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ORIGINAL STUDY

Distal Weight-Bearing Implants Design Featuring an Integrated Groove or Thread

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ABSTRACT

The distal weight-bearing implant was selected from a pool of approximately 17 implant systems that utilize the osseointegration mechanism currently available globally. It stands out due to its modernity, rarity, and creative concept, offering amputees with "above-knee amputation" a range of options that ensure their satisfaction and fulfill their requirements. However, this implant requires additional refinement and adaptation to achieve the highest level of perfection. This research implemented various modifications to the mechanical design of the implant, which were subsequently evaluated using the finite element analysis software "ANSYS." Modifications included substituting the threads along the femoral stem with a groove (internal cut threads) or external thread, while the groove depth was adjusted to enhance stability, while the thread profile was modified to improve mechanical engagement with the bone, resulting in four distinct designs. The mechanical forces acting on the implant at the midstance phase within the femur were simulated and compared to those of the traditional implant under standardized conditions. The results showed that the new modifications exhibited superior resistance to "total deformation," a safer value for "Von-mises" stresses, and a significantly higher (based on observed mechanical performance trends) "safety factor" compared to the traditional design. These findings highlight the potential of the modified implant design to offer improved mechanical performance and patient satisfaction.

Keywords: Osseointegration, Transfemoral, Prostheses, Distal weight-bearing implant

1. Introduction

Considering the substantial and rapid progress in creating a prosthetic limb for transfemoral amputees, who are particularly vulnerable to complications and drawbacks associated with prosthetic limbs in the medium and long term, there is a strong emphasis on developing a medical implant that is directly connected to the human bone to address the deficiency. This implant is inserted into the bone after the amputation, following the principle of osseointegration. It is directly linked to the prosthetic limb, thereby becoming an essential component of the human skeleton [1, 2].

The innovative concept encouraged various companies and countries to develop 17 distinct varieties of implants, among them the contemporary "distal weight-bearing implant," which introduced a groundbreaking concept [1, 3]. The purpose of this implant is to offer support at the end of the socket for individuals who have had a transfemoral amputation. The distal weight-bearing implant serves as a substitute for the femoral condyle in individuals who have a transfemoral amputation, converting the amputee from a transfemoral amputee to a knee disarticulation amputee. As a result, the amputee can fully take advantage of the advantages linked to this specific amputation level [4]. Afterward, the amputee can choose between a conventional prosthetic limb or

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an artificial limb that attaches directly to the femur through a straightforward surgical procedure without any additional complex steps [5].

The significant benefits of the distal weight-bearing implant system prompted its selection and development. The present research primarily focused on enhancing the mechanical qualities of the implant systems since they still needed to reach the desired goal in terms of their mechanical properties [6]. The integrated grooves and threads commonly seen in orthopedic screws used for bone and fracture stabilization had an impact on the design of the modified implants. These modifications were adapted to facilitate both the design and implementation processes.

In 1999, the implant system known as "OPRA" was introduced [7]. The global development of osseointegration prosthetics has garnered attention due to the medium-term success observed with the "OPRA" design implants. Seventeen osseointegration implant designs have been created, encompassing established systems such as the "LPOFS" and "ITAP" implants [8, 9].

Putting together the best parts of both a conventional prosthesis and an Osseo-integrated prosthesis has led to a new and creative idea: a design that combines the two. This idea led to the creation of the distal weight-bearing implant, which can be seen in Fig. 1 [3, 10].

Until this research, there has been no noteworthy development study focused on incorporating a modification or advancement that could enhance the performance of this medical implant system, which is widely regarded as one of the most modern in the world.

Transfemoral amputees still have major difficulties with traditional implants, despite the advances in prosthetic limb technology. These difficulties include poor load distribution, decreased mechanical stability, and long-term issues such as loosening or bone resorption. Although these problems have been addressed by current osseointegration-based implant devices, they still have mechanical drawbacks that impair their overall functionality and durability. By presenting a modified distal weight-bearing implant design that improves load distribution and structural integrity, this study seeks to close this gap. The suggested design aims to increase mechanical contact with the bone, decrease stress concentrations, and improve overall implant stability by implementing an optimum groove (internal cut threads) or external thread arrangement, all of which will eventually improve transfemoral amputees' long-term results.

