INTERNATIONAL JOURNAL OF
ENERGY AND ENVIRONMENT
ISSUE ON APPLIED MECHANICS RESEARCH
Volume 8, Issue 4, 2017 pp.347-356
Journal homepage: www.IJEE.IEEFoundation.org

Manufacturing, testing, and numerical modeling a lower limb orthosis for a patient that has a partial foot amputation

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Received 6 Oct. 2016; Received in revised form 26 Oct. 2016; Accepted 30 Oct. 2016; Available online 1 July 2017

Abstract
This study includes two main parts: The first part includes the process of manufacturing and testing partial foot orthosis for a patient suffering from partial foot amputation. The orthosis was manufactured from lamination Perlon-Carbon-Perlon (4-2-4) and then tested with Force plate and F-Socket. The patient was tested in two cases: the first without wearing the orthosis and the second after wearing the orthosis. The results of gait cycle test show that the gait cycle of the patient was improved dramatically after wearing the orthosis as compared with his state without wearing the orthotic.
The second part of the research involves the analysis of orthosis for all types of used materials by using the engineering analysis program (ANSYS V.15). A model of the manufactured orthosis was designed, the safety factor of fatigue and total deformation were calculated. The results of engineering analysis show the difference in safety factor between the plastic and composite materials which has a value of (4.327) in Perlon-Carbon-Prelon (4-2-4) and (4.757) in Hybrid Carbon fiber – Glass fiber, while in plastics was (1.946) in Polypropylene and (1.297) in Polyethylene. The total deformation in composite materials was much less than the plastic materials. Also the results show that Perlon-Carbon-Prelon (4-2-4) decreases in a percentage of (56.4 and 36.6) % as compared with Polypropylene and Polyethylene respectively. While Hybrid Carbon fiber – Glass fiber decreases in a percentage of (66.8 and 51.8) % as compared with Polypropylene and Polyethylene respectively.

Keywords: Partial foot amputation; Partial foot orthosis; Composite orthosis; Gait cycle; GRF.

1. Introduction

Orthosis is an external apparatus used to restrict or assist movement by supporting, aligning and protecting body parts [1]. There are various factors to consider when designing an orthosis. Manufacturers should make choices about their priorities regarding these factors (Performance, Cosmetics, Cost, Ease of use, and Size availability) [2].
Nowadays, wide selections of man-made and natural materials are used in orthotics. Whether man-made or natural, however, they should still conform to the special requirements of the profession: strength, biocompatibility, light weight, durability, and ease of manufacturing [3].
Partial foot amputation (PFA) is a comparatively popular sequel to advanced vascular insufficiency and diabetes, which is the most popular pathology underlying the need for this surgical interference. Less considerably, the causes of PFA may by trauma or be the result of frostbite, systemic disorders, or congenital anomalies [4].

Nowadays, the finite element method (FEM) is largely used in the most of fields of engineering and science. Taking the advantages of the rapid development of digital computers with large capacity of memory, as well as, fast computation [5]. In this work, a lower limp orthosis has been manufactured and tested for a patient suffering from partial foot amputation. The composite material of (4 Perlon+2 Carbon fiber+4 Perlon) layers were used for the fabrication process. Then, a numerical model has been made for the orthosis for some types of materials (See Table 1) to obtain fatigue safety factor and total deformation. Many of literature were worked on orthosis and prosthesis's design and manufacturing: Ayad M. Takhak et.al [6] worked on Knee-Ankle-Foot Orthotic vibration measurements. Muhsin J. Jwee et.al [7] worked on analysis and manufacturing of Ankle-Foot orthotic. Kadhim K. Resan [8] worked on design a foot prosthetic. Shaker S. Hassan [9] worked on analysis and design of Knee-Ankle-Foot Orthotic.

2. Experimental work

2.1 Case study

The kinetics and kinematics data were collected for a patient of (25 years old) having a weight of (75 kg) and height of (173 cm). This patient is suffering from the partial amputation of his right foot (ray amputation), amputations include the last two fingers of the foot extending to the metatarsals as shown in Figure 1. The cause of the amputation was a grenade explosion during one of the battles of the Iraqi army. The patient foot has some fragments on the foot palm up to the foot surface, as shown in the X-rays image.

(a) (b) (c)

Figure 1. Case study, (a) Anatomic image, (b) Real image, (c) X-Ray image.

2.2 Manufacturing procedure

Measurement, manufacturing, and alignment of partial foot orthosis for patient amputated through the foot were done according to ICRC's physical rehabilitation centers [10].

