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Modular socket system versus vacuum technique in trans-tibial prosthetic socket

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Abstract
Below knee socket manufactured by fast process (working time does not exceed two hours) called Modular Socket System (MSS) that applied direct laminated of 4 carbon layers, The mechanical properties were compared with the available process in Iraq (working time exceed weeks) this is called Vacuum that applied 8 layers of perlon. Materials were subjected to tensile, creep (50°C).Creep test data were analyzed to obtain creep compliance by standard linear solid. Failure characteristics at room temperature, at (50° C) were determined by fatigue testing. Interface pressure was calculated using F-Socket, ANSYS was used to determine safety factor and total deformation. MSS process has high strength at rate 510% and young modulus at rate 263%, and creep compliance reducing at rate87%. MSS has highest fatigue limit, the safety factor of groups A and B decreased at rate (5.6%, 58.5%) respectively with the temperature effect and the total deformation decreased at rate 72%.

Keywords: Socket; Modular; Vacuum technique; Amputation; Interface pressure; ANSYS.

1. Introduction
An Artificial limb is often used as a cosmetic form for an appearance and to restore functional activity to persons having lower limb amputation. Below Knee (BK) prostheses are typically composed of four major components as shown in Figure 1[1], these are:
(1) Socket
(2) Pylon (shank)
(3) Foot prosthetic
(4) Couplings
The coupling between the residual limb (stump) and the prosthesis is typically achieved by a socket, this surrounds the residual limb and by which the remaining components of the prosthesis are coupled [2].
The socket is the interface between the patient's body and an artificial limb. This interaction between stump and socket causes pain, discomfort and damage of soft tissue to a person wearing the artificial limb .At the ancient, the manufacturing of prosthetic socket has depended on the experience of prosthetists [3].
Advances in prosthetics and orthotics have always been achieved as a result of advances in other fields**.**
In his study Mustafa Tariq et. al [4], Studied the temperature effect on prosthetic socket made of different composite materials during the gait cycle of the amputee in hot climate countries . Ramesh K. et. al [5], Manufactured below knee prosthetic sockets (trans tibial) by using vacuum molding technique, in this research five types of fibers were used for reinforced [perlon , glass, carbon, amalgam (carbon and

glass) and amalgam (carbon and glass) with silica elements] and the matrix material is Epoxy. Peter V.S.L.et. al [6], Investigated a low-cost and low-skill dependent manufacturing process called pressure casting technique (PCAST) to manufacture and fit trans tibial (TT) prosthetic sockets in a developing country.

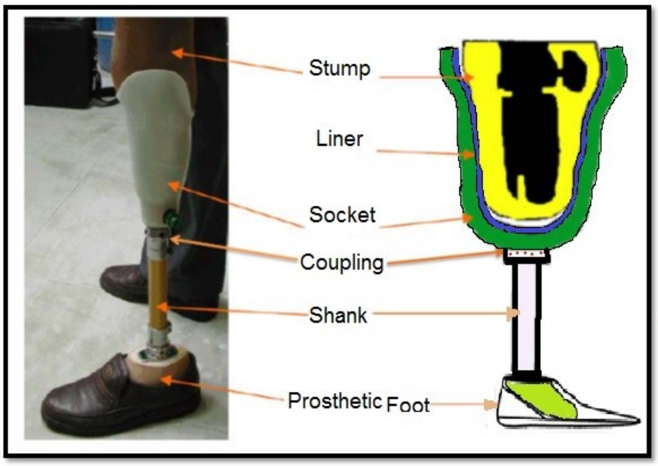

Figure 1. The components of a below knee prosthesis.

There are many types of socket manufacturing methods All these previous methods are handmade, a socket (connecting between the stump and the prosthesis) design will be determined after thoughtful consideration of the shape of the residual limb, skin condition, mobility level and extremity strength .This means its depend on the experience of the prosthetist, but the new manufacturing method is the modular socket system (MSS) that is a complete fabrication system for creating laminated trans-tibial sockets, includes direct lamination on the residual limb and does not depend on the experiences of the prosthetist. The resin handling is contained, making the fabrication process clean and effective, and the heat generated does not exceed 50° C, the benefits of this process are the simplification of fabrication, assembly and replacement of components.

- *Tmperature and time effects on the prosthetic socket*

The mechanical properties of the prosthesis affected by environmental temperature that derives partly from the internal stresses that resulted from the differential thermal coefficients of composite components, and the magnitude of internal stresses change when temperature changes, In some cases at very low temperatures can cause matrix cracking. The glass transition temperature (Tg) at which the polymer transfers from rigid state to rubbery state and produce substantial loss of mechanical properties. Usually the maximum temperature used in polymer is slightly below its glass transition of temperature (Tg) [7]. The isolated environment of the lower-limb prosthesis (trans tibial) can cause increasing in the residual-limb skin temperatures this may participate of skin irritation, blistering, and decreased quality of life. Design and the materials selection of the prosthetic socket, suspension system, and liner can alleviate these conditions, but the load at hot climate may vary with activity and location within the socket, at the fr ontal proximal position of the stump. The skin was cooled and warmed across the posterior section; the temperature at the stump skin depends on the activity of patient, locality and may provide design requirements for new prosthetic socket systems to alleviate temperature related discomfort [8].

2. Materials and methods

Many different kinds of fabrication methods available to patients depending on their activity level, workability and b
est mechanical properties, modular socket system is one of the fabrication methods that difference with the traditional methods when this method is used direct lamination on the residual limb of the patients and manufactured time is not exceed two hours, the scheme of MSS fabrication process consists of several steps as shown in Figure 2.

