [6]. The assessment of mechanical performance is crucial when evaluating prosthetic devices, as it requires strict adherence to specific threshold of 2.0. standards for testing prostheses [7]. Unfortunately, the lack of testing machines in Indonesia that meet the necessary criteria for testing laboratories presents a considerable obstacle. The insufficiency mentioned has implications for domestically produced prosthetic feet in the local market, as they frequently fail to meet both national and international standards.

The establishment of a solid basis for evaluating lower limb prosthetic devices is achieved by adhering to the widely acknowledged ISO 10328 standard [8, 9]. The ISO 10328 standard not only establishes the foundation for conducting tests but also outlines the appropriate coordinate system, loading methodology, and requirements for a testing laboratory. The primary objective of this initiative is to ensure that all prosthetic devices undergo comprehensive testing, thereby providing a predetermined standard of quality before patients utilize them [10]. To effectively assess mechanical properties such as strength, retardation, and energy return in prosthetic testing, the test equipment must be equipped with appropriate components and mechanisms [11]. Specific test devices currently available are limited to vertical motion and provide the capability to select a predetermined tilt angle, which corresponds to the angle formed between the foot and the simulated ground. It should be noted that the tilt angle remains constant throughout the test [12].

Previous studies have developed testing instruments to evaluate prostheses, which precisely assess their mechanical characteristics, including stiffness, hysteresis, and energy return [13]. Hysteresis refers to the dissipation of energy due to complete deformation. These experiments aim to acquire optimal values for rigidity

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and hysteresis while acknowledging notable disparities in stiffness among various prosthetic feet and shoes. The advancement of a simulated foot assessment apparatus has been furthered by subsequent research, which has incorporated a unique pneumatic cylinder as the primary testing mechanism [14].

Juniani *et al.* [15] investigated a test tool framework that examines the design and simulation aspects utilizing Autodesk Fusion 360 software. The research yielded stress analysis data capable of withstanding a pressure of 5000 N. Additionally, the safety factor is assessed for both the lower prosthetic foot and the pneumatic piston bracket [16]. The aforementioned test device designs examine the artificial foot test device to determine its performance in terms of dorsiflexion and hysteresis in prosthetic limbs [17]. The experimental apparatus applies a pressure force of 100 kg with a velocity of 50 mm/min for 15 s. The present work aims to elucidate the test methodology employed for evaluating running shoes, drawing inspiration from the prosthetic foot resistance testing method described in a previous study [18]. The present test is equipped with the capability to generate the dynamics of running movement spanning from the initial heel strike to the subsequent heel strike. The data obtained from the motion laboratory exhibits test results conducted at velocities corresponding to 20%, 40%, 50%, 60%, and 80% of the actual conditions. It is essential to note that this test tool only measures characteristics at a specific speed without considering the whole dynamics of the running cycle or variations in load angle during the tests.

Previous studies, such as those by Juniani *et al.* [15] and Balaramakrishnan *et al.* [12] have contributed to the development of prosthetic foot testing tools, these designs are primarily limited to static loading or specific unidirectional loading scenarios. These limitations hinder accurate simulation of the complex angular variations and dynamic forces encountered during the walking cycle, as prescribed by ISO 10328 standards. In response to these challenges, the present study introduces a novel prosthetic leg testing machine featuring an adjustable loading platform capable of simulating multi-axial and angular loading conditions. Furthermore, a key innovation in this study is the optimization of the collar design, which functions as a critical connector between the load applicator and the prosthetic foot. Through topology optimization and Finite Element Analysis (FEA), the redesigned collar demonstrated a significant increase in safety factor from 2.14 to 3.22, ensuring higher durability and structural integrity during testing. This improvement directly addresses the current gap in the Indonesian prosthetic testing infrastructure, providing a more versatile, accurate, and standardized testing approach aligned with real-world biomechanical conditions and ISO 10328 guidelines.