The manufacturing procedure will illustrate in the following steps as shown in Figure 2: 1- Taking Measurement, 2- Preparing Casting, 3- Cast Rectification, 4- Fabrication of the Soft Insert Line, 5- Preparing the Negative Gypsum Pattern, 6- Trimming and Finishing.

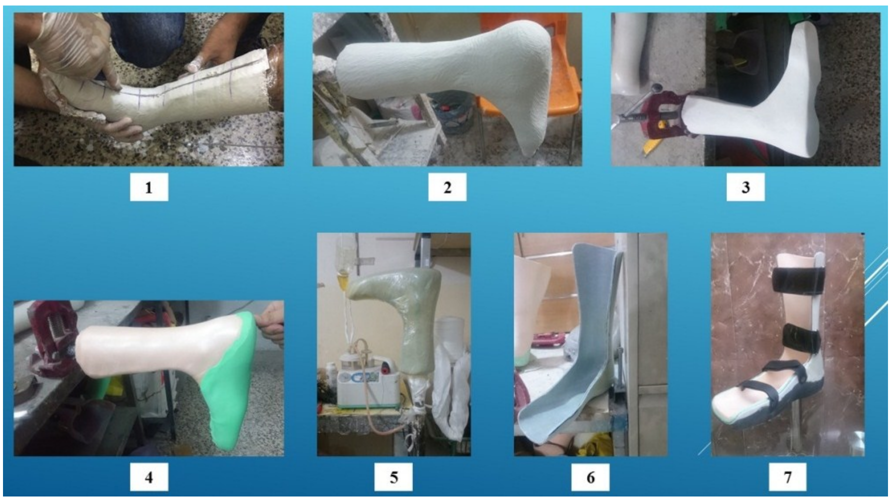

Figure 2. Manufacturing steps.

2.3 Testing the orthosis
This part includes two tests: gait cycle test and interface pressure test. The patient will submit to these tests in two cases (with PFO and without PFO).

2.3.1 Gait cycle & GRF test
Gait cycle analysis was done in the laboratories of the P&O department of Al-Nahrain University on a force plate (Tekscan's Walkway Pressure Assessment Systems).
The Walkway system gives dynamic and static gait data and barefoot force and pressure measurements over some steps using a low profile floor walkway. It is perfect for capturing multiple foot strikes during perturbed or natural gait. The ground reaction force (GRF) introduced below the sole, due to biomechanical actions on the leg during stance phase. The obtained data were compared between the defective right foot with the normal left foot. Stance and swing phase were giving the behavior of gait cycle. The GRF exhibited the difference between the gait pattern for both right and left leg, and this added to these data. The pressure distribution under the insole when the patient is wearing his shoes on both feet. The stride length, cadence and the center of pressure (COP) were collected too. Figure 3 show the patient walking on a force plate with and without PFO.

Figure 3. Patient is walking on a force plate.

2.3.2 Interface pressure test
The alternating load between patient's leg and the calf, who was wearing the PFO, was measured as pressure. The sensor type (MatScan) is more acceptable for this type of dynamic load. The interface pressure was obtained by recording the output signal of the sensor through a multi-meter instrument which is an interface with the computer and recording the data with the time. Figure 4 shows the patient walking with MatScan.

Figure 4. The patient walking with MatScan.

3. Numerical modeling
Nowadays, the finite element method (FEM) is largely used in a different fields of engineering and science. Taking the advantage of the rapid development of digital computers with large memory

capacity, as well as, fast computation. This method is known as one of the most important numerical methods because of its capabilities which include non-linear material properties and complex geometrical boundaries. In this work, ANSYS Workbench V.15 software has been used as numerical tool assistance for FEM to explain the effect of the fatigue performance in a structure element. It is used to determine the behavior of fatigue life, total deformation, and safety factor [8].

The general analysis used by ANSYS has three distinct steps which are:

- Build the geometry as a model.
- Apply the boundary conditions and obtaining the solution.
- Review the results.

3.1 Building up the geometry

ANSYS Workbench V.15 deals with ACIS (.sat), solid works (.SLDPRT, .SLDASM) Mechanical desktop (.dwg), etc. The ACIS with extension (.sat) was selected for exporting process as a command in 3D Max system. Finally, the model can be imported from 3D Max to ANSYS Workbench V.15 according to its extension (.sat). Figure 5 shows the model as drowning in 3D Max

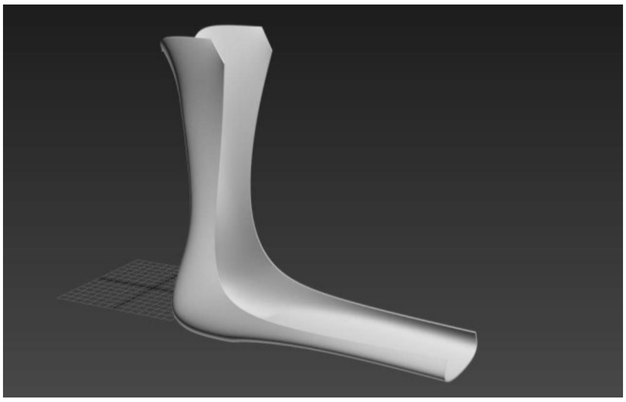

Figure 5. 3D Max model of PFO.