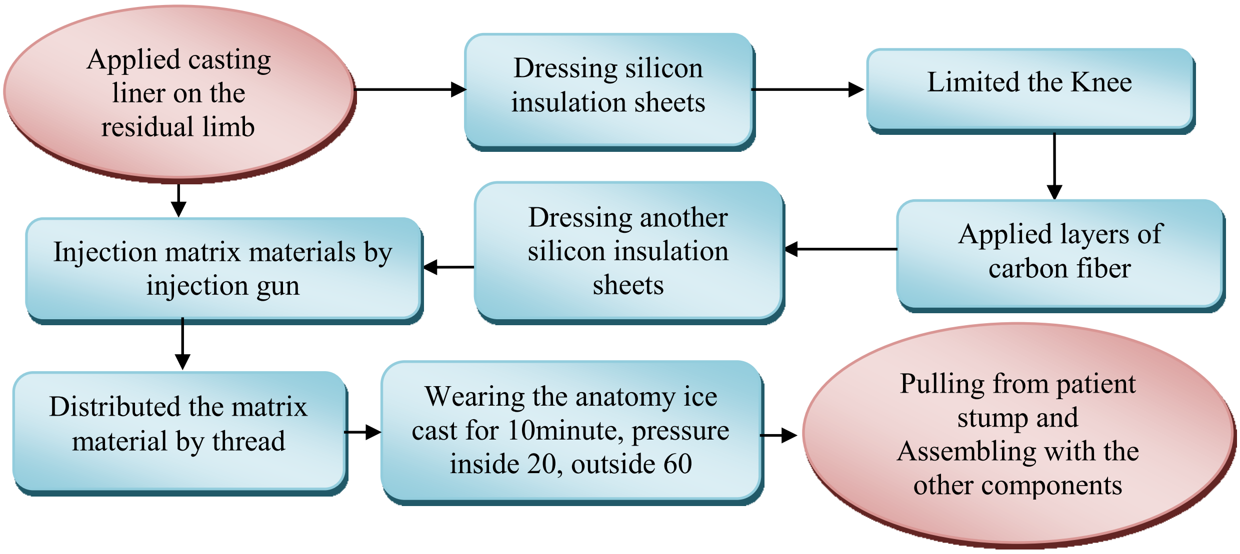

Figure 2. Scheme of modular socket system fabrication process.

3. Experimental procedure of specimens fabrication

3.1 Modular socket system

For manufacturing the specimens by modular socket system, the positive mold of gypsum are prepared with dimensionality (20, 10, 3) cm as shown in Figure 3A , Then the silicon insulation sheets is applied on the mold reinforcement layers of four layers of carbon fiber are applied after that another layer of silicon insulation sheets is put on as shown in Figure 3B&C&D .By injection tool as shown in Figure 3E, the matrix materials are injected to the layers by using small tube as shown in Figure 3F . After that as shown in Figure 3G ice cast anatomy are applied for 10 minute to make clicks of socket on the residual limb ,the mold is now ready for cutting process as shown in Figure 3H.

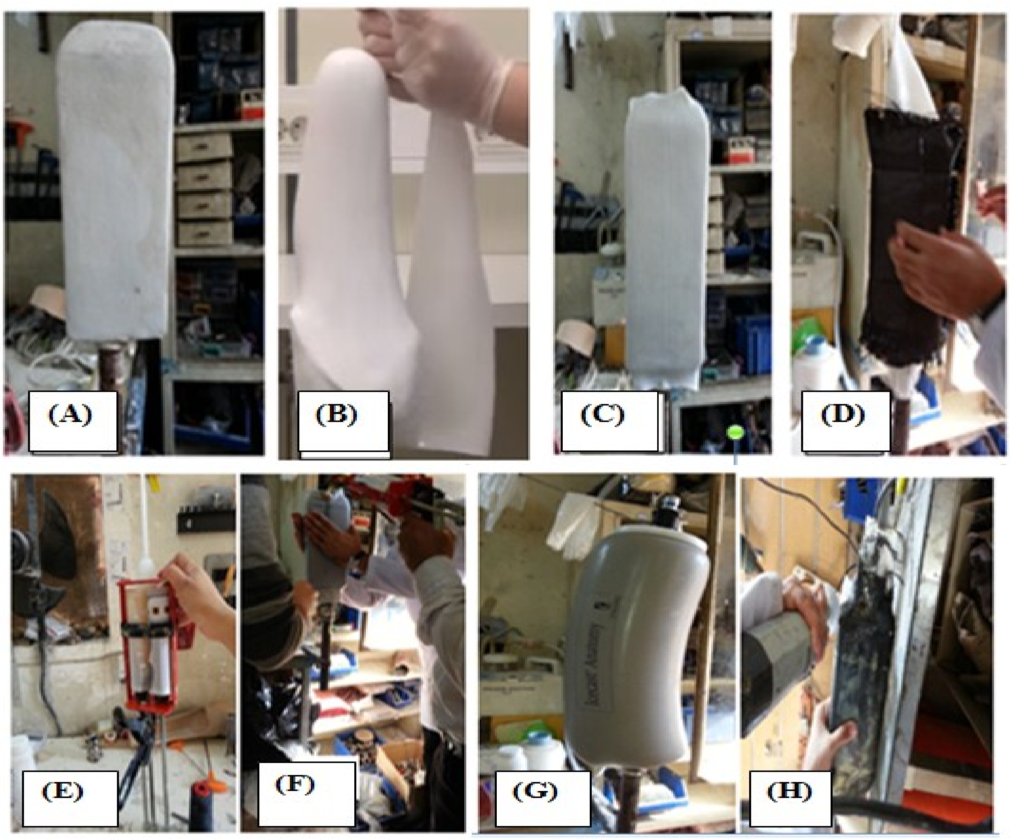

Figure 3. Steps of specimen's fabrication.

