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DESIGN AND MANUFACTURING OF PROSTHETIC BELOW KNEE SOCKET BY MODULAR SOCKWT SYSTEM

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Abstract: The large numbers of terrorist attacks and the difficulty of the situations in Iraq led to the rise of the amputees numbers. However, typically 80% of the amputations are trans-tibial (below knee (BK) lower limb amputations). This research included the fabrication of a new type of socket by a new method (modular socket system) (MSS) that used direct lamination on residual limb of patients. Socket materials were subjected to tensile and creep(50^0 C) in order to determine their mechanical properties. Creep test data were analyzed in order to obtain time dependent creep compliance using the standard linear solid (the zener) model, the socket failure characteristics at room temperature and at high temperature (50^0 C) were determined by fatigue testing. Interface pressure between the socket and the residual limb was calculated using F-Socket software; In addition, a numerical method was used by applying the program ANSYS 15. The present work aim to study the experimental, theoretical and numerical results of tests and compared with the results of other reference. The experimental results show the specimens that manufactured by (MSS) have higher yield stress, medium young modulus, higher resistance to creep and low temperature effect on the S-N curve, where the reducing rate of S-N curve in the presence of temperature of group A(4.5%) compared with group C in which reducing rate (50%). Theoretical results of groups A, B show the creep compliance increased at first at rate (200 %, 11%) respectively but after (50 min.) the creep compliance become constant, The numerical results show that the safety factor of groups A and C decreased at rate (47.6%, 43%) respectively with the temperature effect. From this work was concluded that the (MSS) is the best and fast manufactured process.

Keywords: *modular socket system, amputation, residual limb, creep, interface pressure.*

تصميم وتصنيع وقب أسفل الركبة بطريقة Modular Socket System

الخلاصة : أدت الهجمات الارهابية الكبيرة وصعوبة الاوضاع في العراق الى ارتفاع اعداد المبتورين , عادةً 80% من عمليات البتر هي بتر الطرف السفلي (تحت الركبة) . وهذا البحث تضمن تصنيع وقب جديد باستخدام طريقة جديدة (Modular Socket System) (MSS) والتي تستخدم بشكل مباشر على الطرف المتبقي للمبتورة اطرافهم . مواد الوقب خضعت لاختبار الشد والزحف في درجة حرارة (50 درجة) من اجل تحديد خواصها الميكانيكية . وتم تحليل بيانات اختبار الزحف للحصول على مطاوعة الزحف في اي وقت باستخدام نموذج (زينير). تم ايجاد خصائص فشل الوقب بدرجة حرارة الغرفة وبدرجات حرارة عالية (50 درجة) باستخدام فحص الكلال. وتم حساب الضغط الموجود بين الوقب والطرف المتبقي باستخدام برمجيات F-Socket, وبالإضافة لذلك ,قد استخدمت الطريقة العددية عن

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طريق تطبيق برنامج الانسز 15.الهدف من العمل دراسة النتائج العملية والنظرية والعددية للاختبارات ومقارنتها مع مصادر اخرى. نتائج العملي بينت ان العينات المصنوعة بطريقة (MSS) لها اجهاد خضوع عالي, معامل مرونة متوسط ,مقاومة عالية للزحف وتأثير قليل لدرجة الحرارة على مخطط (S-N)حيث ان نسبة النقصان بوجود الحرارة للمجموعة A كانت (4.5%) مقارنة مع المجموعة C حيث كانت نسبة النقصان (50%), النتائج النظرية للمجموعة A وB اثبتت ان معامل الزحف يزداد بالبداية بنسبة (200%, 11%) على التوالي وبعد (50 دقيقة) معامل الزحف يبقى ثابت , النتائج العددية اثبتت ان معامل الامان للمجموعة Aو C يقل بنسبة (43%, 47.6%) على التوالي بوجود درجة الحرارة. من هذا العمل استنتجنا ان طريقة (MSS) افضل واسرع طريقة تصنيع.

1.Introduction

Prosthesis is often used to restore appearance and functional activity to persons having lower limb amputation. Below Knee (BK) prostheses are typically comprised of four major components as shown in Figure (1), these are:

1- Socket

2- Pylon (shank)

3- Foot prosthetic

4- Couplings

Coupling between the residual limb and the prosthesis is typically achieved by a socket, which surrounds the stump, and to which the remaining components of the prosthesis are attached [1]. The socket is the interface between the patient's body and an artificial prosthesis, for a lower limb amputee the fit of the socket can determine the value of the prosthesis. Historically, the production of prosthetic sockets has depended on the experience of prosthetists [2].