The current state of research on prosthesis testing instruments does not align significantly with walking cycles and ISO 10328 standards. The walking cycle commences with the stance phase, which encompasses the period from when the foot makes contact with the ground until it is lifted off the ground. Following this, the swing phase ensues, which is distinguished by the movement of the foot until it reverts to the stance phase. The stance phase, which accounts for approximately 60% to 65% of the entire cycle, encompasses three crucial elements: first contact, single-piece load, and final contact [19]. The swing phase, which accounts for approximately 35% to 40% of the cycle's total time, can be divided into three distinct components: the commencement of the turn, the middle turn, and the concluding spin [20] During the ambulation phase, the leg achieves a peak angle of 15 degrees in the posterior direction, 20º in the anterior direction, and 7º in the lateral direction (toe out) [21]. Unfortunately, current test equipment does not account for these angular changes in mechanical testing, resulting in less accurate results.

Based on these limitations, this study focuses on developing a below-knee prosthetic leg testing machine that can analyze mechanical characteristics based on specific loading angles [22, 23]. This test machine is designed to evaluate the performance of prosthetic legs under dynamic conditions in addition to static loading. Consequently, the developed test equipment will be equipped with a platform that can be adjusted to accommodate two test conditions and diagonal load forces. In terms of test repeatability, accuracy, and flexibility across various test scenarios, this design aligns more closely with the ISO 10328 standard and real-world use conditions.

II. Materials and Method

The prosthetic testing machine and every component design must allow for adequate freedom of movement for the prosthetic test sample, enabling its deformation under load within the predefined range without constriction. All machine parts are utilized in mechanical testing to aid in configuring, adjusting, and/or measuring the segment lengths and offsets of the prosthetic foot. The study focuses on parts deformation, von Mises stress, and safety factors during mechanical testing simulation. The flow chart depicting the research process is presented in Fig. 1.

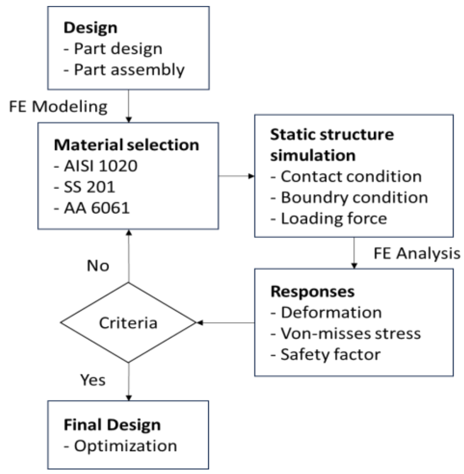

Fig. 1. Flowchart of research.

A. Design Process

Computer-Aided Design (CAD) is a digital technology that enables the creation, modification, and optimization of designs for many applications [24]. The prosthetic testing machine was developed using SolidWorks 2020 software, adhering to the ISO 10328 standard. The design consists of several components. These parts are the top offset adjuster, top end lever, bottom offset adjuster, bottom end lever, and specimen's platform board. A general view of the machine design and its components is shown in Fig. 2. The design process began with the development of a specimen platform board, a bottom-load application point, and a bottom-offset adjuster design that incorporated adjustable positioning. This bottom set is designed to serve as both a footrest and a regulator for testing various conditions. The present platform was designed to support the integration of a foot prosthetic, configured to align the bottom load application point with the actuator line force through the top load application point. The platform is also designed to align the end lever, prosthetic shaft, and bottom end lever. The platform design configuration has been specifically engineered to accommodate dorsiflexion and plantarflexion movements at a maximum bearable angle, whereas the angles for inversion and eversion have been restricted.

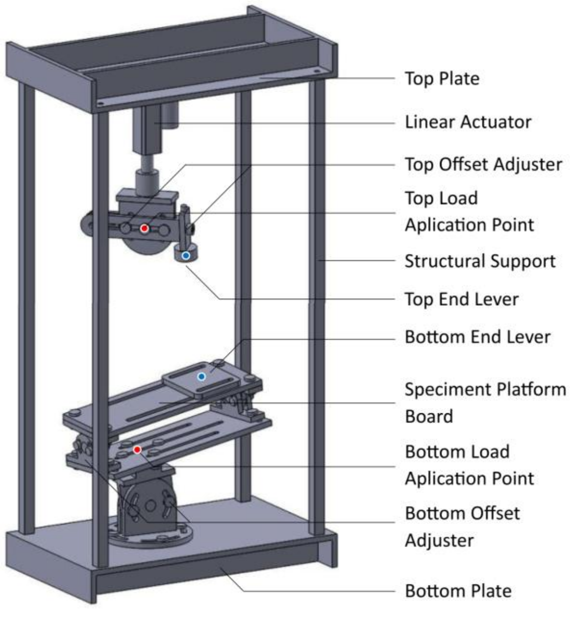

Fig. 2. Design of foot prosthetic test machine.