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3.2 Vacuum technique

For manufactured the specimens ,the positive mold of gypsum prepared with dimensionality (20, 10, 3) cm, a fine film of Polyvinyl Alcohol (PVA) is then applied over the plaster ,Vacuum is applied beneath this film so that it drawn against the mold. Next the reinforcement layers (8 layers of perlon) are applied, over that another PVA bag is applied after put talcum powder inside it to facilitate dressing. This PVA bag is open at the top to accept the liquid plastic (lamination resin and hardener) as it is introduced into the fabrics, after the drying the mold is ready for cutting process. The materials that used in this research shown in table1 in order to compared between materials and methods.

Table 1. Materials used in manufacturing process.

Groups	Materials used	method
A	(4 layers of carbon fiber) with injection resin*	Modular socket system
B	8 layers of perlon with acrylic resin	Vacuum technique

*(AX140401): Contain Diphenylmethanediisocyanate, isomers and homologues, isoparaffinic hydrocarbons, alcoxylated amine.

4. Theory and calculation

From creep and stress relaxation test the basic viscoelastic effects are typically derived. In the test, a specimen is loaded under a constant stress below yield stress for some time and the resulting deformation, which increases with time this called creep [9]. The Maxwell and Kelvin models are very simple and reality more complex is modeled by the use of these simple models so that more spring and dampers added to the system to get a more complex behavior. The standard linear solid model is also known as the Zener model as shown in Figure 4 [10] describes the behavior of viscoelastic materials by using another spring to the Kelvin model (spring and dashpot) [11].

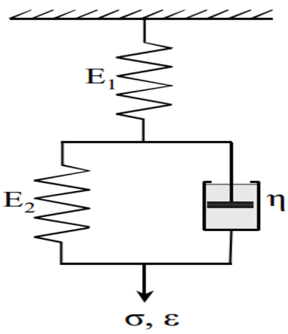

Figure 4. Standard linear model.

From Figure 4,
Stress spring 1(σ_1) = stress spring 2(σ_2) + stress dashpot (σ_d)
The governing equation for this model is as follows [10]:

$$(E_1+E_2)\sigma+\eta\sigma_o=E_1E_2\varepsilon+E_1\eta\varepsilon_o \quad (1)$$

where E_1 = young modulus of first spring, E_2 = young modulus of second spring, η coefficient of viscosity of dashpot, ε_o strain at time equal zero and σ_o stress at time equal zero.
This is a linear equation in stress and strain and their first derivatives, and can be solved by integration for conditions of creep (Stress constant = σ_o), Integration gives[10]:

$$\varepsilon = \frac{\sigma^\circ}{E1} + \frac{\sigma^\circ}{E2}(1 - \exp(\frac{-t}{\tau\sim}) \quad (2)$$

The final equation of creep compliance [10]:

$$D(t)=\frac{\varepsilon(t)}{\sigma^\circ} = \frac{1}{E1} + \frac{1}{E2}(1 - exp(\frac{-t}{\tau\sim}) \quad (3)$$

where relaxation time $\tau\sim = \frac{\eta}{E2}$, $t = time$

The deformation corresponding to the two spring so that the strain is seen to be made up of two components that represents in the Figure 3, and a delayed response corresponding to the Kelvin element [10]. The materials constants (OA represent E1, AĂ represent E2 and tan B represent η) which can be found through the Figure 5, [12] that listed below.

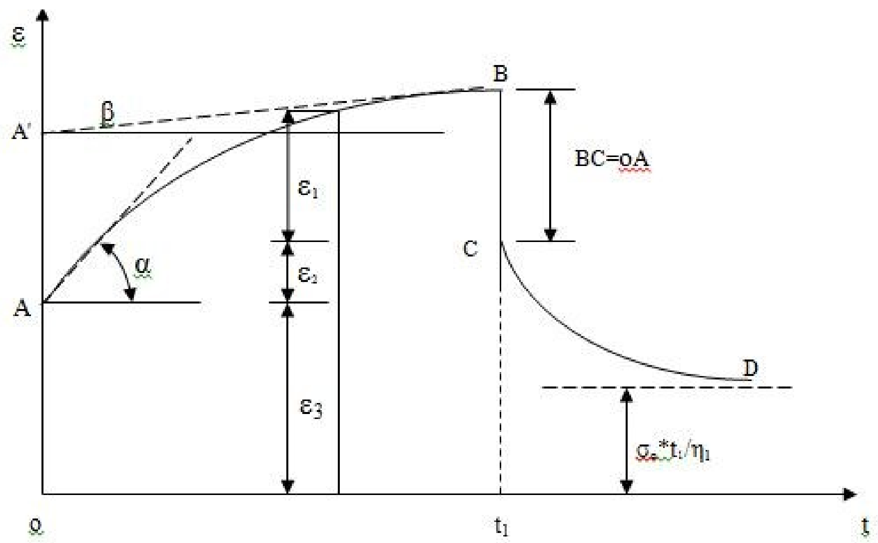

Figure 5. Behavior of creep and recovery.

5. Prepartional of specimens and testing

The cutting process of the specimens is applied by using CNC machine (Rapimill 70) for tensile test, creep test and fatigue test.

5.1 Tensile test

This test was performed at room temperature according ASTM D-638 type IV by using (Tinius Olsen) device for determining the yield strength(σy) , yield point elongation , tensile strength(UTS) and elastic modulus (E),Tensile properties may vary with specimen preparation, with speed(feed speed=5mm/min.) and environment of testing.