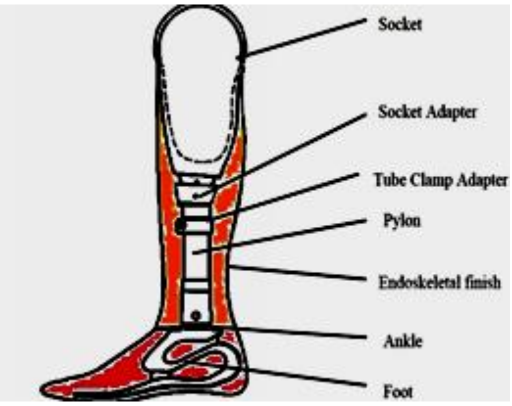


Figure1. The components of a below knee prosthesis [3].

Advances in prosthetics and orthotics have always been achieved as a result of advances in other fields. Mustafa Tariq.et al. [4] studied the effect of temperature in hot climate countries on a socket made of composite materials during the gait. Ramesh K.etal. [5] fabricated transtibial prosthetic sockets by using vacuum molding technique, the matrix Epoxy was reinforced with five types of laced fibers(perlon , glass, carbon, amalgam(carbon and glass) and amalgam (carbon and glass) with silica elements. Peter V.S.L.et al [6] studied a low-cost and low-skill dependent pressure casting technique (PCAST) to fabricate and fit transtibial (TT) prosthetic sockets in a developing country.

The goal of the research: Produce socket by using new method (Modular Socket System) that takes two hours compared to the available methods in Iraq that takes a long time (weeks) in order to alleviate the large numbers of amputees rate who are in our centers and compare the properties with that manufactured by traditional methods in terms of tolerance of weights, activity and for suitability to the conditions of our country as a result of the high temperature in summer.

2. Design, Temperature and Time Effects on the Prosthetic Socket

Designing the socket to distribute the load appropriately is a critical process in lower-limb prosthetic socket, design as improper load distribution may cause injury and pain to the skin and soft tissues. Socket design includes modifications to account for variations in the residual limb shape among amputees and variations in pressure tolerances among soft tissues at different regions of the stump [7], the basic principles for socket design vary from either distributing most of the load over specific load-bearing areas or more uniformly distributing the load over the entire limb.

No matter what kind of design, designers are interested in understanding the load transfer pattern. This will help designers to evaluate the quality of fitting and to enhance their understanding of the underlying biomechanical rationale [8], the mechanical properties of the prosthesis affected by environmental temperature that derives partly from the internal stresses that produces by the differential thermal coefficients of composite components. Such internal stresses change magnitude with temperature change, in some cases producing matrix cracking at very low temperatures.

Usually a polymer has a maximum use temperature slightly below its glass transition temperature (Tg), at which the polymer transfers from rigid state to rubbery state and cause substantial loss of mechanical properties [9].The isolated environment of the lower-limb prosthesis can result increasing residual-limb skin temperatures that may contribute to skin irritation, blistering, and a decreased quality of life. The design and materials of the prosthetic socket, suspension system, and liner can potentially alleviate these conditions, but the thermal load may vary with activity and location within the socket, Thermal contour maps revealed the skin was coolest at the anterior proximal location and warmest across the posterior section, The stump skin temperature depends on activity and locality and may provide design requirements for new prosthetic socket systems to alleviate temperature related discomfort [10].

3.Viscoelastic Modeling

The basic viscoelastic effects are typically studied by creep and stress relaxation. In the test, a specimen is loaded with a constant stress for some time and the resulting strain, which increases with time [11]. Reality is more complex than what can be modeled by the use of the simple Maxwell and Kelvin models. By adding more spring and dampers to the system a more complex behavior can be described. The standard linear solid model is also known as the Zener model and describes the behavior of viscoelastic materials by using two springs and a damper according to Fig. 2 below**[12].**

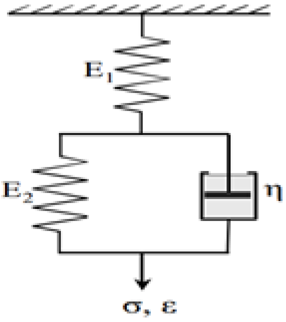


Figure 2.standard linear model [13].

From Fig. 2 it is shown that the:
Stress spring 1(σ_1) = stress spring 2(σ_2)+ stress dashpot(σ_d) ,the governing equation for this model is as follows:

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

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:

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

The creep compliance:

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

Where $\tau\sim=\frac{\eta}{E2}$

The strain is seen to be made up of two components – an instantaneous deformation corresponding to the spring, and a delayed response corresponding to the Kelvin element [13].