B. Simulation Setup

The present study employs the finite element approach to examine the design of the prosthetic test machine. A static structure in Ansys Workbench 19.2 evaluates the structural behaviour. Under test loads, the simulation analyses total deformation, equivalent stress, and safety factor.

The boundary condition applies to two regions (Fig. 3). The load is exerted on the upper portion of the shaft of the foot prosthetic dummy, aligned with the standard top-end lever and bottom-end lever (A). The loading rate for parameter A was determined in discrete increments of 192 N/s, as seen in Fig. 4. The prescribed boundary condition for the bottom plate was a displacement of zero at point B.

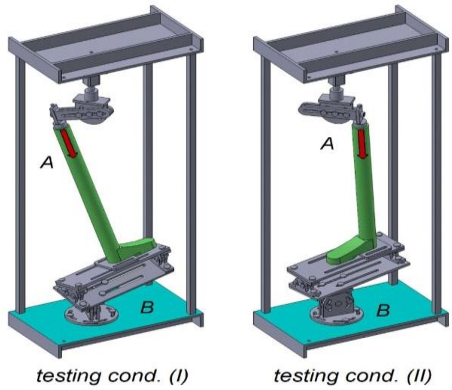

Fig. 3. Boundary conditions for testing condition.

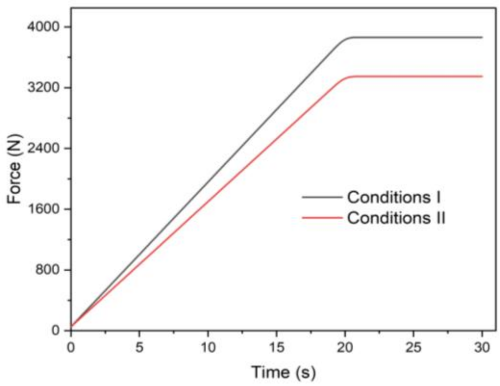

Fig. 4. Loading force rate.

The two loading conditions are followed the ISO10328, labeled I and II, corresponding to maximum loads encountered at various moments throughout the stance phase of regular walking. In this study, we use a normal walking loading force classified as P3 in ISO 10328. In both conditions, the line of load application within the coordinate system must be defined in three dimensions. The precise values for offsets, combined offsets, and test forces for each condition and each principal structural test are outlined in Table I. Test loading condition I corresponds to the moment of peak loading that occurs early in the stance phase of walking. In contrast, test loading condition II corresponds to the moment of peak loading that occurs later in the stance phase of walking.

TABLE I. OFFSET REFERENCE VALUE

Reference	Cond. I	Cond. II
Level, u_T (mm)	650	650
Top, f_T (mm)	81	51
Top, o_T (mm)	−85	−49
Bottom, f_B (mm)	−58	124
Bottom, o_B (mm)	39	−23
Combined offset, S_T (mm)	117	71
Combined offset, S_B (mm)	70	126
Test Force, F_T and F_B (N)	3864	3348

The equipment shall not alter or compromise the mechanical performance of the prosthetic foot and must meet the stiffness requirements during testing. The maximum displacement value, as specified by ISO 10328 for testing machine parts or equipment, was 2.0 mm.

In the testing condition, I applied a force of 50 N, ramped it to 3864 N over 20 s, and then held it for 10 s. The loading force rate is shown in Fig. 5. Testing condition II used a settling test force of 50 N, ramped to 3348 N for 20 s, held for 10 s, and then released. The material properties of each material used in the simulation are presented in Table II.

The prosthetic test machine frame is constructed from four hollow steel components, each measuring 2 mm in thickness and 650 mm in length. The welding process establishes connections between the various frame components of the test equipment. The present examination comprehensively investigates the boundary conditions of multiple structures, considering the available structural material choices, namely AISI 1020 steel, stainless steel (SS 201), and Aluminum Alloy (AA 6061).