5.2 Creep test

Creep is time dependent deformation and it is the inelastic restraint of materials that is loaded at high temperatures. The creep test stocks information to describe and analyze the materials behavior at high temperatures under constant stress or loads. The creep specimens was achieved according to ASTM D-2990 after that the measurement (weight, thickness, width and specimen length) of this specimen may be taking. The first step of this test is putting the specimen in the setup two of the device as shown in the Figure 6, second step inserts the physical information to the device such as (the stress equal to (10) MPa and temperature is 50 °C), Finally compress on the start in order to draw the force, deflection with time.

5.3 Fatigue test

The type of fatigue testing machine is Alternating bending fatigue with constant amplitude as shown in the Figure 7. The specimens were subjected to deflection perpendicular to the axis of specimens at one side of the specimens, and the other side was fixed, developing bending stresses. Fatigue test is started after obtaining the stress yield and young modulus from the tensile test ,selected the maximum stress for the specimen that centered in the reciprocating mechanism in order to start from it to determine the deflection , the speed of the device depends on the materials used and the imposed deflection ,the composite materials need lower speed compared with metals so that the speed of electric motor in this test was (1500 rpm) after that by using the dial gauge the deflection can be measured, the stress begins to be applied until the crack appears in the specimen or the deflection occur ,all that occurred without temperature for eight specimens but the other eight specimens were exposed to heat at (50°C) by using heater and container to save the temperature after that the same steps repeat for this specimens. The main goal of this test to calculated maximum stress against number of cycles until failure.

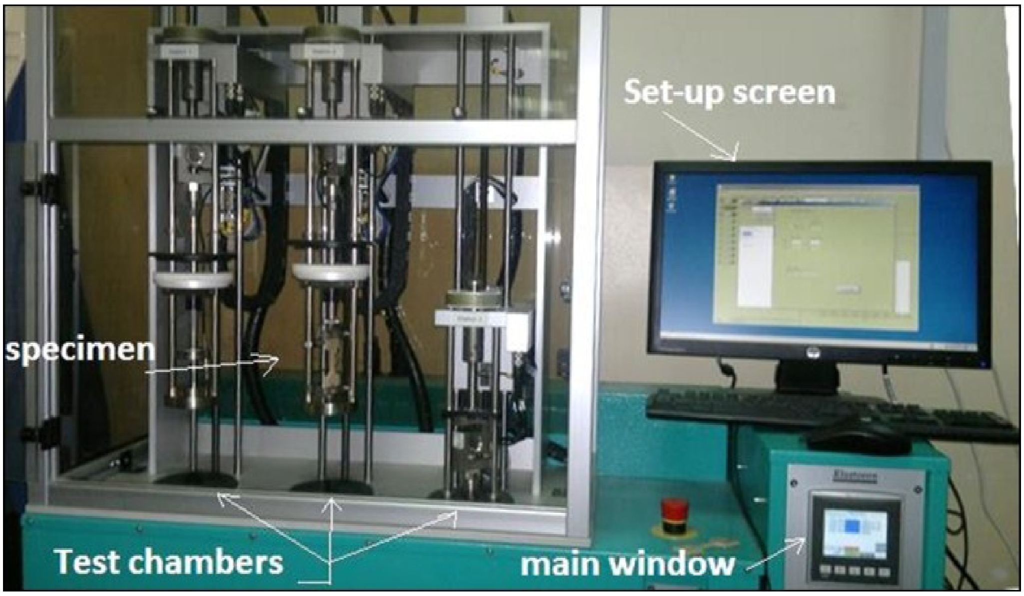

Figure 6. Device of creep/stress relaxation test.

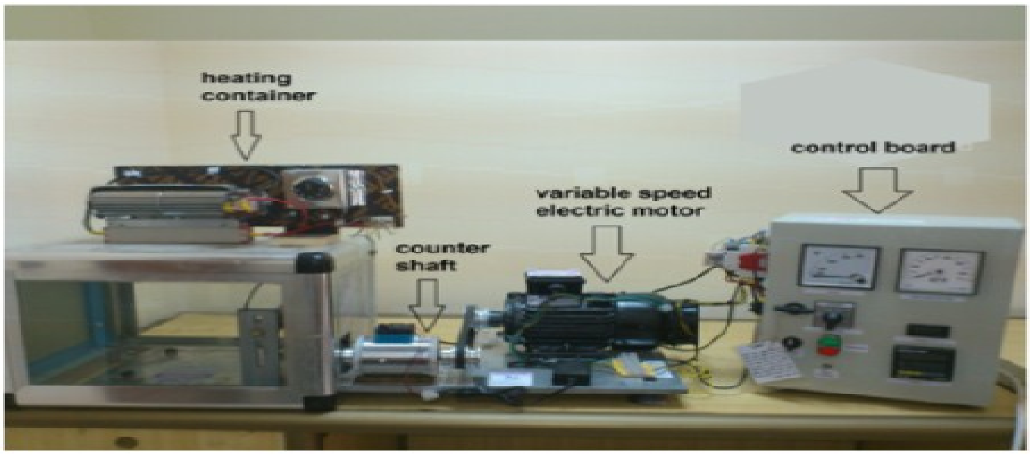

Figure 7. Creep-Fatigue device.

6. Interface pressure and numerical analysis

The interface pressure measured by using F-socket as shown in Figure 8 A&B that consist of sensors so that two main factors must be considered when measuring interface pressure .In particular the sensor must be correctly located under the relevant bony prominence, and also its presence must not introduce errors which would mask any difference between the support systems being evaluated. The test was done on a person has amputation of the two lower limbs as shown in Figure 8 C, who was 23 years old with weight 56 kg and length 158 cm.

After taking the dimensions of the socket, the socket was drawn by using these dimensions and drawing the real shape of below knee socket by using AUTOCAD software (version 2014), the main ANSYS® processes which are: modeling, meshing method, applying loads…etc. Meshing process is applied on the model (type of element =solid brick, total No. of Elements =12601and the total No. of Nodes =26298) and the boundary condition includes the term of load. The load which is used in ANSYS Workbench software will be fixed support at the adapter of socket, while the interface pressure is distributed according to particular positions.