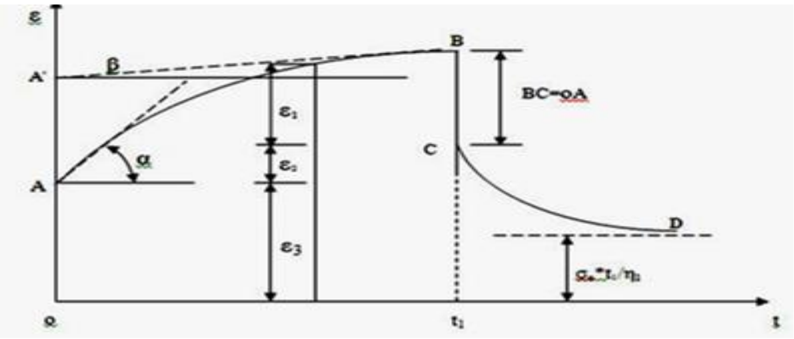


Figure3. Behavior of creep and recovery [14].

4. Experimental Work

4.1 Prosthetic Socket Manufacturing by Modular Socket System:

There are many different kinds of fabrication methods available to patients depending on their individual clinical needs and best 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.

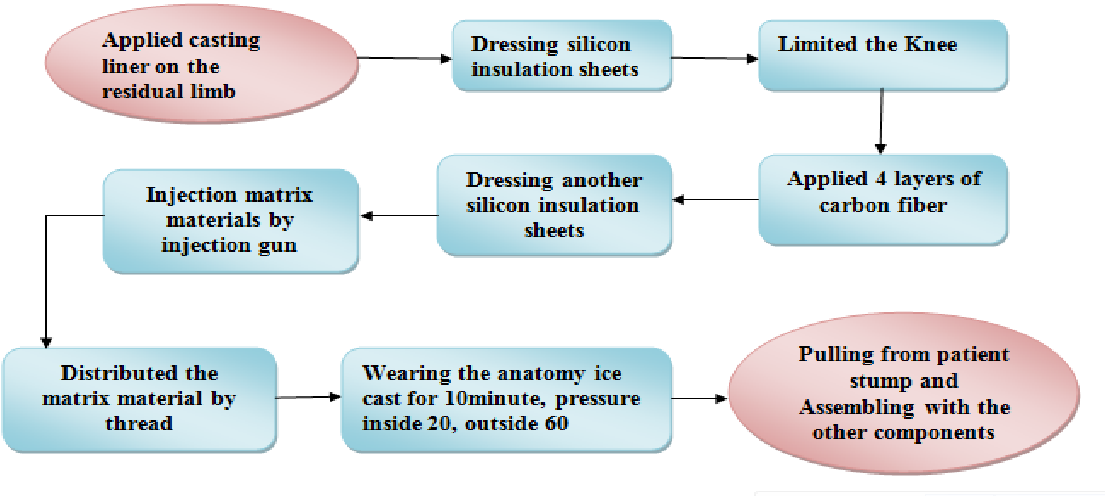


Figure 4. Scheme of Modular Socket System fabrication process

Figure 5.prosthetic socket manufactured by modular socket system

4.2 Experimental Procedure

For manufactured the specimens by modular socket system ,the mold of gypsum are prepared with dimensionality (20,10,3) cm, silicon insulation sheets is applied on the mold, reinforcement layers (4 layers of carbon fiber) are applied after that another layer of silicon insulation sheets is put on, by injection tool the matrix materials (AX140401) are injected to the layers by small tube after that 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**.**

Figure 6.Steps of specimen's fabrication

Table 1.Materials used in manufacturing process

Groups	Materials used	Method
A	(4 layers of carbon fiber) with injection resin(*AX140401)	Modular socket system
B [15]	(2 perlon ,2 fiberglass , 2 perlon and 2 fiber) with acrylic resin	Vacuum molding technique
C [4]	(4 perlon , 4 fiber glass and 4 perlon) with acrylic resin	Vacuum molding technique

***AX140401** contain Diphenylmethanediisocyanate , isomers and homologues, isoparaffinic hydrocarbons ,alcoxylated amine.

5. Preparation 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 used at room temperature according ASTM D-638 type IV by using (Tinius Olsen) device for determined yield strength(σy), yield point elongation, tensile strength (UTS), elongation (ΔL%), 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 the inelastic response of materials loaded at high temperatures and it is time dependent deformation .The creep test provides valuable information to analyze the materials behavior under constant loads and high temperatures. A typical creep test consist of subjecting a specimen to a constant load or stress while maintaining the temperature constant; deformation or strain is measured and plotted as a function of elapsed time, creep specimens cutting according to ASTM D-2990.