TABLE II. MATERIAL PROPERTIES OF SS 201, AA6061, AND AISI 1020

Materials	Young Modulus (GPa)	Density (kg/m^3)	Poisson's Ratio	Ultimate Strength (MPa)	Yield Strength (MPa)
AISI 1020	186	7870	0.29	420	350
AA6061	71	2770	0.33	310	280
SS 201	193	7750	0.31	586	207

III. RESULTS AND DISCUSSION

The two primary sources of research information used for creating the prosthetic foot testing machine are the standard paper on prosthetic feet published by the American Orthotic and Prosthetic Association (AOPA) and the ISO 16328:2016 standard. A test engine for prosthetic feet was developed to evaluate the proof strength and ultimate strength of the prosthesis foot within the P3 activity category, as specified in the ISO 1632:2016 standard. The finite element simulation was performed by applying forces of 1610 N and 3220 N. The deformation threshold conditions are defined using strict criteria, employing a standard deviation measure of 1% and a maximum limit of 0.25 mm.

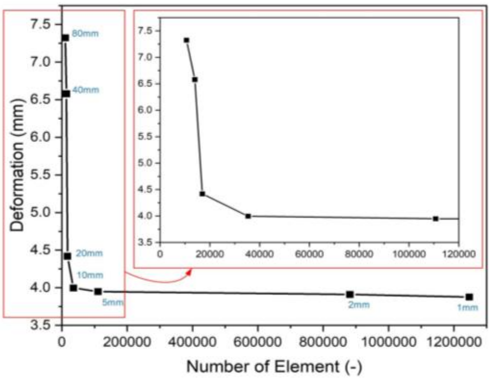

Fig. 5. Mesh convergence study for the models.

Finite Element Analysis (FEA) involves discretizing an infinite domain into a finite number of elements. However, this approach has some disadvantages, such as coarse mesh leading to lower computational time, but reduced accuracy compared to finer mesh [25, 26]. Therefore, a mesh refinement study is necessary to ensure that the chosen element size does not significantly affect the results. The mesh study for the model in this study is presented in Fig. 5. An element size of 5 mm with 110,719 elements was selected for the analysis in this study, as it resulted in a difference of less than 1.2%.

A. Deformation

The analysis of deformation is a critical methodology that helps in ascertaining the response of materials under external forces, which in turn is necessary for the development of more substantial, durable, and safer structures [27]. A maximum permitted deformation for prosthetic test equipment is 2.0 mm, as defined by ISO 10328, to ensure accurate and safe mechanical testing. Fig. 6 presents a detailed analysis of the deformation behavior for three structural materials (AISI 1020, SS 201, and AA 6061) under two different loading conditions. The loading force (N) to structural deformation in millimeters. The curves for two deformation trends were represented: Loading Condition I and Loading Condition II. The SS 201 material exhibits a consistent loading condition I, which is 1.7% lower than loading condition II in deformation, whereas the other material shows less than 1.3% in deformation. It means that in deformation, the loading conditions I and II have an insignificant effect.

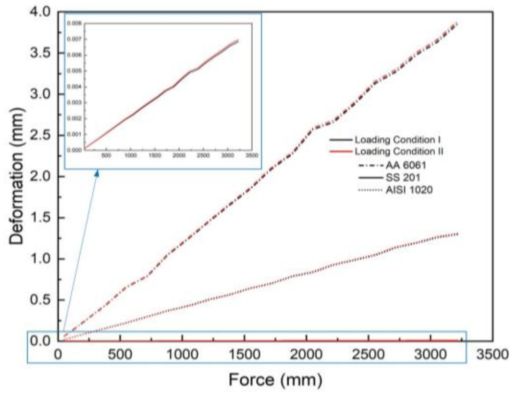

Fig. 6. The relationship between forces against displacement from materials under two loading conditions.

A closer examination of the materials reveals significant differences in performance. The greatest deformation was in AA 6061, with values above 0.5 mm. While under the 2.0 mm threshold of ISO 10328, the value was still 99.8% higher than that of SS 201 and 65%

higher than that of AISI 1020. The fact that it is less resistant to loading forces indicates its weaker resistance. Such a high deformation value indeed depicts that AA 6061 has weak resistance to external forces when compared to the other two materials [28]. On the other hand, SS 201 has demonstrated excellent strength and resistance to deformation, with its strength being approximately 190.19 times greater than that of AISI 1020. SS 201's elastic-plastic deformation behavior showed a balanced combination. Reversible deformation occurred within the elastic region, but it generated permanent deformation in the plastic region [29]. The capability of this material to withstand extreme conditions during plastic deformation, as specified by Loading Condition I, indicates its superior behavior compared to Loading Condition II. The difference in the downward trend of the test force in the two conditions suggests the difference in the deformation behavior of the material. The simulation results indicate that the material under test loading condition I is stronger and more resistant to external loads than the material under test loading condition II. Thus, it can be concluded that the material in test loading condition II has better plastic deformation capability than the material in test loading condition I.

