Development and Manufacturing of Flexible Lightweight Walker for Fractured Foot

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Abstract. This study includes two main parts. The first part encompasses the manufacturing process; we made two types of AFO’s modified static AFO and adjustable hinge AFO. The materials used in manufacturing are polypropylene and steel. Fabrication is done using a vacuum molding technique. An ankle orthosis test for a patient who suffers from ankle fracture caused by a sports injury. The second part of the research involves testing with dynamic gait analysis on the treadmill and F-Socket. Besides, the analysis of the AFO’s models is illustrated to determine the fatigue safety factor and the analysis of the Von-Mises stress. Also, the results of the gait cycle (GRF, Pressure distribution, Center of Pressure (COP), Candace, Stride length, and footprint analysis) used to show the significant difference between the pathological subjects and normal person who are wearing ankle-foot orthoses (AFO’s) compare with a normal subject (healthy person). Measuring the interference (pressure and force) between the legs with AFO’s area of contact for all subjects then using this data for analysis of the mathematical models by used ANSYS V.15 software. Where it shows that the highest stress concentration in the ankle joint region, where the stress reached 418.9 MPa, the safety factor is 2.4 in adjustable hinge AFO, and for modified static AFO (192.8 MPa), the safety factor (0.447). On the other side, a questionnaire was conducted for a certain number of patients to find the difference between the manufactured models, to know the acceptance by the patient for AFO’s.

Keywords. AFO, Lightweight walker, Fractured foot, GRF, COP.

1. Introduction

The orthosis is an external device used to restrict or assist the movement by supporting, aligning, and protecting body parts. Orthotics can enhance the body’s moving function and prevent or correct deformity. The orthosis is a medical device that is used externally to restore or improve the functional and structural properties of the musculoskeletal system and the nervous system. It is designed to support, supplement, or augment the function of a limb or part of the body. Lower limb orthosis is a device that is applied or attached to the lower part of the body to improve its function by controlling movement, providing support by stabilizing the gait, reducing pain by transferring the load to another area, correcting elastic deformities, and preventing the development of fixed deformities. [1]. The fracture ankles are commonly referred to as a broken ankle, which means that one of more than one of the bones that make up the ankle joint has been broken. Fractures range from simple fractures of a single bone, which may not prevent people from walking, to multiple fractures, which can push the ankle out of place and may require the person to bear his/her weight on the ankle for a few months. The more broken bones a person has, the more stable the ankle will be. Ligaments, which hold the
joints and ankle bones in their correct position, may also be damaged. People of all ages can be affected by ankle fractures. Over the past three or four decades, doctors have discovered an increasing number and severity of ankle fractures, especially for active and older people [2]. The foot is controlled by two joints, the ankle joint, and the subtalar joint. The ankle joint is the joint between the ankle and the shin, and the sub-ankle joint is between the ankle and the heel [3].

2. Experimental work

2.1. Case study
Kinematic and kinematic information were collected for two young men. The first was around 26 years, 168 cm in height, and 69 kg weight. The patient was wearing two types of AFO orthoses with the lower-left limb, while the second man was in a healthy case, and his age was about 24 years, 168 cm in height, and 62 kg weight. Figure 1a shows that the ankle joint consists of three different bones: the shin bone (tibia), the smaller bone in the lower leg (the fibula), and the small bone that lies between the heel bone, the fibula, and the tibia (the ankle). Doctors often classify the fracture based on the area where the fracture occurs. There are often two joints when a fracture occurs, as shown in Figure 1b, the ankle joint, where the ankle, fibula, and tibia meet, and the syndactyly joint, which is located between the fibula and the tibia and is joined together by ligaments. However, several straps are required to stabilize the ankle joint [2].

![Figure 1](image.jpg)

Figure 1. A case study: (a) Anatomical picture, (b) X-Ray image for a fracture [2].

2.2. Materials used
The materials required to build the models in this study are:
- Materials for Jepson.
- Perlon stockinet white (Ottobock health care 623T3) that is used for covering the Jepson.
- Polypropylene.
- Hinge made of steel.

