

FACULTY OF ENGINEERING AND ARCHITECTURE DEPARTMENT OF BIOMEDICAL ENGINEERING

Comparison of Two Different Ankle Prosthetics Design

Approaches Using Finite Element Analysis

GRADUATION/DESIGN PROJECT

in partial fulfillment of the requirements for the degree of BACHELOR OF SCIENCE

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by

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ABSTRACT

The ankle joint is one of the most essential skeletal joints due to its unique structure. As opposed to other joints such as the hip and knee, the ankle joint is expected to experience loads along three axes in the stance of gait. Since the 19th century's final quarter, this characteristic has rendered total ankle replacement unsuccessful. This work seeks to compare two commercially available total ankle replacement prostheses tibial component models using finite element analysis in order to determine the effects of different TAR design techniques. Von mises stresses and URES values are accepted as the primary comparative variables. Using knowledge from the literature, SolidWorks is used to create CAD drawings. SolidWorks Simulation Tool utilized for FEA. This study demonstrates that the design of bars offers advantages in terms of stress and deformation.

Keywords: Total Ankle Replacement, Computer Aided Drawing, Finite Element Analysis, Orthopedics, Biomechanics.

ÖZET

Ayak bileği eklemi, yapısı itibari ile iskelet sistemindeki en önemli eklemlerden biridir. Diz ve kalça eklemlerinin tersine, ayak bileği eklemi yürüme esnasında üç doğrultuda da yüke maruz kalabilir. 19. yüzyılın son çeyreğinden beridir bu özelliği total ayak bileği replasmanının başarısızlığına sebep olmuştur. Bu çalışma ise iki ticari ayak bileği protezinin tibial komponent modellerinin sonlu elemanlar analizi ile karşılaştırılarak, TAR dizayn tekniklerinin etkilerini incelemeyi amaçlamıştır. Von Mises stres ve URES değerleri karşılaştırmanın birincil değerleri olarak kabul edilmiştir. Literatürde bulunan bilgiler kullanılarak bilgisayar destekli çizimler SolidWorks üzerinde gerçekleştirilmiştir. SolidWorks yazılımının simülasyon aracı kullanılarak sonlu elemanlar analizi gerçekleştirilmiştir. Bu çalışma çubuk dizaynının stres ve deformasyon için daha avantajlı olduğu kanısına varmıştır.

Anahtar Kelimeler: Total Ayak Bileği Replasmanı, Bilgisayar Destekli Çizim, Sonlu Elemanlar Analizi, Ortopedi, Biyomekanik

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ACRONYMS

AF Ankle Fusion

TAR Total Ankle Replacement

FDA U.S. Food and Drug Administration

OA Osteoarthritis

FEA Finite Element Analysis

USA United States of America

FE Finite Element

TA Total Ankle

UHMWPE Ultra High Molecular Weight Polyethylene

CAD Computer Aided Drawing

I. INTRODUCTION

The human ankle is one of the most important skeletal structures. The primary reason for its significance is because the ankle is one of the joints that bears the entire body weight, and it is possible to experience stresses in the sagittal, coronal, and transverse planes during the gait cycle [1]. To achieve a perfect gait cycle, the ankle also coordinates the movement of the tibia and talus bones. To maintain a correct gait cycle, it is essential to maintain healthy ankles.

Figure I: Diagram of ankle joint[2].

The diagram (Figure 1) demonstrates that the ankle joint primarily joins the tibia and talus bones. As a result of its function, ankle problems can induce anomalies in the gait cycle. Therefore, it is essential to keep healthy ankles. The ankle is composed of hyaline cartilage. Therefore, the ankle cannot be totally repaired by the body itself [3]. Therefore, it must be cured with medicinal applications.

1.1. Disorders

Ankle deformities may be caused by a number of factors, including crushes, sprains, sports injuries, excessive physical activity, and inflammation. Patients in this instance are also reported to experience significant pain complaints. Osteoarthritis is the most significant disease that forms in the ankle joint. Ankle osteoarthritis (OA) is a disease characterized by pain, decreased range of motion, loss of quality of life, general disability, and other incapacitating symptoms [4]. The majority of these conditions required surgical intervention. Several surgical procedures exist to alleviate the patient's pain and correct the anatomy of the ankle.

1.2. Treatments

Ankle joint cannot be repaired by the body. Therefore if there is an injury or infection in the ankle it needs to be treated. First priority of these treatments is to relieve pain and survivalization of patients . Second priority of the methods is to provide a perfect gait cycle. Unfortunately most of these methods cannot ensure a normal gait cycle.