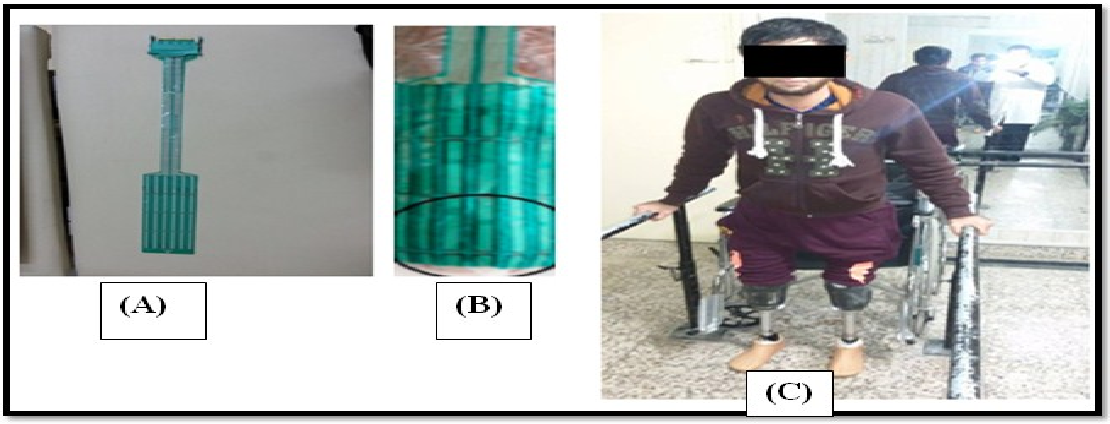

Figure 8. F-socket software with patient.

7. Results and discussion

7.1 Tensile test

Table 2 shows that the materials (group A) has higher yield stress and higher modulus of elasticity this is due to carbon fiber and matrix materials that have excellent tensile properties, matrix materials (AX140401) considered thermoset polymer and this improves the materials mechanical properties. Contrary to the materials (group C) has lower yield stress and modulus of elasticity .The varying in manufacturing methods, reinforcing and matrix materials leads to varying the mechanical properties of the specimens, and makes it change.

Table 2. Result of tensile test.

Groups	Yield stress (σy) MPa	Ultimate tensile strength MPa	Young modulus (E) MPa
A	140.895	195.352	2348.97
B	23.01	32.04	646.64

7.2 Creep test

The creep test data as shown in Figure 9 A of group A that consists of (4layers) of carbon fiber as a reinforcement, AX140401 as a matrix and manufactured by Modular Socket System (MSS) method, the specimen thickness of (2.26 mm), the specimen length (88.73mm), weight of the specimen (3.94 g.), the applied force of (58.8 N), the current position (-38.20) and the time of creep test (180min). The creep test data as shown in Figure 9 B of group B consists of (8layers) of perlon as a reinforcement, acrylic resin with hardener as a matrix and manufactured by vacuum molding technique method, the specimen thickness of (3.33 mm), the specimen length (89.32mm),weight of the specimen (6.28 g.), the applied force of (85.5N),the current position (-81.40) and the time of creep test (90min.), the materials constants (η, E1, E2) can be determined from Figure 9 of group A, listed in Table 3 and from Figure 9 of group B, listed in Table 4.

Creep compliance of group A after compensation the materials constants at equation (3):

$$D(t)=4.07*10\text{-}5+7.87*10\text{-}7(1\text{-}e\left(\frac{-t}{0.605}\right)) \quad (4)$$

Creep compliance of group B after compensation the materials constants at equation (3):

$$D(t)=2.8*10\text{-}4+3.94*10\text{-}5[1\text{-}e^{-0.807t}] \quad (5)$$

The creep compliance of the groups (A and B) as shown in Figure 10 have high increasing rate with the period of time from (0 to 50 min) but after 50 min. the creep compliance remain constant, The increase of creep compliance in higher rate of (group B) than the (group A) because these materials (polymer materials) have high viscoelastic properties ,the creep compliance of group A increases but at slow rate because these materials have low viscoelastic properties because these are composite materials.