Figure7. Device of creep/stress relaxation test.

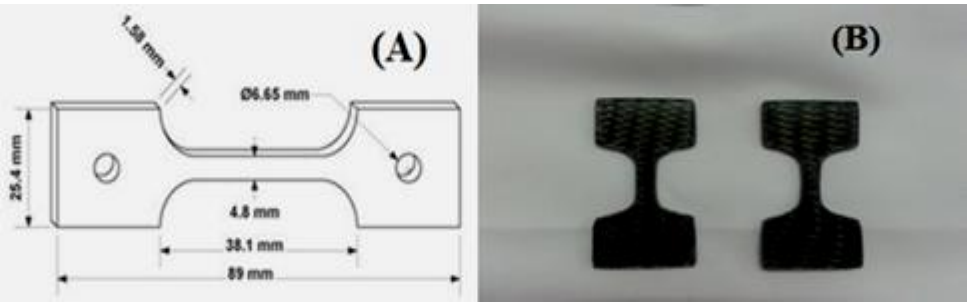


Figure8 .A: Dimensional of standard specimen, B: Creep specimens

5.3 Fatigue Test

The type of fatigue testing machine is Alternating bending fatigue with constant amplitude. 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.

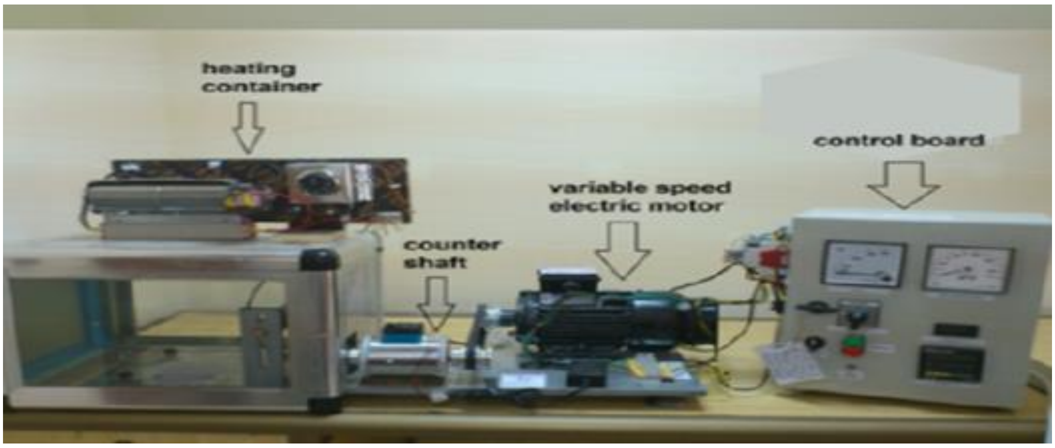


Figure 9.Creep-Fatigue device.

5.4 Interface Pressure and Numerical Analysis

The interface pressure measured by using F-socket 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.

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) as shown in the figure 10. The main ANSYS® processes which are: modeling, meshing method, applying loads…etc. Meshing process is applied on the model and then the interface pressure is distributed according to particular positions, number of element =12601 and the number of nodes =26298.

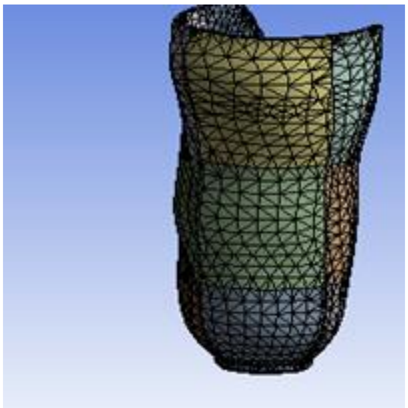


Figure 11. Meshing process of the socket

Figure10. F-Socket device

6. Results and Discussion

6.1 Results of Tensile Test

The results of the mechanical properties (tensile test)of the socket materials are shown in Table 2. From Table 2 it shows that the materials (group A) has higher yield stress than the other groups because carbon fiber and matrix materials have excellent tensile properties, matrix materials (AX140401) considered thermoset polymer and this improve the material's mechanical properties ,but this group has medium modulus of elasticity because the brittleness of carbon fiber. The difference in the mechanical properties is related with types of materials.

Table 2.Mechanical properties of socket materials

Groups	Yield stress (σy) MPa	Young modulus (E) GPa
A	140.895	2.35
B	26.5	1.2928
C	78.2	12.4

6.2 Results of Creep Test

The materials were tested in creep/stress relaxation machine with allowable stress (7 or 10MPa)at temperature (50̊ C).