2.3. Manufacturing steps
The fabrication and measurement were performed according to the ICRC physical rehabilitation center for ankle-foot orthosis to a person with a fractured ankle [4]. Figure 2 demonstrates the main steps for model manufacturing.
2.4. Testing the AFO model

The testing includes two parts: the gait-cycle test by using dynamic gait analysis on the treadmill, and the other test is based on the F-socket system for measuring the interference pressure. The tests are divided into two cases, normal and pathological.

2.4.1. Gait-cycle and ground reaction force test. The gait cycle was analyzed at the University of Babylon/Sport Education College, on a force plate treadmill (Zebris, FDM – T), as shown in Figure 3. The obtained data were compared with the right leg, which was defective with the left as a normal leg (stance and swing phase). The gait-cycle behavior is shown in Figure 4. The ground reaction force exhibited the difference between the gait pattern for both right and left legs. Also, the pressure distribution under the sole was measured when a patient wears his shoe on both feet.

![Figure 3. The force plate treadmill.](image)

![Figure 4. The patient walks onto the force plate.](image)
output signal through a multi-meter instrument, which is interfaced with the computer. The data was recorded over time, as shown in Figures 5 and 6.

![Figure 5](image1.png)  ![Figure 6](image2.png)

(a) Adjustable hinged AFO.  (b) Modified static AFO

**Figure 5.** The F-socket sensor between the leg and calf.  **Figure 6.** The F-Socket pressure system.

3. Numerical modeling

The finite element analysis (FEA) is commonly used for engineering and science applications, taking advantage of the rapid development of high memory capacity, digital computers, and fast computing. Due to its capabilities, which include complex geometrical boundaries and nonlinear material properties, FEA is recognized as one of the most significant numerical methods. Throughout this study, finite element analysis has been used as a numerical method with the help of ANSYS Workbench V.15 software to demonstrate the effect of fatigue performance on a structural feature to assess the behavior of total deformation behavior of stress, total distortion, and safety factor [5]. By using ANSYS, the general analysis includes three distinct stages which are:

- Constructing the model geometry.
- Apply the load limiting conditions and obtain the solution.
- Checking the results.

3.1. Building the geometry

In this research, there are two types of ankle-foot orthosis (AFO) models, only plastic and plastic-metal. The procedure of using the ANSYS Workbench program for the plastic-metal model will be used as a case study in this research to simplify the demonstrating of the primary ANSYS process, which is modeling, meshing method, and applying loads. This model was drawn using CAD software (Solid-work version 2016), as illustrated in Figure 7. The model was built according to an original 3D model, where most of the details on those models were taken into consideration in the sketching.

![Figure 7](image3.png)

**Figure 7.** Solid-work models of the two-type adjustable hinged and modified static AFO.
3.2. The geometry determination
In this paper, two primary materials are used for ankle-foot orthosis (AFO) (as shown in Table 1 and Figure 8. Figure 9 illustrates the AFO models used in ANSYS-Workbench V.15. This model was drawn using SolidWorks according to the original 3D prototype, and most of the small details have been taken into consideration when drawing this model.

3.3. Define the types of elements and meshing
The element type of solid, Brick 8 node 45 is used; a solid 45 is used for the 3D modeling of the solid structures. The element is known as 8 nodes with 3 degrees of freedom in each one, translations in the directions of nodes (x, y, z) [6]. The meshing process was done by choosing the size, then the shape of the element was chosen as a tetrahedron (automatic mesh), as shown in Figure 10.

| Material       | σy (MPa) | σult (MPa) | E (GPa) |
|----------------|----------|------------|--------|
| Polypropylene  | 27.20    | 37.30      | 1.24   |
| Stainless Steel| 792      | 820        | 192    |

**Figure 8.** S-N curves for: (a) steel [7], (b) polypropylene [8].

**Figure 9.** Types of AFO models used in this work.
3.4. Defining the analysis type and applying load
The load expression includes boundary conditions (constraints, supports, location of applied load & boundary field specification), and the other internally and externally applied loads. The load used in ANSYS Workbench V.15 will be a fixed prop on the AFO side heel segment [9]. The interface pressure was distributed at specific positions by a value taken from the interface pressure test for adjustable hinged AFO started from zero to 277 kPa. The interface pressure for the modified static AFO started from zero to 240.32 kPa, as shown in Figure 11. The fatigue tool is used to find the equivalent stress and safety factor. The other solutions include deformation, stress, strain, etc.