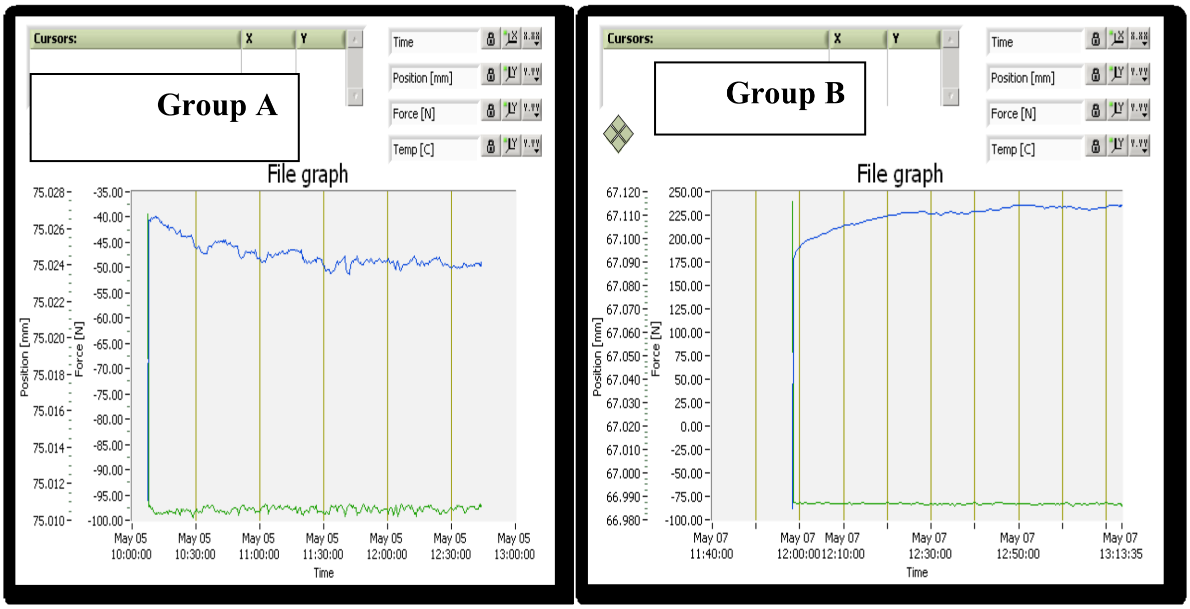

Figure 9. Creep behavior curve of group A &B.

Table 3. The materials constants [12] determined from the experimental data for creep test (group A).

Equation	Materials constant result
tan B = 1.3*10-5= $\frac{\sigma^{\circ}}{\eta 1}$,σ∘= 10MPa	η =769230.8 MPa.min
OA =0.0155/ 38.1=4.068 *10-4 = $\frac{\sigma o}{E1}$	E1=24582 MPa
AĂ =3*10-4/38.1=7.87 * 10-6 = $\frac{\sigma 0}{E2}$	E2=1270648 MPa

Table 4. The materials constants [12] determined from the experimental data for creep test (group B).

Equation	Materials constant Result
tan $\boldsymbol{\beta}$= 3.18*10-4 = $\frac{\sigma_{\circ}}{\eta}$	η =31446.5 MPa.min
OA =0.108/38.1= 2.8*10-3 = $\frac{\sigma o}{E1}$	E1 =3571.4 MPa
AA˜ = 0.015/38.1=3.94*10-4 = $\frac{\sigma 0}{E2}$	E2 =25380.7 MPa

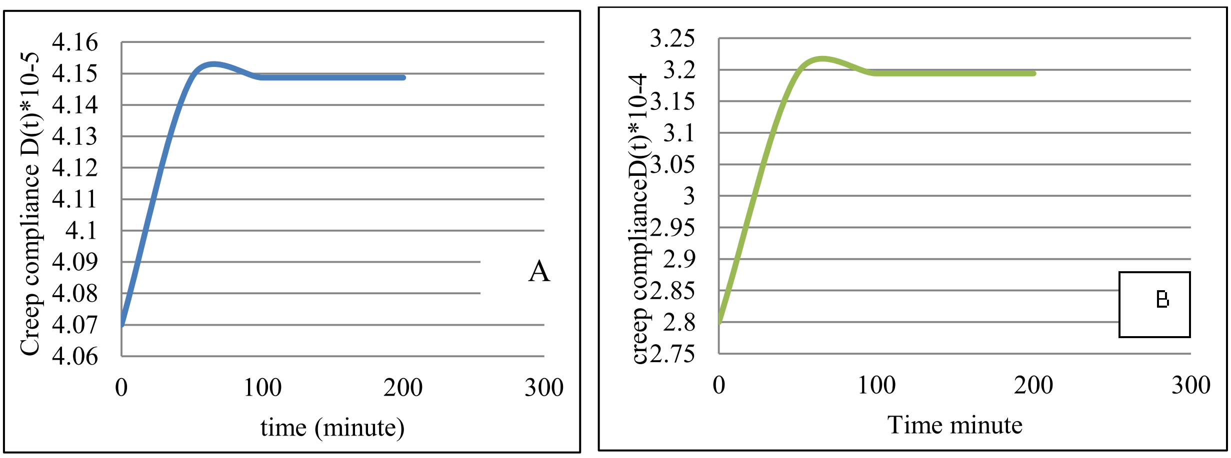

Figure 10. Creep compliance curve of groups A &B with time.

7.3 Fatigue test

In Figure 11, S-N curve of group A show that the temperature effects is very low at the first when low number of cycle was used but with the increased the number of cycle, the temperature effect on the materials began increased this occur because the material (carbon fiber) have high thermal, chemical stability superior fatigue properties and the matrix material consider thermost polymer that have high resistance when the temperature increased. The effect of temperature on the material group (B) as shown in Figure 12 is high because the perlon material have low resistance to increase in temperature and less thermal stability. .

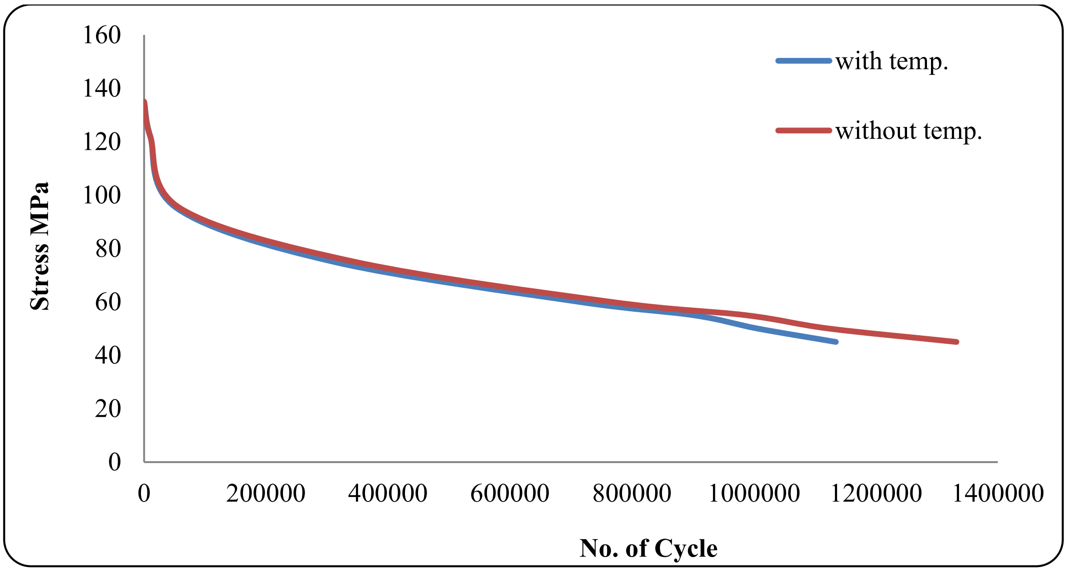

Figure 11. S-N Curves of group A, with and without temperature effect.