1.2.1. Amputation

The most conventional technique is amputation. Amputation caused a disability in walking. Consequently, amputation is the least desirable treatment option. Actually, there is no treatment of disorders in this method. Amputation primarily eliminates the diseased body part and relieves the patient's pain. There are three objectives that amputation must achieve. The first objective is to reduce healing failures. The second objective is to promote rehabilitation. Last one is to reduce hospitalization duration [5]. It can be deduced that none of these goals involve providing treatment. For this reason, it is impossible to guarantee the quality of life entirely.

Figure II: Below Knee Amputation [6].

1.2.2. Ankle Fusion

Ankle fusion is the gold standard for treating advanced arthritis. Albert et al. introduced the first ankle fusion operation in 1879 [7]. Since its initial application, ankle fusion has undergone numerous modifications. Ankle fusion can also be used to fix total ankle replacement failures, fracture dislocations, neuroarthropathic collapse of the ankle, tumor resections, etc. The intermediate-term outcomes of AF are satisfactory. On the other hand, immobilization of the ankle, changes in biomechanics of the ankle, changes in gait pattern, and degeneration of adjacent joints are the primary concerns regarding the long-term clinical outcomes of ankle fusion [8].

Figure III: Radiography images of fused ankle. Anterior plane (A), lateral plane (B) [9].

1.2.3. Total Ankle Replacement

Total ankle replacement was first introduced in the 1970s by Lord and Marotte [10] in order to achieve superior results compared to Ankle fusion and overcome previously mentioned disadvantages, particularly to provide perfect ankle biomechanics and a gait cycle. Aim of the procedure is to change joint structure with an implant produced to be able to take the ankle joint's place. However, the first generation of TAR was nearly 100 percent

unsuccessful over a 10-year period. And TAR applications have been halted [11]. Since then, more than 20 TAR prostheses have been commercialized, with results nearly identical to initial designs. In 1996, Kitaoka et al. recommended "that should not be performed" in reference to TAR [12].

Figure IV: Old Generation of Ankle Implant [13].

Figure V: The Smith TA, First generation of TAs [14].

A second generation of TAR prostheses was developed in the late 1990s. In 1999, the first TAR prosthesis approved by the FDA was the Agility prosthesis (DePuy, Warsaw, IN). At the beginning of the 2010s, the FDA had approved six TAR designs [15]. In this study it is aimed to compare two FDA approved prostheses with finite element analysis in order to determine which design approach is better in biomechanic view. FEA is a golden standard procedure in testing orthopedic implants because of the possibility of high loads on implants. For example because of the location of the ankle joint, it is expected that a load of half body weight times coefficient of gravity. For example it is expected to have a load of 350N force for a 70kg weighted patient in the stance of gait. In the simulations of orthopedic implants for ankle joints, load per an ankle can be increased up to 3500N to simulate the worst case scenario[16].

Two types of TAR prosthesis exist. Two different types of prostheses are distinguished by their number of components and mobility. The first type of TAR prosthesis consists of two bearing components. The second prosthesis consists of three moveable bearing components. Which is superior? The initial query comes to mind. The majority of TAR prostheses globally consist of three movable components. However, in the United States (the largest market for TAR prosthesis), two component fixed bearing models use more. There is no exact clinical evidence that one has advantages over another at this moment. [17].

Figure V: Modern Ankle Replacement Models. Comprises metallic Tibial and Talar Components as well as a polymer Tibial Insert in order to function as a joint either attached to tibial component (A) or articulating with other components (B) [13].

II. MATERIAL AND METHODS

2.1. Finite Element Analysis

An important function of finite element analysis is to analyze the characteristic features of complex structures and/or components. In the 1970s, FEA was first utilized in orthopedics to analyze bone stress. Since then, FEA has been utilized extensively to study the stress, deformation, and micromotion of various tissues and orthopedic implants [18].

By means of a meshing technique, the structure to be tested is divided into small parts as part of the FE operation. The term finite elements is derived from this application. Each element has its own unique characteristics, which are reflected in the element stiffness matrix. This matrix contains characteristics of the elements, such as material and geometric characteristics, that influence the resistance to external forces [19]. If displacements of the structure are determined using solid mechanics, the structure's orientation can be determined [20].

2.2. Computer Aided Design

This study analyzes prosthesis designs created with SolidWorks Software (Dassault Systèmes SOLIDWORKS Corp.). Dimensions are drawn using the literature as a guide. The tibial inserts and talus components remain the same due to a lack of knowledge. Due to this circumstance, the primary objective of this study is to compare two distinct design techniques for two commercially available prosthetic tibial components.