The simulation results also indicate that SS 201 exhibits superior strength, resistance to deformation, and plastic deformation capability compared to both AISI 1020 and AA 6061. Furthermore, while both SS 201 and AISI 1020 were within the 0.25 mm limit for the structure of the prosthetic foot test machine, AA 6061 exceeded this limit and, therefore, is not suitable for the application. According to these, SS 201 is identified as the most appropriate material for the prototype. Due to its high strength, minimal deformation under loading, and excellent capability of resisting plastic deformation, it is optimal for ensuring the structural integrity and reliability of the prosthetic foot test machine. The selection of SS 201 will not only provide deformations within the limit but also increase the service life and safety of the structure.

B. *Safety Factor*

Safety is one of the most crucial factors in designing a prosthesis testing machine, ensuring reliability, safety, and consistency during tests [30]. The safety factor is defined as the ratio between the maximum capacity of the testing machine and the expected load applied on the prosthetic leg. A sufficient safety factor must be maintained to ensure that the test machine can bear the applied loads without risking structural failure or harm to users.

To validate the choice of material for the structural design of the foot prosthetic testing machine, the safety factor has to be checked for the most extreme operating conditions, with a minimum threshold of 2.0 [31]. The safety factor values obtained from the simulations for each material are presented in Table III.

The safety factor for AISI 1020 shows that under the given load conditions, material failure is within a reasonable factor of safety. On the other hand, under Loading Condition II, the safety factor drops to 1.94, which is lower than the normally acceptable level. This lower value indicates that, with higher loads, the material approaches its structural limit; therefore, it should be used with caution in highly stressed applications.

TABLE III. OVERALL SIMULATION RESULTS FOR EACH MATERIAL

Material	Test Loading Condition	Maximum Deformation (mm)	Maximum Equivalent Stress (MPa)	Minimum Safety Factor
AISI 1020	I	0.967	169.53	2.643
	II	1.309	230.59	1.94
SS 201	I	1.04×10^{-3}	8.96	17
	II	6.97×10^{-3}	6.99	17
AA 6061	I	4.117	169.64	2.198
	II	3.888	232.26	1.605

The results for SS 201 consistently showed a safety factor of 15 for both loading conditions. This means that SS 201 is highly reliable, with outstanding performance and a minimal likelihood of failure. Even though this may indicate an overdesigned system, the use of SS 201 remains justified for a number of reasons. The first advantage of SS 201 is its excellent corrosion resistance and mechanical durability, making it optimal for repetitive testing in diverse environments where reliability and long-term stability are critical [32, 33]. SS 201 was selected in part because of its strength, but also because it was readily available, weldable, and cost-effective within the local manufacturing environment. Although a lower safety factor would be sufficient structurally, the adoption of SS 201 ensures that the testing machine will remain robust under all anticipated loading conditions without requiring frequent maintenance or experiencing premature failure [34, 35]. Accordingly, the high safety factor used in this case is a deliberate design choice aimed at maximizing operational safety and durability and reducing life cycle costs over efficiency.

In the case of AA 6061, the material exhibits a safety factor of 2.198 under Loading Condition I, which is near the threshold acceptability value. However, in Loading Condition II, this value further decreases to 1.605, indicating a highly stressed material and one that is not far from its performance limit. This implies an increased likelihood of failure under high-load conditions; therefore, AA 6061 is not suitable for applications involving heavy loads.