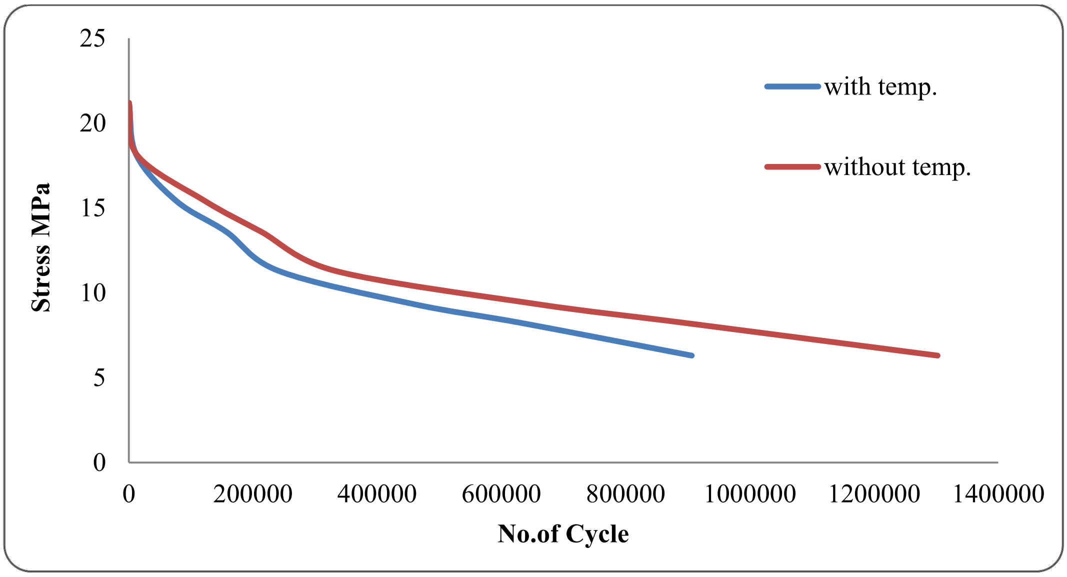

Figure 12. S-N curves of group b, with and without temperature effect.

8. Numerical Ansys results

The interface pressures between socket and residual limb were recorded as the participant walked at self-selected speed in order to analysis motion's system of the patient, the result of the applied pressure of the case study from F-socket software. During the gait cycle of the patient, the pressure reached the peak point at mid-stance which begins with the rising of the posterior leg (which is in mid swing) and ends when the weight of the body is aligned with the anterior foot.

8.1 Safety factor results

In ANSYS, Maximum factor of safety displayed is 15, values less than one indicate failure before the design life has been reached ,it can be noticed in Figure 13 the distribution of safe and unsafe regions of the composites with and without temperature. The model of 4 carbon layers (Group A) noticed that, for fatigue safety factor was about (4.1234) without temperature and (3.8908) with temperature effect, which are safe in design and no failure will occur. While, the model of (group B) with temperature effect will unsafe because it's safety factor value (0.73552) is less than 1 which indicate that failure will take place before the design life is reached.