Figure VI: Dimensions that have been authorized as a schematics of geometrical elements of designs as design guidelines for the study [21].

Table I: Dimensions that are established as guidelines for study designs [21]. TNG: total number of geometries. Parameters of designs are in bold font.

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Figure VIII: Design of second prosthesis tibial component that contains peg grip.

Figure IX: Tibial insert design.

Figure X: Talus (Talar) component.

Figure XI: Assembled model of bar design. (Red - Tibial Component, Green - Tibial Insert. Blue - Talar Component)

Figure XII: Assembled model of peg design. (Red - Tibial Component, Green - Tibial Insert. Blue - Talar Component)

SolidWorks 2016 x64 Edition SP05 was used for the creation of these designs. SolidWorks is the market-leading CAD software [22]. The 2016 model is chosen because of its improved stability. Dimensions gathered from published sources for designs (see Figure: VI and Table: I).

2.3. Finite Element Analysis of Designs

Assembled designs transferred into the simulation tool of SolidWorks in order to complete FEA.

2.3.1. Material Properties

Literature-based expertise was utilized to select the materials for the TA prosthesis complex. In the third and fourth generations of TAR designs, tibial components are manufactured from the implant-grade alloy Ti6Al4V. To imitate currently available TA prostheses, ultra high molecular weight polyethylene (UHMWPE) is used for the tibial component and Co-Cr alloy is chosen for the talar component (for material parameters, see Table I) [23].

Table II: Material Properties of ankle prosthesis complex.

2.3.2. Fixed Geometry

In the fixation step, an attempt is made to simulate the gait stance. The lateral faces of components and the tibial insert are fixed for this purpose. Additionally, components' superior and inferior surfaces are fixed. Because these surfaces are attached to the tibia and talus bones of the ankle complex, there are no motions or forces expected in these directions.

Figure XIII: Fixed geometries of bar design.

Figure XIV: Fixed geometries of peg design.

2.3.3. Force Features

To imitate the stance of gait, forces are applied in the -x direction, parallel to the acceleration of gravity. The forces ranged from 2000N to 3500N and increased by 500N each time. To replicate the worst-case scenario, force ranges are used to simulate a patient weighing 70 kg multiplied by approximately 3 to 5 [21].

Figure XV: Direction of the force shown with purple arrows for bar design.

Figure XVI: Direction of the force shown with purple arrows for peg design.

2.3.4. Mesh Alignment

It is stated that meshing is one of the most important operations in FEA. SolidWorks Simulation Tool, software used for FEA in this study, offers a setting for mesh density. Mesh density set as the finest possible option (see figure XXIII-XXIV for mesh details).

Table III: Mesh Details of Designs.

Figure XVII: Meshed status of bar design.

Figure XVIII: Meshed status of peg design.

III. RESULTS AND DISCUSSION

3.1. Results

FEA data from two sources are compared. The first is Von Mises stress, whereas the second is URES. The Von Mises stress is used to illustrate whether or not a material will yield or fracture. It is widely used for ductile materials such as metals (as used in the designs.). Second, URES is the structural displacement that expresses deformation.

There were a total of six FEA tests conducted, three for each of the two designs.

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Figure XXVII: URES of peg design in 3000N load.

Figure XXVIII: Von Mises stress of peg design in 3500N load.

Figure XXIX: URES of peg design in 3500N load.

3.2. Discussion

Our investigation revealed that the design approaches of tibial components have a substantial effect on the prosthesis' deformation and stress. Consequently, study of design strategies is essential. Peg design yielded the highest URES and Von Mises values. This result indicates that bar design is more durable than peg design.

It is found in the literature that dimensions of designs have noticable changes on stress and deformation values. Yu et al. proved that if radius, length and distance between bars increase, peak micromotion of the bar design prosthesis increases as well. Thus, if the radius and length of each peg increase, peak micromotion increases too [16].

The knowledge that is obtained in this study can lead to a unique design of a TAR prosthesis as a future study.

REFERENCES

[1] Castro MD. Ankle biomechanics. *Foot Ankle Clin.* 2002;**7**(4):679–93. Dec.