The primary objective of this study is to develop a novel distal weight-bearing implant that enhances its mechanical characteristics compared to the traditional implant and demonstrates improved performance compared to other implant systems.

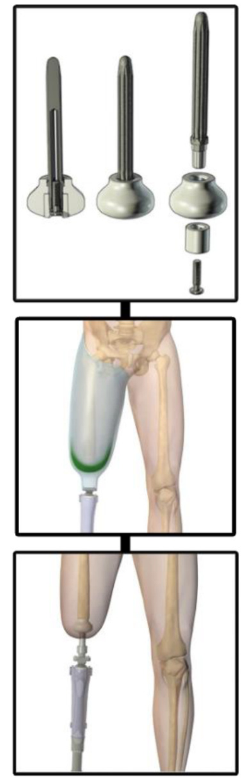

Fig. 1. The distal weight-bearing implant offers amputees the opportunity to avail themselves of its benefits through the selection of a prosthetic limb type.

2. Theory and formula

The present study employs a research methodology that integrates numerical techniques and biomedical engineering simulation to forecast the performance of distal weight-bearing implants.

2.1. Materials and dimensions of implant components

To accurately replicate the dimensions of the traditional implant and ascertain the composition of the distal weight-bearing implant, measurements were conducted directly on an actual implant to validate the accuracy of the measurements. It was also decided to consult references for more assistance [3, 10, 11]. Additionally, energy dispersive spectroscopy (EDS) was used on the distal weight-bearing implant to precisely identify the alloy that was used to make this implant. The distal weight-bearing implant has four fundamental components:

Fig. 2. (A) The traditional implant with separate grooves after the design process; (B) the femoral implant that has been inserted into the bone.

1. The femoral stem. It is 16.5 mm in diameter and 120 mm in length. It is composed of a Ti-6Al-4V alloy and is the implanted component within the femur.
2. The spacer. The diameter measures 60 mm. Composed of ultra-high molecular weight polyethylene (UHMWPE); it replicates the mechanical action of the femoral condyle.
3. The plug is a hollow, cylindrical structure that serves as one of the two connecting elements between the spacer and the femoral stem. It is constructed from UHMWPE material.
4. The screw, serving as the second element that interfaces the spacer with the femoral stem, is composed of a Ti-6Al-4V alloy.

2.2. Design of the distal weight-bearing implant

The earliest steps in the design process involved the determination of dimensions and measurements. Subsequently, the implant was meticulously built utilizing the engineering program known as SOLIDWORKS 2023.

The distal weight-bearing implant is constructed by assembling the four designed components; Fig. 2 illustrates the final implant after the design process. Following this, the implant must be inserted into a femur model. The process of constructing the three-dimensional geometric representation of the femur involved consulting a reference that provides precise measurements of the femur's dimensions in a healthy adult male weighing 85 kg [12]. Calculating the dimensions of the excavated area to insert the implant involves multiple stages. The initial stage involves reaming the marrow cavity along the entire length of the femoral stem. The diameter of the hole should be marginally smaller than the outer diameter of the femoral stem. Screwing the implant into the bone due to inserting the stem into the drill cavity until it reaches the apex of the spacer constitutes the subsequent procedure.

Table 1. The critical modified implants design dimensions.

i	The implant design	Pitch Length of groove/thread (mm)	Thickness of groove/thread (mm)
1	Short integrated groove	37.00	3.00
2	Long integrated groove	22.00	3.00
3	Short integrated thread	37.00	2.00
4	Long integrated thread	22.00	2.00

2.3. Modification in design of implant

The implant significantly impacts the livelihood of the amputee. Effective fabrication is an essential undertaking in the field of design. Each of these items is a custom-made product with physiological similarities to the human body. The patient will experience increased comfort and safety with a more suitable design.