The specimen of group A has thickness of (2.26 mm),the s length (88.73mm), the applied force of (58.8 N)and the time of creep test (180min.).The curve is shown as follows in Fig.11

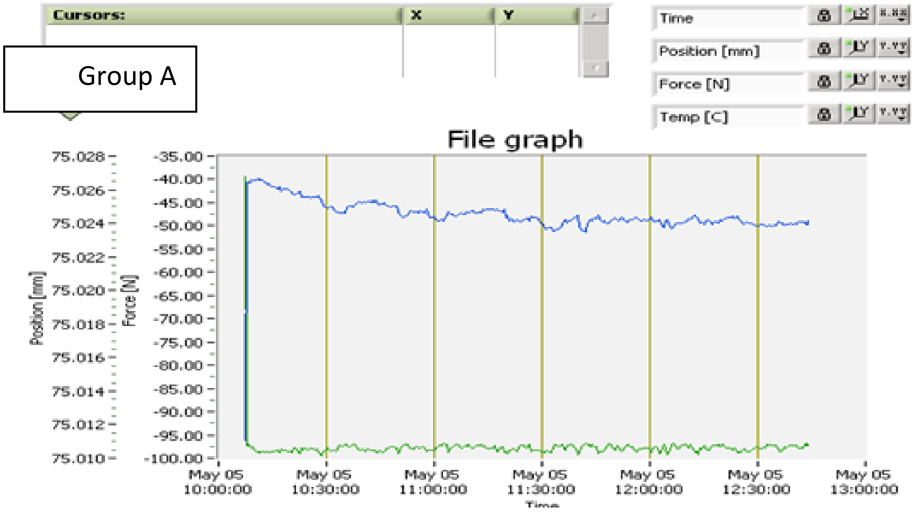


Figure 12: Creep behavior curve of group A

Table 3.The material constant determined from the experimental data for creep test (group A).

Equation	Symbol	Result
tan B = $1.3*10^{-5}= \frac{\sigma^\circ}{\eta 1}$,σ°= 10MPa	η_1 =	769230.8 MPa.min
tan α = $8 * 10^{-5} = \sigma_o [\frac{1}{\eta 1} + \frac{1}{\eta 2}]$	η_2 =	149031.3 MPa.min
OA = $4.068 *10^{-4} = \frac{\sigma o}{E1}$	E_1=	24582 MPa
AĂ =$7.87 * 10^{-6} = \frac{\sigma 0}{E2}$	E_2=	1270648 MPa

Creep compliance of group A:

$$D(t) = 4.07*10^{-5} + 7.87*10^{-5} (1- e (\frac{-t}{0.605}))$$

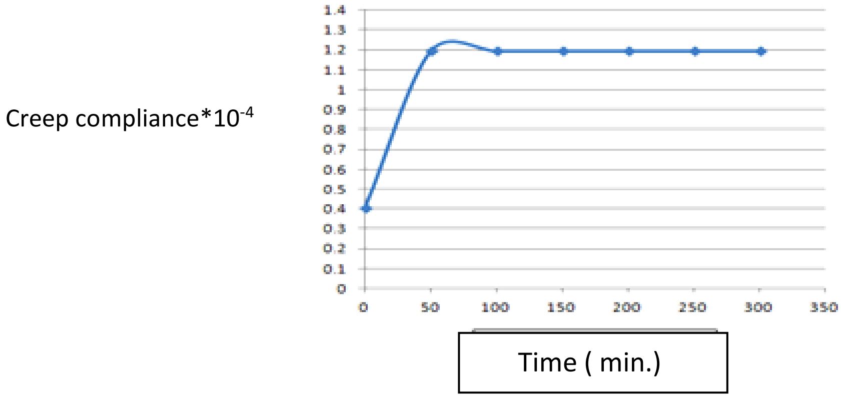
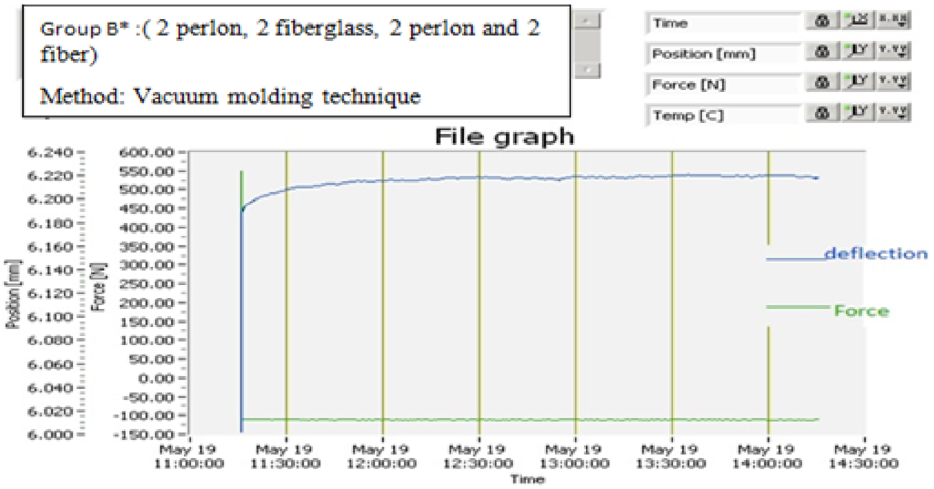