3.2 Determination of the geometry

In this paper, four types of partial foot orthosis (PFO) models (two plastic and two composite materials), are used as it will be explained in Table 1 and Figure 6. The model of partial foot orthosis that used in ANSYS Workbench V.15 is illustrated in Figure 7.

This model was drawn by using 3D Max program which fabricated according to an original prototype in three dimensions. Most of the small details in were taken into account at drawing this model.

3.3 Defining element types and creating the mesh in the model

In this work, the element (solid, Brick 8 node 45) was used; solid 45 is used for the 3D modeling of solid structures. The element is known by eight nodes having three degrees of freedom at each one: translations in the nodal x, y, z directions.

The meshing process has been done by volume choosing, then the shape of the element was selected as a tetrahedron (Automatic meshing), as shown in Figure 8. The number of elements was (34475 elements) and a number of nodes were (64603 nodes).

Table 1. Mechanical properties of materials used in the numerical model.

Material	Lay Up	σ_y (MPa)	σ_{ult} (MPa)	E (GPa)
Polypropylene	1	16	24	0.602
Polyethylene	1	21	32.5	0.875
P-C-P	424	41.8	79	1.778
Hybrid Cf-Gf	8	56.6	112.8	2.341

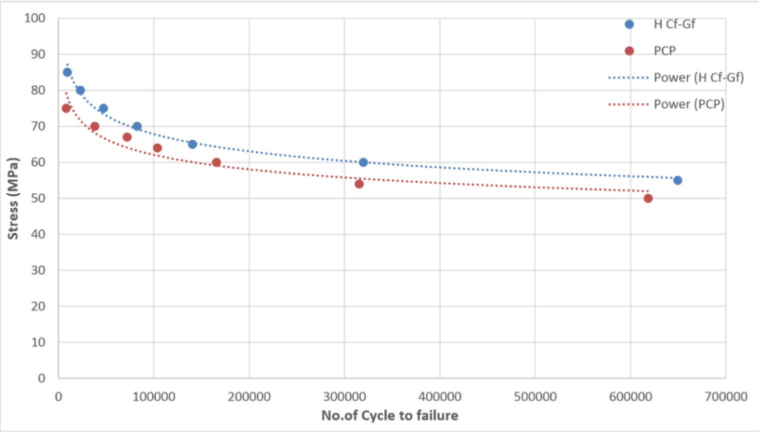

Figure 6. S-N Curves for composite materials.

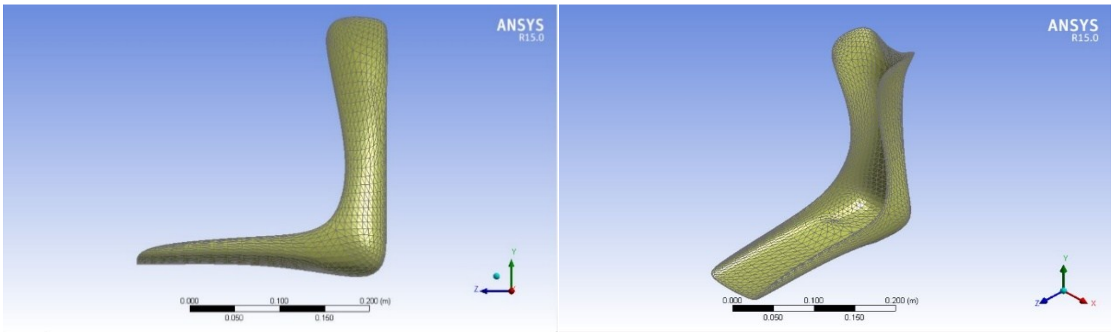

Figure 7. PFO model which used in this work.