To facilitate a broader investigation into viable and potentially groundbreaking outcomes, adjustments were implemented to the femoral stem design utilizing the SOLIDWORKS 2023 software. The concept behind the alteration entails substituting the threads that run along the stem with a spiral groove (internal cut threads) or external thread. The design of orthopedic screws has an impact on these designs. As illustrated in Fig. 3, the modifications yielded four distinct designs. The individual, separate threads were substituted in two designs with a spiral-integrated groove along the stem. The variation between the two designs is attributed to the groove length. However, the remaining two designs involved substituting the fundamental threads with a spiral shape and an integrated thread, the length of which varied between the two designs. The main dimensions of modified implants with integrated groove/thread are provided, as shown in Fig. 4, to illustrate the structural differences and design characteristics. The critical modified implants design dimensions are displayed in Table 1.

The modifications applied to the designs result in distinct structural differences. Specifically, the first two designs feature extruding threads, whereas the other two have cut threads. This distinction plays a crucial role in the performance and mechanical behavior of the modified designs.

These design modifications function as an investigation into whether there are any noteworthy outcomes and as a foundation for further development to refine and implement additional designs until the most optimal and suitable one is achieved.

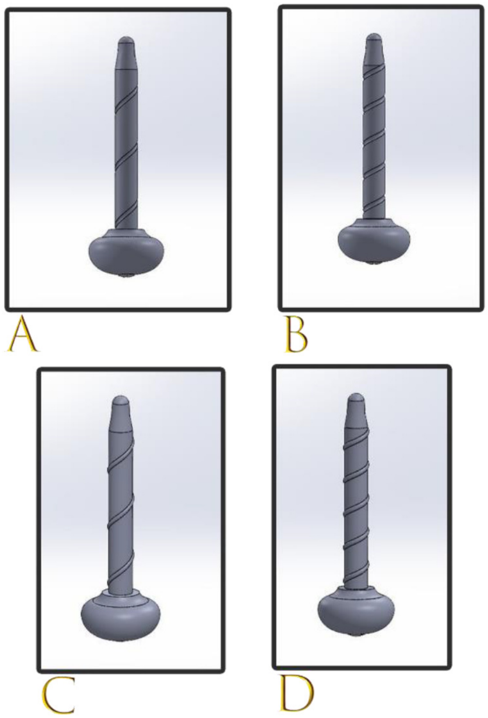

Fig. 3. The modified distal weight-bearing implants including several types of spiral-integrated groove or thread: (A) short spiral-integrated groove, (B) long spiral-integrated groove, (C) short extruded spiral-integrated thread, and (D) long extruded spiral-integrated thread.

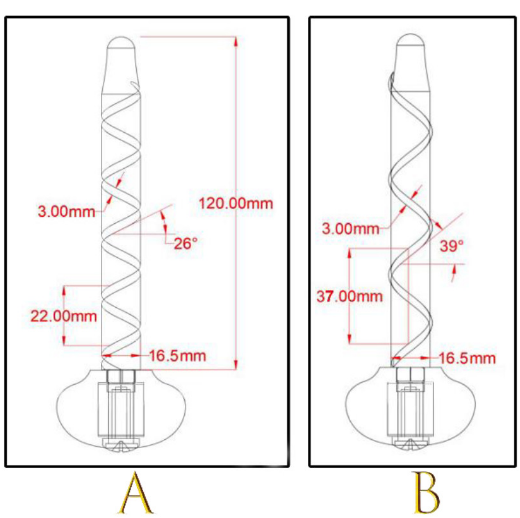

Fig. 4. Geometric dimensions of modified implant with (A) long integrated groove, and (B) short integrated thread.