Figure13. Creep compliance curve of group A with time

The specimen of group B has thickness of (3.39 mm),the s length (89.01mm), the applied force of (113.9N)and the time of creep test (210min.).The curve is shown as follows in Fig.13.


Group B* :(2 perlon, 2 fiberglass, 2 perlon and 2 fiber)

Method: Vacuum molding technique

Figure 14: Creep behavior curve of group B

Table 4.The material constant determined from the experimental data for creep test (group B).

Equation	Symbol	Result
$\tan B = 9.33*10^{-5} = \frac{\sigma}{\eta 1}$,$\sigma_{\circ}$=7MPa	η_1 =	75026 MPa.min
$\tan \boldsymbol{\alpha} = 2.13 * 10^{-3} = \sigma_o [\frac{1}{\eta 1} + \frac{1}{\eta 2}]$	η_2 =	3436.9 MPa.min
$OA = 6.01 * 10^{-3} = \frac{\sigma o}{E1}$	E_1 =	1164 MPa
$A\breve{A} = 6.65 * 10^{-4} = \frac{\sigma 0}{E2}$	E_2 =	10670 MPa

Creep compliance of group B :

$$D(t) = 8.6*10^{-4} + 9.4*10^{-5}(1 - e^{\frac{-t}{7.03}})$$

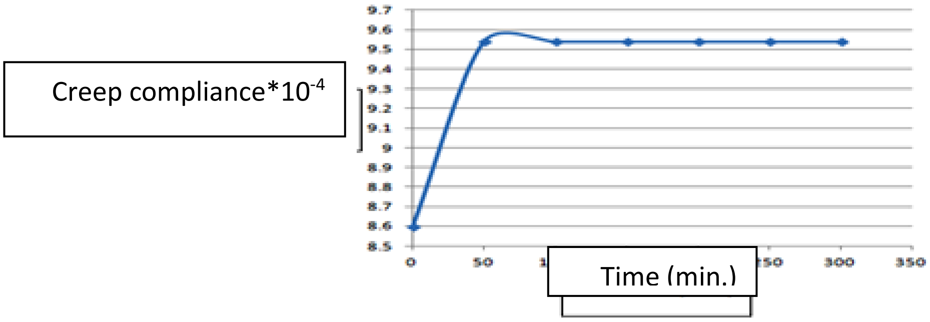


Figure15 .Creep compliance of group B with time

From the fig. 12 and fig. 14 of creep test, it can be seen that the material (group A) has less deflection than the group B which has high deflection, this means the group A has high resistance to creep because carbon fiber that has excellent creep resistance ,but the group B has low resistance to creep because the perlon that has lower resistance to creep .The creep compliance of groups A and B increased with rate (200% ,11%) respectively with time at first because the temperature effects is low at first time ,but after (50 min)the creep compliance become constant because the composite materials is low effected by creep .

6-3 Results of Fatigue Test

The stress- number of cycle diagram is often used to interpret the fatigue failures of materials, the results of stress over large number of cycle of all materials socket (groups A and B) are shown in the figures below.

From Fig. 16 and Fig. 17, it can be seen that the group A has high S-N curve and endurance limit because carbon fibers are characterized by superior fatigue properties but the group B has low S-N curve and endurance limit because perlon unsuitable for use in fatigue resistant composites ,it show that the temperature effect on the S-N curve of group A is very less because carbon fiber has high thermal and chemical stabilities and matrix (AX140401) consider thermoset polymer and contain polymers that cross link together during the curing process, cross linking process eliminates the remelting process when heat is applied and this making thermoset more resistant to high temperature, but the temperature effect of group C is high because perlon effected in high degree by temperature and acrylic resin consider thermoplastic polymer , where the reducing rate of S-N curve in the presence of temperature of group A(4.5%) compared with group C in which reducing rate (50%).