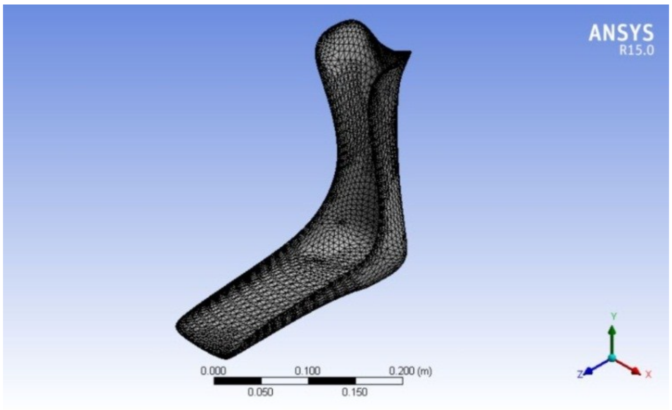

Figure 8. The model of PFO with meshing.

3.4 Defining the analysis type and applying load

The expression 'load' includes the boundary conditions (supports, constraints, and boundary field specification), as well as other internally and externally applied loads. The load used in the ANSYS Workbench V.15 software will be fixed support at the side of the PFO heel segment. The interface pressure was distributed at particular positions in a value taken from the interface pressure test (150, 100, 75, 75) KPa, as shown in Figure 9.

For fatigue solution, the fatigue tool is used to find the equivalent stress, safety factor, and life at particular loads. The other solutions include deformation, stress, strain, etc.

4. Results and discussion

4.1 Orthosis testing

After testing the patient in the Force Plate and F-Socket, walking software will analyze the results and turn them into tables and curves.

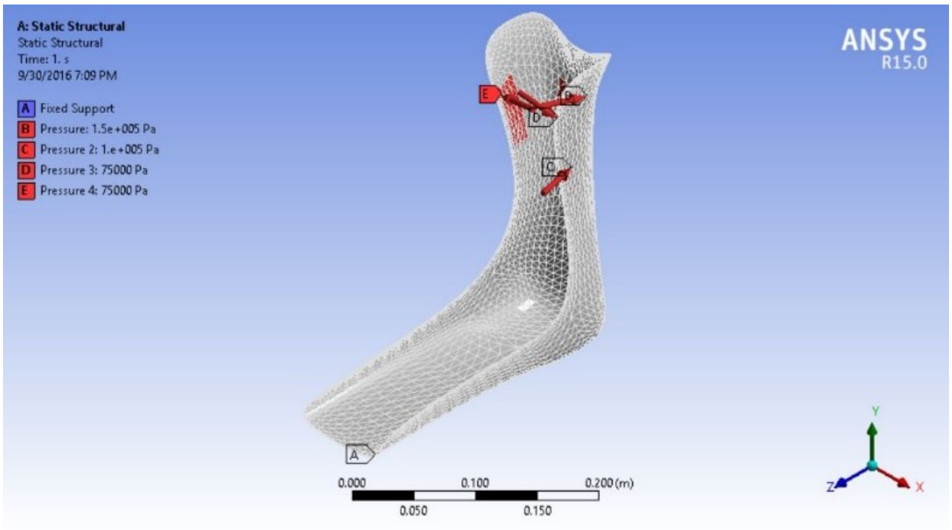

Figure 9. The model subjected to pressure load with fixed support.

4.1.1 Gait cycle & GRF test

The test includes walking two main parts: before and after wearing Partial Foot Orthosis (PFO). Table 2 shows the gait table for both cases. The results will be detailed in each case as follows:

The main parameters are shown in Tables 3 & 4 which describe the behavior of the gait cycle for patient separately as average data for one complete gait cycle from heel to heel strike. The results show that the right is different from the left foot of the patient. Table 5 describes the symmetry percentage of all data.

Table 2. Gait table.

Case 1		Case 2	
Gait table	Patient	Gait table	Patient
Number of strikes	10	Number of strikes	22
Cadence (steps/min)	27.7	Cadence (steps/min)	69.5
Gait time (sec)	12.99	Gait time (sec)	12.09
Gait distance (cm)	323.9	Gait distance (cm)	670.9
Gait velocity (cm/sec)	24.9	Gait velocity (cm/sec)	55.5
Gait velocity/Leg Length (LL/sec)	0.9	Gait velocity/Leg Length (LL/sec)	1.9

Table 3. Gait cycle table (sec).