4. The results and discussion
The patients were tested in dynamic gait analysis on the treadmill and f-socket. The walking program will analyze the results and convert them into values and curves.
4.1. Gait cycle & GRF test

The data obtained from the gait-cycle test were compared between the two conditions (healthy and pathological) to recognizing the main difference between the parameters of the left and right legs. The comparison results obtained for the normal case are shown in Figure 12, and the pathological case study is shown in Figure 13. Moreover, Figure 14 and Table 2 show the difference between the left and right feet for the three cases. The difference can be detected as in the stance phase percent for the left leg is 68.4% and for the right leg is 72.0% when an adjustable hinged AFO, left leg is 67.7%, and the right leg is 70.0% for a modified static AFO, while the normal case is 70.4% and (8.4 %, respectively. Table 2 shows significant differences between both cases, the difference between the left and right foot of change stance phase, change load response, change pre-swing, change swing phase, total double support, stride length, stride time, and cadence was 2, 0.4, 2, 0.3, 2 and 38.7 %, respectively in the normal case, but in the pathological subject of wearing adjustable hinged AFO, the results were (3.6, 8.2, 4, 8.3, 3.6 and 40.5 %, when the patient wearing a modified static AFO the results well be 2.3, 2.7, 2.1, 2.8, 2.3 and 37.9 %. The ground reaction force to the normal and pathological case for the left leg; also, the effect of wearing the AFO on the right foot can be seen in Figures 15,16 and 17, respectively. Regardless of the size of the GRF, which depends on the weight of the subject, the discussion will be supported by the behavior of the GRF curve. This curve can be divided into three parts. The first part from the beginning to the first peak represents the heel strike, the second part of the curve is the mid-posture stage and distributes the body’s load over the entire foot area, and the third part is considered from the first-second climax that is equivalent to the toe outside the stage. All of these GRFs occurred during the standing phase. The pressure distribution for the normal and pathological cases for the left and right lower limb is represented in Figures 18,19 and 20, respectively. There is a sufficient difference at the initial curve as a sudden valley in the normal case, which is due to the distribution of the load under the subject’s heel of his shoe. Simultaneously, it is not clear at the pathological case, and this is related to the using of the patient’s heel in a gradual manner. The butterfly form refers to the abduction and adduction between the feet through the ambulation, as explained in Figures 21, 22, 23 and 24, representing the contour of pressure distribution in three dimensions for normal and pathological cases, respectively. The COP path for the normal case is presented in FigureS 21,22, 23 and 24, for the right and left feet, and the butterfly form. This data shows the behavior of the COP under the foot, which started from the heel strike, mid stance, and toe-off stage. Therefore, through each of these stages, there is a maximum value of pressure.

4.1.1. The parameters of the gait cycle

| Table 2. The difference result between left and right foot on gait analysis. |
|----------------------------|----------------------------|-----------------|
| Change Foot rotation (degree) | Normal Subject | Adjustable hinged AFO | Modified static AFO |
| Change Step Length (cm) | 2 | 5 | 7 |
| Change Step time (sec) | 0.03 | 0.07 | 0.01 |
| Change stance phase (%) | 2 | 3.6 | 2.3 |
| Change load response (%) | 0.4 | 8.2 | 2.7 |
| Change single support (%) | 2 | 4 | 2.1 |
| Change pre-swing (%) | 0.3 | 8.3 | 2.8 |
| Change swing Phase (%) | 2 | 3.6 | 2.3 |
| Total double support (%) | 38.7 | 40.5 | 37.9 |
| Stride length (cm) | 88 | 97 | 93 |
| Stride time (sec) | 1.47 | 1.59 | 1.56 |
| Cadence, (strides/min) | 41 | 38.4 | 39 |

Sample of calculation:
The difference between left and right foot = Result of left - result of right = 21.3 - 19.4 = 1.9
Figure 12. The gait cycle parameters for the normal case.
Figure 13. The gait cycle parameters for the pathological case wearing adjustable hinged AFO on his left leg.
Figure 14. The gait cycle parameters for the pathological case wearing modified static AFO on his left leg.
4.1.2 The Ground Reaction Force (GRF) for all cases.