2.4. Mechanical properties of the components

For several reasons, it is crucial to identify and determine the mechanical properties of the implant and femur components. The primary importance lies in accurately defining the materials used in mechanical analysis programs to obtain realistic mechanical results. To achieve this, the mechanical properties of the Ti-6Al-4V alloy were assessed through compression and Vickers micro-hardness tests conducted on specimens of the same alloy under rigorous scientific conditions. These specimens were made using the wire-cut technique in accordance with measurements that were accepted by scientific references [13, 14]. Because tensile test specimens could not be obtained, these two tests were employed as alternatives. Reliable references were utilized to ascertain the mechanical characteristics of UHMWPE and the femur [15–17].

Understanding the alloy type is essential for assessing its mechanical properties, compatibility with the altered design, and overall efficacy. Incorporating the EDS test facilitated a thorough evaluation of the implant's material properties, essential for substantiating the efficacy of the design alterations. Understanding the alloy type is essential for assessing its mechanical properties, compatibility with the altered design, and overall efficacy performance. Incorporating the EDS test facilitated a thorough evaluation of the implant's material properties, which are crucial for validating the effectiveness of the design modifications.

The incorporation of the hardness test in the investigation of implant modification is essential for various reasons. Initially, it functions as an indirect approach to ascertain the tensile yield strength of the implant materials [18]. Due to the absence of appropriate samples for direct tensile testing, the hardness test serves as a viable alternative for evaluating this mechanical property of the implants. Furthermore, comprehending the material's hardness aids in forecasting its wear resistance and overall durability, hence reinforcing the necessity of incorporating the hardness test in the study to guarantee a thorough assessment of the implant alterations.

2.5. Finite element analysis

Finite Element Analysis (FEA) involves mathematically modelling a complicated structure by splitting it into elements and applying physical principles to each little unit, usually with a simple shape. Researchers utilize this strategy to minimize the quantity of physical prototypes and trials and enhance the components in their design phase to develop superior items prior to the production phase.

FEA allows for the assessment of interactions between bones, implants, and prosthetic components that cannot be studied in vivo or in vitro. This allows for comprehensive monitoring of stress on implants and surrounding bone (Von-mises stress), total deformation, and safety factor.

Table 2. The number of nodes and elements for different distal weight-bearing implant designs.

i	The implant design (inserted into the femur)	Nodes	Elements
1	Traditional	45,710	25,200
2	Short integrated groove	34,339	18,821
3	Long integrated groove	34,034	18,556
4	Short integrated thread	36,141	19,888
5	Long integrated thread	35,521	19,377

A static structural analysis system was implemented in the ANSYS Workbench 2020. This type of evaluation is essential for ensuring the durability and dependability of the implant. It facilitates comprehension of the implant's interaction with the human bone and is capable of forecasting possible failure modes. The Ti-6Al-4V material obtained from mechanical tests has been input into the ANSYS software database. The reference materials used were the femur and UHMWPE.

2.5.1. Finite element mesh

The distal weight-bearing implants are divided into tiny tetrahedral samples via interlocking. In the case of static structural, the element quality is utilized, and the tetrahedral element has a dimension of 5.0 mm. The data presented in Table 2 pertains to the quantity of elements and nodes incorporated in each distinct implant design. The variances in element and node counts are attributable to the constructions of the implants. The variances in element and node counts are attributable to the constructions of the implants [12].

2.5.2. Midstance boundary conditions

The hip joint is capable of transferring significant dynamic loads, up to seven or eight times one's body weight during the midstance moment at gait cycle [19]. The midstance phase is a critical component of the gait cycle that takes place during walking; it also ensures stability. Mechanical force analysis was implemented during the midpoint of the standing moment (midstance). Based on the reference, it may be estimated that the force acting on the implant head ranges from 2000 N to 4000 N; these values correspond to the assumptions made for a human weighing 50 to 100 kg [20]. The test's objective is to determine, using the measured forces, how effective the medical implants are. In order to prevent the contact elements from moving past each other, the implant-bone connection was set to be fully bonded. A weight estimate of 85 kg was made for the amputee. Fig. 5 shows the locations of the fixed supports, which were placed in the considered femoral head, and the implant spacer that was subjected to a vertical force of 3400 N. For each type of implant that was designed, the process was repeated.