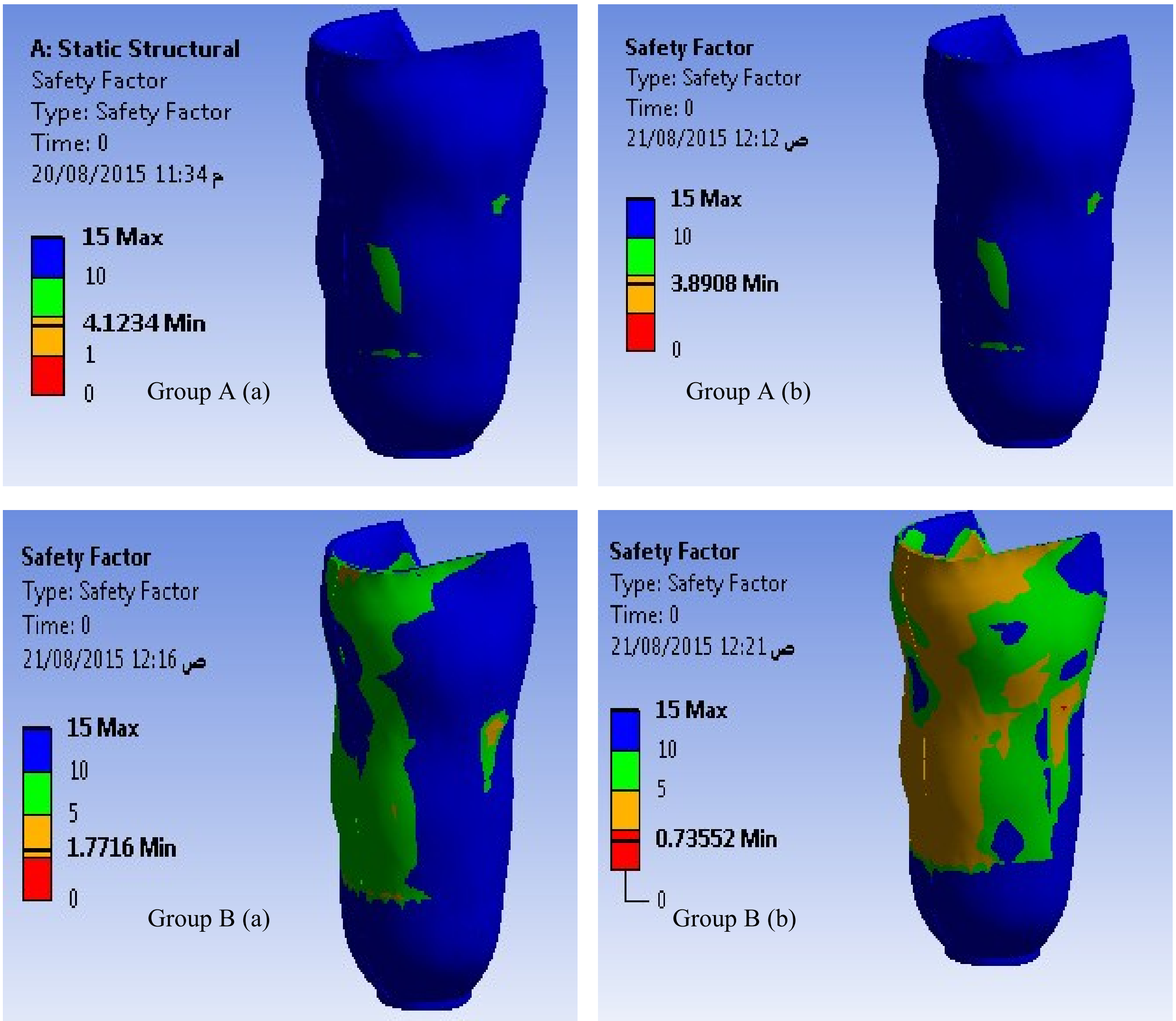

Figure 13. Safety factor of Group A&B, a: without temperature, b: with temperature.

8.2 Deformation results

The results of maximum deformation that represent comfortable socket occur in the materials (group B) in the fig.14 B. Because its values (5.4376mm) in the rang (2-6) mm, this group has lower modulus of elasticity this means the stiffness of this group is very low. The groups (A) have low deformation as shown in Figure 14 a lower than 2 mm because the high values of young modulus and this means the stiffness of these groups high.

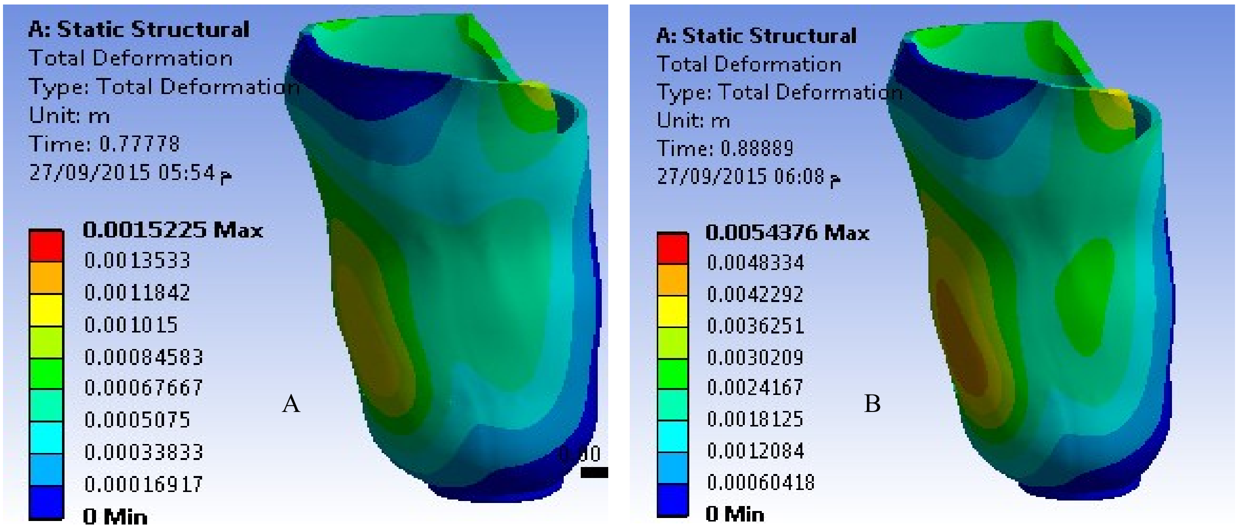

Figure 14. Deformation of group A and B.

9. Conclusion

1. Yield stress of materials that used MSS process increasing at rate 512% than the other yield stress of materials that can used traditional process for manufacturing the socket.
2. In MSS process the influence in change the temperature is low, this is observed in the creep (creep compliance reducing at rate87%) and fatigue test without and with temperature (safety factor of groups A and B decreased at rate (5.6%, 58.5%) respectively with the temperature effect).
3. It is possible to use the MSS process in Iraqi environments, it has high resistance to loads (has high strength at rate 510%) and not affected by hot climates.
4. MSS process is fast process (does not exceed two hour) and this reduced the large numbers of amputees in our centers.

Acknowledgments

To Eng. Ali Fahdil Abaas, Rasha S.Mohammed and Eng. Sherein Hassan

Nomenclatures and units

MSS	Modular Socket System	………
BK	Below Knee	……….
E	Elastic modulus of spring	MPa
η	Viscosity of damping element	MPa.min
D(t)	Creep compliance	1/MPa
E(t)	Stress relaxation modulus	MPa

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