**Figure 15.** The GRF (left and right) for the normal case.

**Figure 16.** The GRF (left and right) for pathological case wearing adjustable hinged AFO.
Figure 17. The GRF (left and right) for pathological case wearing modified static AFO.

4.1.3. The pressure distribution through the gait cycle for all cases.

Figure 18. The pressure distribution (left and right) for the normal case.
Figure 19. The pressure distribution (left and right) for pathological case wearing adjustable hinged AFO.

Figure 20. The pressure distribution (left and right) for pathological case wearing modified static AFO.
4.1.4. The Center of pressure path (COP) for all cases.

| Butterfly Parameters          | 15-02-2009 Gait Analysis |
|-------------------------------|--------------------------|
|                               | Left                     | Right                    |
| Gait line length, mm          | 256±13                   | 268±10                   |
| Single support line, mm       | 93±16                    | 94±17                    |
| Ant/post position, mm         |                          | 135                      |
| Ant/post variability, mm      |                          | 5                        |
| Lateral symmetry, mm          |                          | -2                       |
| Lateral variability, mm       |                          | 10                       |

Figure 21. The footprint for (a) normal case, (b) pathological case wearing adjustable hinged AFO, and (c) pathological case wearing modified static AFO.

Figure 22. The gait cycle butterfly parameters for the COP path in the normal case.
4.2. Interface pressure test

Only pressures during the gait cycle are considered by the patient contact method and AFO in the calf area. The data were normalized to 100% of the gait cycle [9]. The pressure for people to accept...
weight varies from patient to patient. In this test, the interference pressure and force between the leg and calf inside orthosis were measured; the experimental part of this case study with ankle fracture damage due to a sport injury, the results showed that the maximum value of the interface-pressure between the AFO and the patient’s leg was recorded in the upper part of the adjustable hinged AFO (277 kPa) and decreasing in the direction of the lower part of the AFO, for modified static AFO is 240.32 kPa. Figure 25. Figure 26 illustrates that the maximum applied force on the leg is 111.2 N for adjustable hinged AFO and 79.8 N for modified static AFO.

![Graph](image)

**Figure 25.** The interference pressure between the left leg and AFO’s model.

![Graph](image)

**Figure 26.** The interference force between the left leg and AFO’s model.

### 4.3 Results of the numerical model

AFO model analysis was normalized by FEM software to calculate the equivalent stress (Von-Mises) and safety factor for fatigue. According to Von-Mises theory, which regards the yield pressure as a standard:
(σe < σy, safe), (σe = σy, critical) and (σe > σy, failed).

Where (σe) is the equivalent stress, and (σy) is the yield stress. Safety-factor for fatigue will be safe in design if the value is around or more than 1.25 [10].

4.3.1 Adjustable hinged AFO model. The Von-Mises stress and the safety factor for the adjustable hinged AFO model are depicted in Figure 27.

![Figure 27](image)

(a) The result of the adjustable hinge analysis AFO: (a) The equivalent stress (Von-Mises) (b) Safety factor.

4.3.2 Modified static AFO polypropylene model

The Von-Mises stress and a safety factor for the modified static model are shown in Figure 28.

![Figure 28](image)

(a) The result of modified static analysis AFO in (a) The equivalent stress (Von-Mises) (b) Safety factor.

4.4 Patient’s opinion

The study was made for ten patients suffering from sports injuries, drop foot, and ankles injuries. This study was done at Jalinous medical institute and Baghdad Center for prostheses and medical supports. They wore AFOs and tested by walking continuously on a specially designed path with a length of
three meters. After that, a survey was introduced to evaluate their experience considering the feeling of the weight of the AFO’s, besides the level of comfort and the outer appearance. In this study, a comparison was made between two AFO models in Figure 29. The pie chart shows that the percentage of weight comparison of modified static is 67% greater than the other model; this is due to the material and thickness of the used sheet, Figure 30. The same model is taking advantage of comfortability on walking with a percentage of 42% comparing with other models. For the last comparison, see Figure 31. Models are having approximately near value but modified static is very optimizing.