[2] Hirsch, B. E., Udupa, J. K., Siegler, S., & Winkelstein, B. A. (2009). *The application of 3D image processing to studies of the musculoskeletal system. MIPPR 2009: Medical Imaging, Parallel Processing of Images, and Optimization Techniques.* doi:10.1117/12.851181

[3] Silver, F. H., & Glasgold, A. I. (1995). *Cartilage Wound Healing: An Overview. Otolaryngologic Clinics of North America, 28(5), 847–864.* doi:10.1016/s0030-6665(20)30463-1

[4] Valderrabano, V., Nigg, B. M., von Tscharner, V., Stefanyshyn, D. J., Goepfert, B., & Hintermann, B. (2007). Gait analysis in ankle osteoarthritis and total ankle replacement. *Clinical Biomechanics*, *22*(8), 894-904.

[5] Roon, A. J., Moore, W. S., & Goldstone, J. (1977). Below-knee amputation: A modern approach. The American Journal of Surgery, 134(1), 153–158. doi:10.1016/0002-9610(77)90299-9

[6] Colombo, G., Rizzi, C., Regazzoni, D., & Vitali, A. (2018). *3D interactive environment for the design of medical devices. International Journal on Interactive Design and Manufacturing (IJIDeM), 12(2), 699–715.* doi:10.1007/s12008-018-0458-8

[7] Albert E. Beitrage zur operativen chiurgie. Zur resection des kniegelenkes. Wien Med Press. 1879;20:705-708.

[8] Raikin, S. M., Rasouli, M. R., Espandar, R., & Maltenfort, M. G. (2014). Trends in treatment of advanced ankle arthropathy by total ankle replacement or ankle fusion. *Foot & Ankle International*, *35*(3), 216-224.

[9] Stapleton, J. J. (2011). Management of diabetic neuropathic foot and ankle malunions and nonunions. *Diabetic Foot & Ankle*, *2*(1), 6287.

[10] Lord G, Marotte JH. Total ankle prosthesis. Technic and 1st results. Apropos of 12 cases [in French]. Rev Chir Orthop Reparatrice Appar Mot. 1973;59:139-151.

[11] Marotte JH, Lord G. Total ankle replacement [in French]. Revue de chirurgie orthopedique et réparatrice de l'appareil moteur. 1980;66:527-530.

[12] Kitaoka HB, Patzer GL. Clinical results of the Mayo total ankle arthroplasty. J Bone Joint Surg Am. 1996;78: 1658-1664.

[13] Gougoulias, N. E., Khanna, A., & Maffulli, N. (2009). History and evolution in total ankle arthroplasty. *British medical bulletin*, *89*(1), 111-151.

[14] Vickerstaff, J. A., Miles, A. W., & Cunningham, J. L. (2007). A brief history of total ankle replacement and a review of the current status. *Medical engineering & physics*, *29*(10), 1056-1064.

[15] Park JS, Mroczek KJ. Total ankle arthroplasty. Bull NYU Hosp Jt Dis. 2011;69:27-35

[16] Yu, J., Zhang, C., Chen, W. M., Zhao, D., Chu, P., Wang, S., ... & Ma, X. (2020). Finite-element analysis of the influence of tibial implant fixation design of total ankle replacement on bone–implant interfacial biomechanical performance. *Journal of Orthopedic Surgery*, *28*(3),

[17] Daniels, T. R., Younger, A. S., Penner, M., Wing, K., Dryden, P. J., Wong, H., & Glazebrook, M. (2014). Intermediate-term results of total ankle replacement and ankle arthrodesis: a COFAS multicenter study. *JBJS*, *96*(2), 135-142.

[18] Huiskes, R. and E. Y. S. Chao (1983). "A survey of finite element analysis in orthopedic biomechanics: The first decade." Journal of Biomechanics 16(6): 385-409.

[19] Hutton, D. V. (2004). Fundamentals of finite element analysis. Boston, McGraw-Hill (ISBN: 0072395362 (acid-free paper) 0071122311 (ISE)).

[20] Bhavikatti, S. S. (2005). Finite Element Analysis, New Age International (P) Limited, Publishers (ISBN: 9788122415896).

[21] Yu, J., Zhang, C., Chen, W. M., Zhao, D., Chu, P., Wang, S., ... & Ma, X. (2020). Finite-element analysis of the influence of tibial implant fixation design of total ankle replacement on bone–implant interfacial biomechanical performance. *Journal of Orthopaedic Surgery*, *28*(3), 2309499020966125.

[22] SolidWorks, D. S., Street, W., & Waltham, M. (2015). SOLIDWORKS 2016. *Online help, Accessed*, 03-20.

[23] Elliot, B. J., Gundapaneni, D., & Goswami, T. (2014). Finite element analysis of stress and wear characterization in total ankle replacements. *Journal of the mechanical behavior of biomedical materials*, *34*, 134-145.

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