Case 1				Case 2			
Gait cycle table (sec)	Patient			Gait cycle table (sec)	Patient		
	Left	Right	Diff.		Left	Right	Diff.
Gait cycle time	2.76	1.15	-1.61	Gait cycle time	1.31	1.27	-0.04
Stance time	1.04	0.82	-0.22	Stance time	0.83	0.81	-0.02
Swing time	1.72	0.54	-1.18	Swing time	0.48	0.47	-0.01
Single support time	0.61	0.42	-0.19	Single support time	0.44	0.44	0
Initial double support time	0.15	0.19	0.04	Initial double support time	0.16	0.18	0.02
Terminal double support time	0.18	0.14	-0.04	Terminal double support time	0.19	0.17	-0.02
Total double support time	0.35	0.35	0	Total double support time	0.35	0.35	0
Heel contact time	0.63	0.2	-0.43	Heel contact time	0.57	0.46	-0.11
Foot flat time	0.47	0.02	-0.45	Foot flat time	0.4	0.31	-0.09
Mid stance time	0.7	0.2	-0.5	Mid stance time	0.38	0.23	-0.15
Propulsion time	0.37	0.72	0.35	Propulsion time	0.25	0.33	0.08
Active propulsion time	0.22	0.41	0.19	Active propulsion time	0.11	0.16	0.05
Passive propulsion time	0.15	0.21	0.06	Passive propulsion time	0.12	0.13	0.01

Table 4. Step-stride table.

Case 1				Case 2			
Step-stride table	Patient			Step-stride table	Patient		
	Left	Right	Diff.		Left	Right	Diff.
Step time (sec)	0.13	1.82	1.70	Step time (sec)	0.83	0.79	-0.04
Step length (cm)	106.5	67.9	-38.6	Step length (cm)	43.2	78.2	35.1
Step velocity (cm/sec)	831.6	37.2	-794.4	Step velocity (cm/sec)	1.49	2.70	1.21
Step length/leg length (ratio)	3.67	2.34	-1.33	Step length/leg length (ratio)	69.0	68.4	-0.6
Maximum force (%BW)	46.5	53.6	7.1	Maximum force (%BW)	48.31	47.89	-0.43
Maximum force (kg)	32.57	37.53	4.96	Maximum force (kg)	58.2	43.5	-14.8
Impulse (%BW*sec)	46.3	63.5	17.2	Impulse (%BW*sec)	40.77	30.44	-10.33
Impulse (kg*sec)	32.39	44.46	12.07	Impulse (kg*sec)	209	207	-2
Maximum peak Pressure (KPa)	136	126	-10	Maximum peak Pressure (KPa)	0.83	0.79	-0.04

Table 5. Symmetry table.

Case 1		Case 2	
Symmetry table	%	Symmetry table	%
Maximum peak pressure (%)	92.7	Maximum peak pressure (%)	99.1
Step Time (%)	7	Step time (%)	94.9
Step Length (%)	63.8	Step length (%)	55.2
Step Velocity (%)	4.5	Step velocity (%)	52.4
Step length/leg length (%)	63.8	Step length/leg length (%)	55.2
Maximum Force (%)	86.8	Maximum force (%)	99.1
Impulse (%)	72.8	Impulse (%)	74.7
Initial double support time (%)	15.2	Initial double support time (%)	54.4
Total double support time (%)	100	Total double support time (%)	100
Heel contact time (%)	93.8	Heel contact time (%)	89.4
Foot flat time (%)	81	Foot flat time (%)	48.9
Propulsion Time (%)	31.2	Propulsion time (%)	68.1
Terminal double support time (%)	15.2	Terminal double support time (%)	54.4
Active propulsion time (%)	25.5	Active propulsion time (%)	7.7
Passive propulsion time (%)	33.1	Passive propulsion time (%)	62.0

From the comparison results obtained from the patient's data (in two cases), as shown in the tables above. The difference between the right and left foot in the gait cycle time for a patient without wearing PFO equal to (-1.61) sec but with lamination (composite material) PFO equal to (-0.04) sec. The stance and swing time differences for the patient without PFO equal to (-0.22 & -1.18) sec respectively, but with composite PFO equal to (-0.02 & -0.01) sec. The heel contact time differences between right and left foot in case of only walking on foot is a (-0.43) sec, but with wearing PFO became (-0.11) sec. In strip stride tables, the step time difference in the case of walking without wearing PFO was equal to (1.7) sec, but with PFO equal to (0.04) sec. The maximum force and peak pressure differences of the patient in the first case equal to (4.69 kg and -10 KPa), but in the second case equal to (-0.43 kg and -2 KPa).
The force and pressure distribution developed under sole due to patient gait for two feet are shown in Figures 10 and 11.
The results show that the force and pressure distribution developed under the sole was modified in case 2 as shown in figures, the PFO make that correction for the pressure and force.