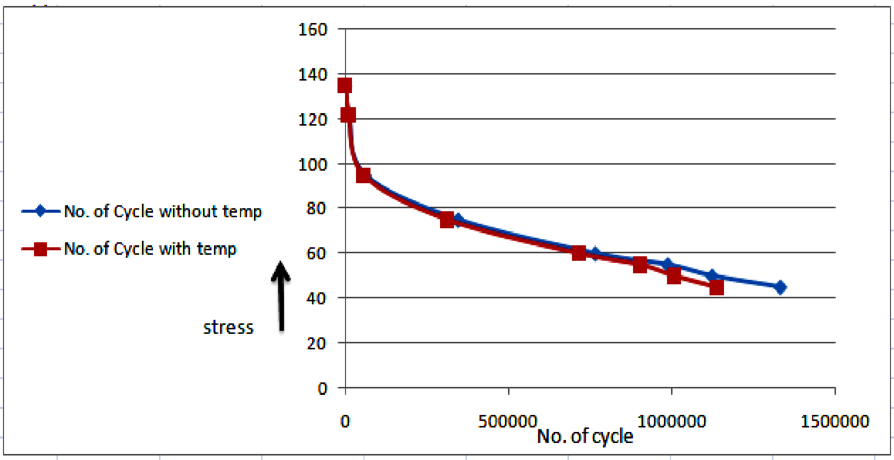


Figure16. S-N Curves of group A, with and without Temperature Effect

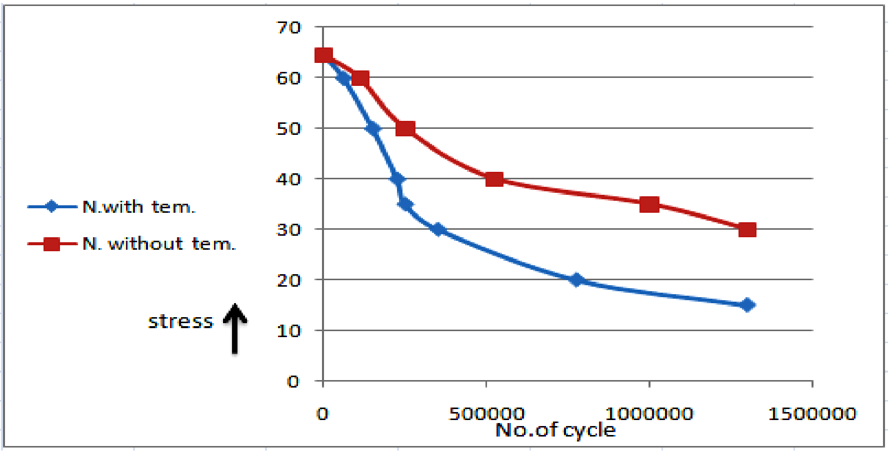


Figure17. S-N Curves of group C, with and without Temperature Effect

6-4. 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 is shown in Fig. 18. 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.

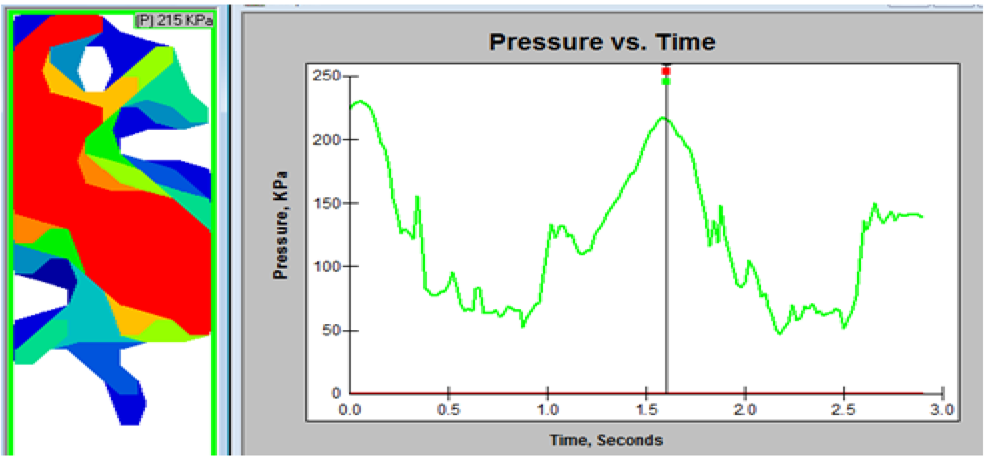


Figure 18.The applied pressure results from the F-socket test

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 fig. 18 A &B below for group A the distribution of safe and unsafe regions of the composites with and without temperature.