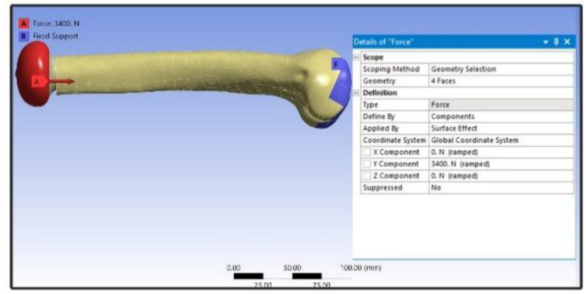

Fig. 5. The details of the boundary conditions that were applied to the distal weight-bearing implant at the midstance phase of the gait.

3. Result and discussions

3.1. Energy dispersive spectroscopy

The EDS was employed to determine the chemical composition of the distal weight-bearing implant. The patterns depicted in Fig. 6 exhibit a transition energy of (4.508 KeV), which corresponds to the energy of (Ti (Kα) KeV). The element (Al (Kα) KeV) is observed to possess an energy of (1.486 KeV). The energy of the element (V) is (4.949 KeV). Similarly, the element silicon (Si) is shown to form a precipitate with an energy of (1.739 KeV). The alloy utilized in the production of the implant was verified, and mechanical test specimens were fabricated accordingly.

Given the presence of a traditional implant and the necessity for accurate data regarding its material properties, the EDS test offered a dependable approach to identify and study the elemental composition of the alloy [21].

3.2. Compression and hardness tests

By subjecting three specimens of Ti-6Al-4V alloy to compression testing, a stress-strain curve was derived. The mechanical properties needed for this study were derived from the curve, as indicated in Table 2. Then, it was added to the finite element analysis program's material database after averaging them.

Regarding the Vickers micro-hardness test, the necessary property to meet the study's requirements was determined. Specifically, the average tensile yield stress was determined, as outlined in Table 3, by conducting hardness testing on three specimens prepared from the same alloy. The averaged mechanical attribute was also incorporated into the database fields of the finite element analysis program.

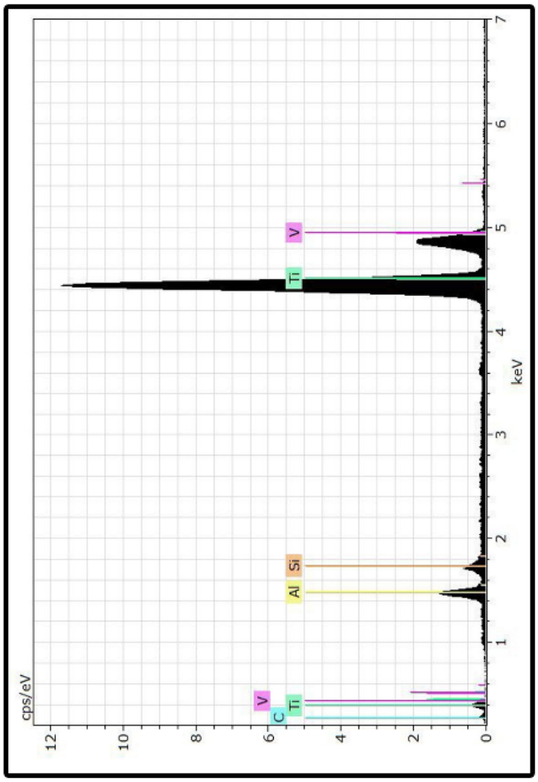

Fig. 6. The transition energies of the implant alloy that were extracted due to the EDS.

Table 3. Values of mechanical properties obtained from compression testing and tensile yield stress values extracted from the hardness test.

i	Yield stress (MPa)	Ultimate stress (MPa)	Elastic modulus (GPa)	Tensile yield stress (MPa)
1	985.1594	2078.6233	84.222	1129.179
2	985.1594	2078.6233	84.222	1160
3	994.9725	2116.5664	90.917	1107.895

3.3. Finite element analysis for mechanical testing

The findings from the mechanical testing of both the traditional implant and the modified versions were acquired through the utilization of finite element analysis software (ANSYS Workbench 2020) to simulate the integration of the implant with the inner femur interface. These results are presented in Table 4.