4.1.2 Interface pressure test

The pressures are only considered over the gait cycle by contact method between the patients and the PFO at the calf reign. The data are normalized to 100 percent of the gait cycle. The pressure for subjects is different at weight acceptance from one patient to another. The experimental part of this case study with partial foot amputation and severing from the muscle damage due to the explosion. The results show that the maximum value of interface pressure between PFO and patent's leg is recorded at the upper part of the PFO (150 KPa) and decreased in the direction of lower part of the PFO. The reason for this behavior is that the calf muscles have more activity as comparing with the foot muscles. The pressure distribution with a percentage for a patient of the right lower limb is represented in Figure 12.

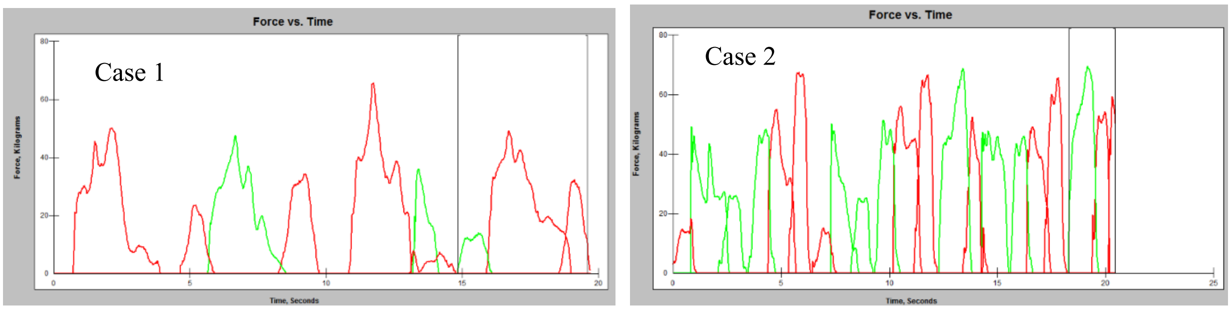

Figure 10. Force vs. time.

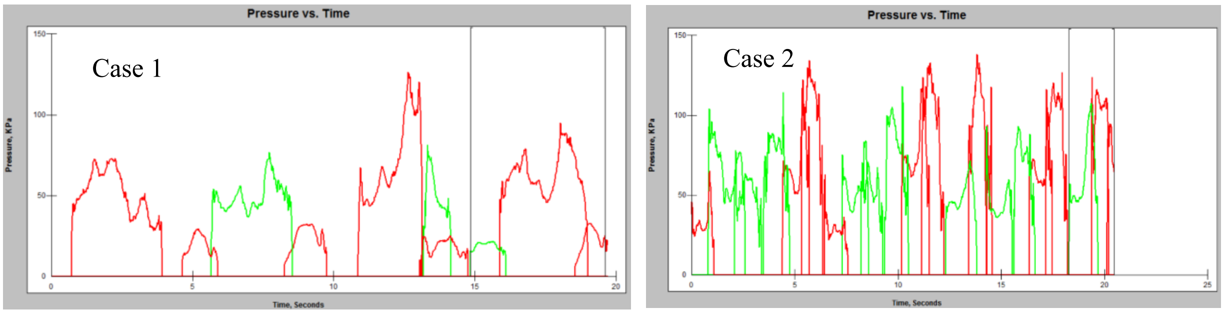

Figure 11. Pressure vs. time.

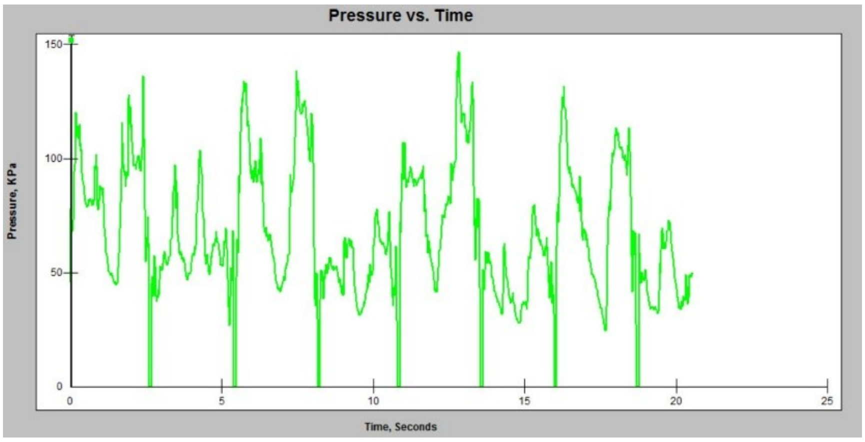

Figure 12. Pressure vs. time for F-socket.