![Figure 29. The weight comparison.](image)

![Figure 30. The comfortability comparison.](image)

![Figure 31. The appearance comparison.](image)

5. Conclusions
From the above results, the following points can be concluded:

1. The comparison process between the normal and pathological cases in the gait cycle test showed significant differences between the two cases, related to the circumduction.
2. The gait-cycle test results show significant differences between the two conditions. For example, the difference between the left and right foot of change stance phase, change load response, change pre-swing, change swing phase, total double support, stride length, stride time, and cadence was 2, 0.4, 2, 0.3, 2, and 38.7 % respectively in the normal case, but in the pathological case of wearing adjustable hinged AFO, the results were 3.6, 8.2, 4.8, 3.6 and 40.5 %, when the patient wearing a modified static AFO the results were 2.3, 2.7, 2.1, 2.8, 2.3 and 37.9 %.

3. The Mat-Sean sensor used for measuring the interface pressure and force is suitable for the alternating load between the calf and the leg of the patient.

4. The max interface pressure result is 277 kPa for adjustable hinged AFO, and for the modified static AFO is (240.32 KPa).

5. The modified static AFO, the polypropylene type, showed a failure to design fatigue life when the safety factor value was approx 0.447.

6. The adjustable hinged AFO gave satisfactory results in the fatigue analysis (equivalent stress and safety factor), and these results demonstrated in more extended life design. This type of AFO is recommended for a limited type of patient, depending on their weights, due to the concentration of forces between stainless steel hinge areas and the patient’s foot, causing patient discomfort.

7. The survey results showed the modified static AFO is getting the best reviews in terms of weight, appearance, and comfort, compared with the adjustable hinge AFO.

### Abbreviations

| Symbol | Abbreviation                  | Symbol | Abbreviation                  |
|--------|-------------------------------|--------|-------------------------------|
| COP    | Center of pressure            | AFO    | Ankle foot orthosis           |
| E      | Modulus of elasticity (GPa)   | KAFO   | Knee ankle-foot orthosis      |
| FEM    | Finite element method         | P&O    | Prosthesis and orthosis       |
| GRF    | Ground reaction force         | σ_y    | Yield stress (MPa)            |
| PP     | Polypropylene                 | σ_ult  | Ultimate stress (MPa)         |

### References

[1] Yasmeen A Mohammed 2008 *The Role of New Technology in Designing and Fabrication of Orthosis and Prosthetics* (M.Sc. Thesis, Zagazig University)

[2] https://www.rehabmypatient.com/ankle/ankle-fracture.

[3] O P Chen J, Siegler S and Schneck CD 1988 *The Three-Dimensional Rinematics and Flexibility Characteristics of the Human Ankle and Subtalar Joint Part II: Flexibility Characteristics* (J Biomech Eng.) vol 110 pp 374–85

[4] International Committee of the Red Cross 2006 *Manufacturing Guideless*

[5] Kadhim K Resan, Ali H, Al Hili and Muslim Muhsin Ali 2011 *Design and Analysis of a New Prosthetic Foot for People of Special Needs* (the Iraqi Journal for Mechanical and Material Engineering) vol 11 no 2

[6] ANSYS Program Help Version 15

[7] S Lampman 1996 *Fatigue and Fracture, Properties of Stainless Steels* (ASM International Handbook) vol 19 p 1811

[8] Maier C and Calafut T 1998 *Polypropylene—the Definitive user’s Guide and Data Book* (In:Woishnis, W. (Eds.), Plastics Design Library a Division of William Andrew Inc. New York)

[9] Takhakh, Ayad Murad and Hassanein Salih Hussain 2017 *Manufacturing, Testing, and Numerical Modeling a Lower Limb Orthosis for a Patient that has a Partial Foot Amputation* (International Journal of Energy and Environment vol 8 no 4 pp347–356

[10] Shaker S Hassan, Khadim K Resan and Akeel Zeki Mahdi 2013 *Design and Analysis of Knee Ankle Foot Orthosis (KAFO) for Paraplegia Person* (Eng. & Tech. Journal) vol 31 Part (A) no 8