C. *The Von Mises Stress*

The von Mises stress criterion serves as a key tool for evaluating material performance under multi-axial stress conditions, particularly crucial for prosthetic components with complex geometrical shapes. This criterion simplifies yield analysis by utilizing equivalent stress derived from uniaxial tensile test results, aiding in the prediction of material failure under combined loading. However, its limitations, especially in addressing the anisotropic nature of biological tissues and advanced materials, highlight the need to explore alternative failure criteria. For instance, trabecular bone demonstrates greater strength in compression than in tension, a behavior the von Mises criterion fails to capture [36]. Additionally, incorporating von Mises stress into finite element analyses has advanced the modeling of composite materials and advanced metallic alloys, which is essential for accurate performance predictions under complex loading conditions [37]. While the von Mises criterion is widely applicable, a thorough understanding of material behavior under multi-axial loading is vital for improving the reliability and performance of engineering components, such as turbine blades and prosthetic devices [38].

In the case of AISI 1020, the von Mises stress due to Loading Condition I is 169.53 MPa, which is within safe limits, corresponding to a safety factor of 2.643. However, under Loading Condition II, the von Mises stress rises to 230.59 MPa, approaching the material's yield strength. Correspondingly, the safety factor reduces to 1.94, indicating a significantly increased risk of failure, particularly under higher forces and other conditions. This postulates that AISI 1020 will see yielding and deformation problems under higher load conditions.

Regarding SS 201, very low von Mises stresses are obtained: 8.96 MPa and 6.99 MPa for Loading Condition I and Loading Condition II, respectively. These corresponding safety factors remain constant at a high value of 15. Therefore, one can conclude that the use of SS 201 involves a highly overdesigned material under the given loading conditions, as extremely low stresses and, similarly, deformation are observed here.

In the case of AA 6061, for Loading Condition I, the von Mises is 169.64 MPa, while the safety factor for this condition is 2.198, reflecting a moderate level of stress and a reasonable safety margin. Under Loading Condition II, the von Mises increases to 232.26 MPa, while the safety factor drops to 1.605, an indication of a critical reduction in the safety margin. In addition, under both conditions, the maximum deformation of AA 6061 has already surpassed 2 mm and, therefore, doesn't satisfy the requirements stated by ISO on deformation in the case of end attachments. This evidence highlights the limitations of AA 6061 for applications that require strict adherence to deformation and safety standards.

IV. Conclusion

The design and simulation of a foot prosthetic testing machine compliant with the ISO 10328 Standard represents a critical step forward in ensuring the safety, reliability, and effectiveness of orthopedic prostheses. This project aimed to address the specific requirements outlined in ISO 10328, creating a robust testing platform capable of accurately assessing prosthetic performance under various loading conditions. Through this study, several key insights and outcomes have been achieved:

1. The development process focused on aligning with the stringent guidelines set forth by ISO 10328, ensuring that the testing machine meets the necessary safety and performance criteria for evaluating prosthetic devices.
2. The design phase emphasized integrating engineering principles, such as structural analysis and material science, to optimize the testing machine's performance.
3. Extensive simulation and validation studies were conducted to assess the machine's functionality and performance. This involved analyzing stress distributions, load capacities, and structural integrity using tools like Finite Element Analysis (FEA).
4. The resulting testing machine offers enhanced capabilities to replicate real-world loading conditions on foot prostheses, enabling more accurate and reliable assessments of durability and functionality.
5. By incorporating safety factors, including considerations for Von Mises stress analysis, the machine's design prioritizes user safety and ensures the integrity of prosthetic components during testing.
6. The successful development of this compliant testing machine has practical implications for both prosthetic manufacturers and healthcare professionals. It provides a standardized platform for evaluating prosthetic performance, resulting in enhanced product development and improved patient care.

The design and simulation of a foot prosthetic testing machine that conforms to ISO 10328 standards represents a significant contribution to the field of orthopedic prosthetics. This project underscores the significance of rigorous testing protocols in ensuring the quality and safety of prosthetic devices, ultimately benefiting individuals who rely on these technologies for improved mobility and enhanced quality of life. Furthermore, future research could investigate advancements in testing methodologies and technologies to improve the evaluation of foot prosthetics continually.

Conflict of Interest

The authors declare no conflict of interest

Author Contributions

NA conducted the research, analyzed the data and wrote the original manuscript. AKF was responsible for the finite element simulation, analyzed the data, and wrote the original manuscript. MDPL contributed data analysis and wrote the manuscript. WDL handled the validation, supervised the work and reviewed the manuscript. All authors had approved the final version.

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