4.2 Results of numerical model

The analysis of PFO's model was settled by FEM software to compute the total deformation and safety factor of fatigue.

4.2.1 Safety factor

The safety factor for fatigue will be acceptable in design if it equals or more than (1.25) [11]. The safety factor for both plastic and composite materials of PFO models are passed in design as shown in Figure 13. The model of composite material PFO showed that the fatigue safety factor for (4 perlon+2 carbon fiber+4 perlon) layers is about (4.327) and for (8 Hybrid Cf-Gf) layers about (4.757) which are safe in design. The model of plastic material (PP) PFO showed that the fatigue safety factor is about (1.946) which is safe also where the model of (PE) PFO model showed a fatigue safety factor of (1.297). These differences in results may be due to the change of properties of materials, where the area remains constant.

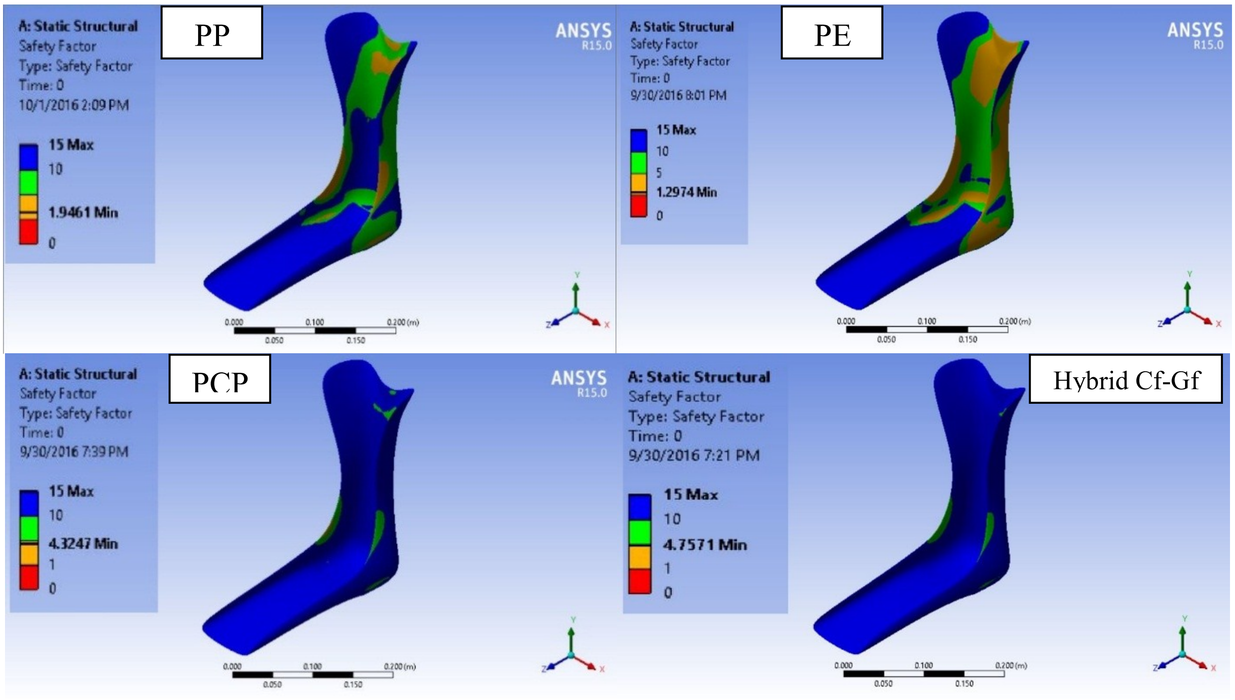

Figure 13. The safety factor of fatigue for all types of materials.

4.2.2 Total deformation

The total deformation for plastic PFO models and composite material PFO models are passed in design as shown in Figure 14.