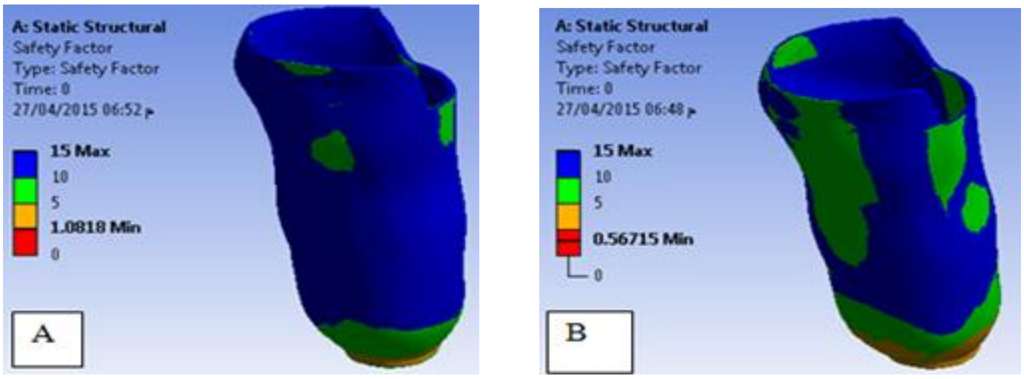


Figure 19.Safety factor of group A, A: without temperature ,B: with temperature

The model of (4) carbon layers (Group A) noticed that, for fatigue safety factor was about (1.08), which is safe in design without temperature effect and no failure will occur. While, the model of group A with temperature effect will unsafe because it's safety factor value (0.567) is less than 1 which indicate that failure will take place before the design life is reached**.**

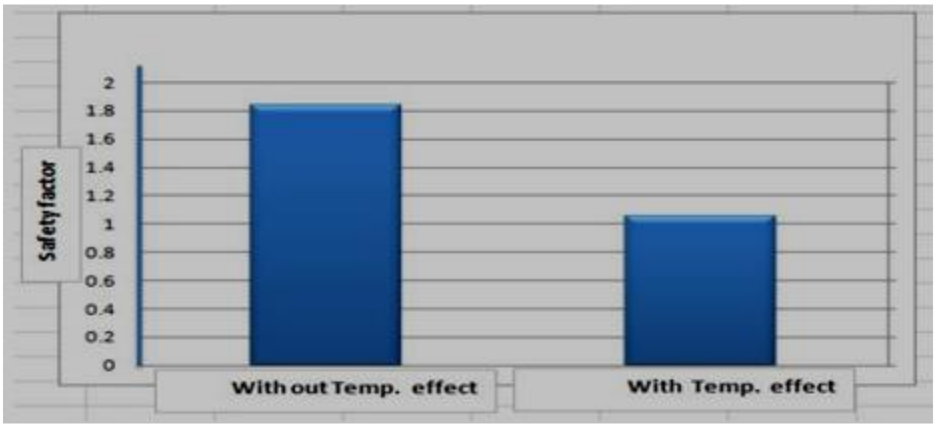


Figure 20. Safety factor of socket without and with effect of temperature of group C

It is obvious in the fig. 19. that material group C is safe without temperature effects and safety factor was (1.8) ,while safety factor equal (1) with temperature which it also safe ,these differences in the results were due to the change of properties of materials because the effect of temperature , where the area still constant. The numerical results show that the safety factor of groups A and C decreased at rate (47.6% ,43%)respectively with the temperature effect.

7. Conclusion and Recommendation

1. Yield stress of materials that used MSS process is the highest 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 and fatigue test without and with temperature.
3. It is possible to use the MSS process in Iraqi environments, it has high resistance to loads and not affected by hot climates.

Recommended suggestions for future work it is possible used (glass-carbon fiber) composite material instead of carbon fiber where it is characterized by resistance to loads, heat and enough flexible to socket.

Acknowledgments

Eng.Ali Fahdil Abaas ,Rasha S.Mohammed and Eng.Shireen Hassan

Nomenclature

Symbol	Meaning	Units
E_1	Elastic modulus of spring	MPa

E_2	Elastic modulus of spring	MPa
η	Viscosity of damping element	MPa.min
σ	Stress	Mpa
σ°	Stress at time =0	MPa
ε	Strain	-------
ε°	Strain at time=0	--------
t	Time	min.
$\tau^{\sim}$	Relaxation time	min

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