Modified implants exhibit distinct variations from the traditional implant. However, the traditional implant demonstrated consistent outcomes, as evidenced by its significantly lower Von-mises stress value compared to the ITAP implant, indicating its superior resistance to failure [22, 23]. According to the reference, it exhibits a greater value for the same stress when compared to the OPRA and LPOFS systems [20]. Similarly, the altered implants have demonstrated stable outcomes and exhibit increased resistance to deformation and yielding, as well as improved safety compared to the traditional implant.

Table 4. The results of mechanical evaluations of the traditional and modified distal weight-bearing implants utilizing the finite element analysis.

Implant	Total deformation (mm)	Von-mises stress (MPa)	Safety factor
Traditional (Fig. 2A)	0.14299	35.063	3.1799
Modified 1 (Fig. 3A)	0.065787	15.738	6.6518
Modified 2 (Fig. 3B)	0.074928	13.076	8.6333
Modified 3 (Fig. 3C)	0.065773	25.499	5.7058
Modified 4 (Fig. 3D)	0.06836	22.455	4.7243

The implant with long integrated groove (internal cut threads), as depicted in Fig. 3B, had exceptional outcomes as compared to both the other implant systems and the traditional implant, as shown in Fig. 7. It demonstrated stability against yielding (13.076 MPa) compared to the other implant systems mentioned in the reference (OPRA = 19.80 MPa), (LPOFS = 22.29 MPa), and (ITAP = 70.42 MPa) based on the Von-mises stresses. It also had a safety factor of (8.6333), indicating a resistance approximately eight times the expected load and a total deformation of (0.074928 mm). This deformation is lower than the traditional implant (0.14299 mm), similar to the modified implants, and slightly higher than the referenced implant systems. A comparison is presented in Fig. 8 between the outcomes of FEA conducted on the modified and traditional distal weight-bearing implants and the implants that were mentioned in the reference [20].

It is crucial to recognize that although our findings indicate an increased safety factor and reduced deformation for the modified implants, these metrics alone do not inherently suggest a superior or safer design in comparison to the traditional implant. The traditional design is already considered safe and effective. Consequently, the clinical significance of these findings pertains to the prospective advantages for patients, including enhanced comfort and less likelihood of mechanical failure. An elevated safety factor signifies a greater margin of safety, potentially augmenting the implant's durability and reliability throughout diverse loading situations [19]. Furthermore, less deformation may enhance fit and stability, hence increasing the entire user experience [15]. These factors are crucial for converting mechanical enhancements into tangible advantages for patients.

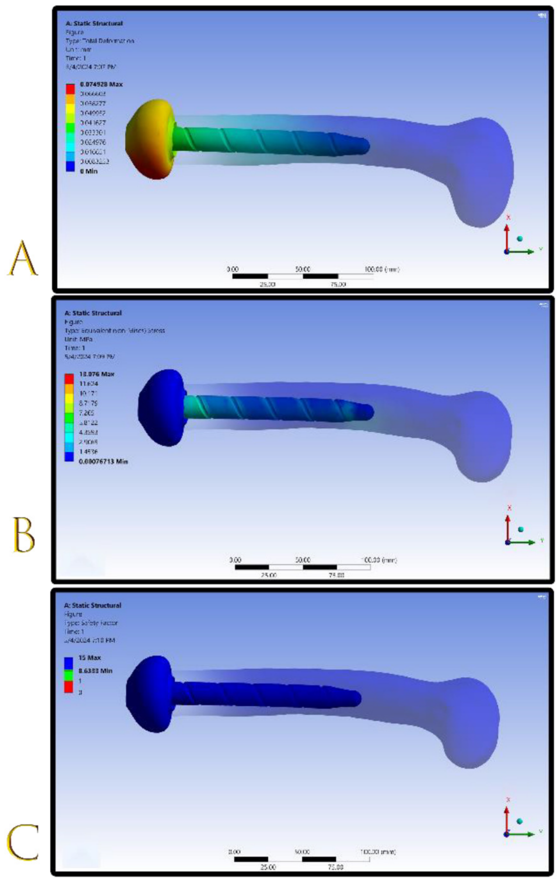

Fig. 7. The FEA results for the distal weight-bearing implant with long spiral-integrated groove (Modified 2) at the midstance phase include (A) the total deformation, (B) the Von Mises stress, and (C) the safety factor.