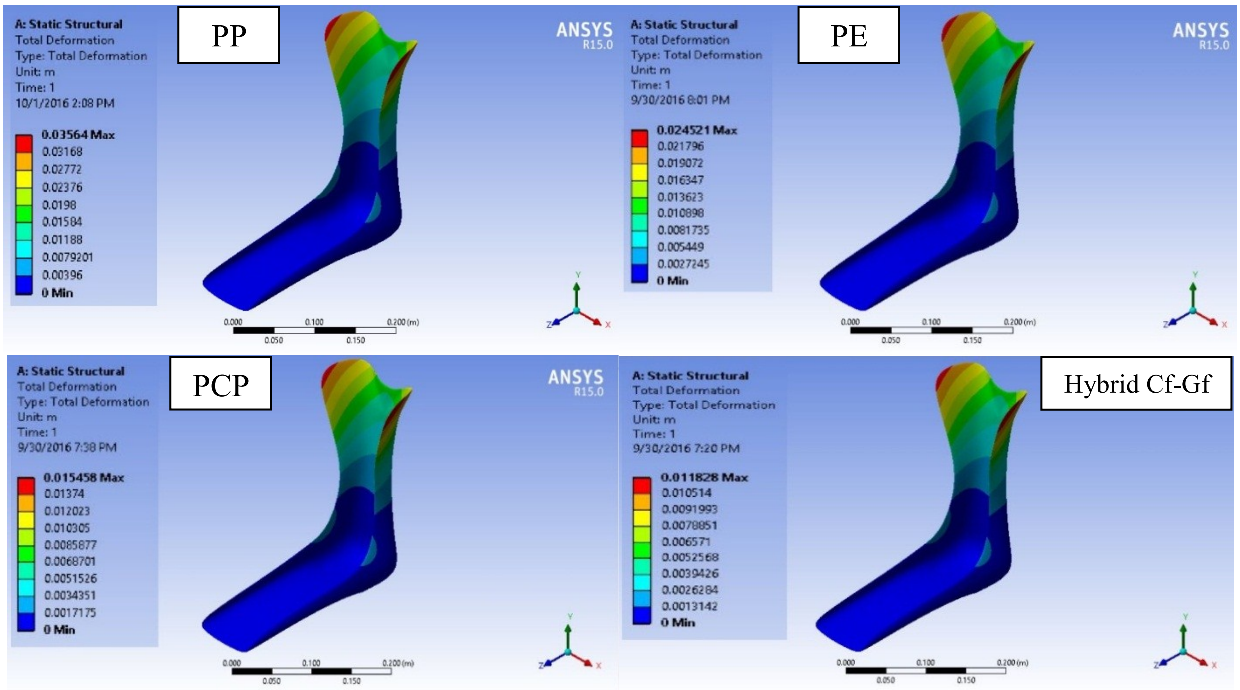

Figure 14. Total deformation of all types of materials.

The model of composite material PFO showed that the total deformation for (4 perlon+2 carbon fiber+4 perlon) layers is about (15.458 mm) and for (8 Hybrid Cf-Gf) layers about (11.828 mm).The model of plastic material (PP) PFO showed that the total deformation is about (35.64 mm) where the model of

(PE) PFO model showed a total deformation of (24.521 mm). These differences in results are due to the change in the properties of materials, where the area remains constant.

5. Conclusions

1. Manufacturing the partial foot orthosis from the composite materials reduced the cost to the patient and increased the efficiency and the lifetime of the orthosis, unlike the plastic orthosis which is affected by temperature and other conditions.
2. The results of gait cycle test show large differences between both cases. For example, the percentage of step time, step velocity, maximum force and maximum peak pressure was (7, 4.5, 86.8 and 92.7) % respectively in the case of walking without PFO, but in the case of wearing PFO, the results were (94.9, 52.4, 99.1 and 99.1) %.
3. The model of composite material PFO showed that the fatigue safety factor for (PCP 424) layers is about (4.327) and for (8 Hybrid Cf-Gf) layers (4.757) which are safe in design. For plastic material (PP) PFO showed that the fatigue safety factor is about (1.946) and (1.297) for PE which is also safe in design.
4. The composite material PFO model showed that the total deformation for Perlon-Carbon-Prelon (4-2-4) decreases in a percentage of (56.4 and 36.6) % as compared with Polypropylene and Polyethylene respectively. While Hybrid Carbon fiber – Glass fiber decreases in a percentage of (66.8 and 51.8) % as compared with Polypropylene and Polyethylene respectively.

Abbreviations

Symbol	Abbreviation	Symbol	Abbreviation
COP	Center of pressure	PP	Polypropylene
E	Modulus of elasticity (GPa)	PFA	Partial foot amputation
FEM	Finite element method	PFO	Partial foot orthosis
GRF	Ground reaction force	P&O	Prosthesis and orthosis
Hybrid Cf-Gf	Hybrid carbon fiber – glass fiber	PCP	Prelon-carbon-perlon
ICRC	International committee of the red cross	σ_y	Yield stress (MPa)
PE	Polyethylene	σ_{ult}	Ultimate stress (MPa)

Acknowledgment

This work was carried out under the supervision of Asst. Prof. Dr. Ayad Murad Takhakh to whom the author wishes to express his sincere appreciation for his help, discussion and criticism during the execution of the work described in this article. I would like to express my thanks to Saif Mohammed for giving me a helping hand.

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