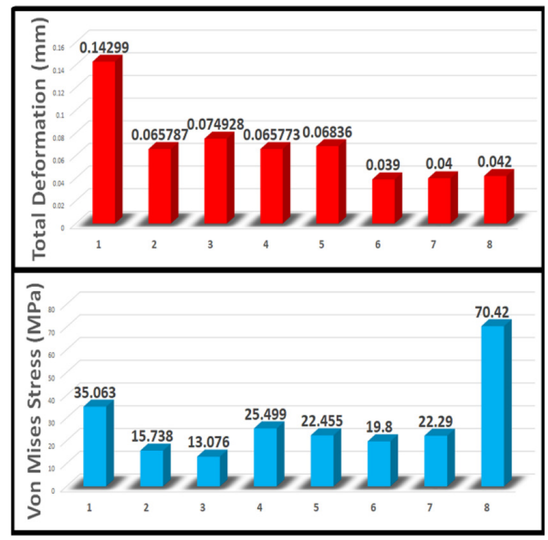

Fig. 8. A chart to compare the results of FEA under identical boundary conditions, where (1) the traditional distal weight-bearing, (2) modified 1, (3) modified 2, (4) modified 3, (5) modified 4, (6) OPRA, (7) LPOFS, and (8) ITAP, implant systems.

In a broad sense, the variation in design with regard to the manipulation of groove or thread shape and length had a notable influence on stress distribution and resistance to deformation, hence enhancing the safety of the implant, albeit to a certain extent. The main objective of implementing alterations is to facilitate progress towards the development of a distal weight-bearing implant that attains maximum mechanical stability.

3.4. Potential limitations of the design

While the modified distal weight-bearing implants showed a superior resistance to deformation, lower Von-Mises stresses, and higher safety factors compared to traditional designs, certain limitations must be considered. One of the primary risks associated with the modified designs is the potential for loosening or detachment from the femoral stem over time. This concern arises due to the mechanical forces and repetitive stress experienced during gait cycles, particularly at high load levels or over extended usage periods. Such detachment could lead to instability, compromised functionality, and reduced comfort for the amputee. Therefore, both experimental testing and clinical investigations should be used to further assess the implant's longevity and dependability under extended use. To guarantee the changed designs' long-term efficacy and safety, these evaluations are crucial.

4. Conclusions

Four novel designs were created, drawing inspiration from the integrated groove (internal cut threads) or external thread design found in orthopedic screws employed for fracture and bone stabilization. The concept involved the transformation of the several grooves present in the traditional design into an integrated groove or external thread. The creative designs vary in terms of the length of the groove or thread.

In comparison to the traditional distal weight-bearing implant at midstance phase of gait cycle, the modified implants exhibit enhanced resistance to deformation, lower Von-mises stresses, and an increased safety factor.

The study observed that modified implants incorporating an integrated groove exhibit reduced Von-mises stress values in comparison to implants from other implant systems (OPRA, LPOFS, and ITAP). Specifically, the implant with the long-integrated groove demonstrated a Von-mises stress of 13.076 MPa, a total deformation of 0.074928 mm, and a safety factor of 8.6333. These results indicate that the modified implant design offers improved mechanical performance compared to both the traditional implant and other implant systems.

The benefits and limitations of the modified implants are discussed in detail. While the modified designs show superior resistance to total deformation and higher safety factors, it is important to note that in some cases, greater deformation could be preferable, particularly in applications where ductility is beneficial. Therefore, the clinical significance of these findings should be carefully considered.

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