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Research Article

Study and analysis of the mechanical properties and pressure socket for through-knee amputation

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Abstract
Individuals using through-knee (TK) prostheses often face an increased risk of socket failure in various scenarios. This vulnerability is influenced by several factors, including the material of the prosthetic socket and the prevailing stress conditions. The primary objective of this study was to determine the optimal composite materials for TK prostheses, specifically in the context of withstanding fatigue loading in Iraqi rehabilitation centers catering to special-needs patients. A practical investigation was undertaken to evaluate the composite materials utilized in the construction of TK prosthetic sockets. These materials were categorized into three distinct groups: group A comprised three layers of perlon, followed by three layers of carbon, and concluded with three more layers of perlon; group B consisted of three layers of perlon, succeeded by three layers of fiberglass, and concluded with an additional three layers of perlon; and group C featured a total of six layers of perlon. The performance of these groups was assessed through a battery of mechanical tests, encompassing tensile, bending, and fatigue tests conducted in accordance with American Society for Testing and Materials (ASTM) standards. Significantly, group A demonstrated the most favorable mechanical characteristics, primarily attributable to the inclusion of three carbon layers and their intricate matrix configuration. In comparison to groups B and C, the modulus of elasticity for group A increased by 42% and 93%, respectively, and its ultimate stress rose by 21% and an impressive 319%. Consequently, the decision was made to fabricate the TK prosthetic socket using the composite materials from group A. Furthermore, an assessment of socket pressure revealed elevated pressure concentrations within the anterior and lateral regions of the TK prosthetic socket. In order to mitigate discomfort, adjustments were made to the prosthetic legs, resulting in shorter stance phases, extended swing phases, reduced propulsive power, and overall shorter, slower strides. This comprehensive analysis of the TK prosthesis contributes to the refinement of socket fitting techniques and the development of patient-specific customizable sockets, guided by insights derived from gait analysis and interface pressure assessment.

Keywords
Through knee prosthesis, Composite materials, Interface pressure, Gait analysis, Tensile, Bending, Fatigue.

1.Introduction
The ongoing battles in Iraq and Afghanistan resulted to 1660 amputations as of January 31, 2015 [1], where 75% are of lower extremity amputations [2]. The amputation level is determined by disease severity. Below-knee (BK) amputation is used when amputation goes beyond the ankle. The above-knee (AK) amputation is often performed as a subsequent surgery when there is a more proximal disease or insignificant wound healing after the BK amputation.

Through-knee (TK) amputation, in which the amputation is performed on the joint line, has the potential to be more advantageous than AK amputation. The advantages include a weight-bearing stump at the end, increased stability from the preservation of the adductor muscle insertion [3], simplified prosthetic device creation due to fewer articulations [4], reducing the effort required to swing a prosthetic limb when walking, as well as aiding sitting balance and transition from bed to chair. In addition, higher rehabilitative potential and enhanced postoperative quality of life have been recorded [5].

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A prosthetic lower limb socket must be designed to withstand the stresses that will be placed on the prosthesis while walking. Additionally, the design should be optimised to effectively transfer these stresses to tissues with different stiffnesses, saving stiffer tissues from excessive pressure and decreasing undesired relative motion caused by soft tissue compression. Instead of, as in the case of the AK stump, necessitating load transfer to the pelvis through the ischium and gluteal muscles, a healthy TK stump can absorb the majority of the vertical support load on the end-bearing surface. Since the support point is almost in the same vertical line as the gluteal, the toppling effect is comparable to use the ischial and gluteal as supports. Thus, the lateral stabilising force must be distal and the medial proximal for the combined effects to function in the same general location. In the design of the socket, the application of these pressures is crucial. If the socket's lateral wall is improperly configured to transfer force, the force will be transferred as a shear force in the tissue of the stump's end. Many different approaches have been taken in fitting the knee disarticulation prosthesis [6]. In terms of patient outcomes, TK amputation surgical approaches are improving infection, survival, morbidity, and dehiscence rates [7, 8] and decreasing the reported pain levels [6]. The condyles of the femur are then used as a weight-bearing surface. The method of suspension usually uses the supracondylar area. The knee mechanisms always try to reduce the length of the thigh in their positioning set-up. Knee disarticulation enables direct weight transmission to the remaining leg with improved walking mobility and less energy usage than a transfemoral amputation but greater than a transtibial amputation. Functional replacement, necessary owing to knee joint loss, provides the same difficulty as with AK amputation, with greater hip control capability but restrictions in the supply of mechanical devices in terms of stump and prosthesis [9].

The TK prosthesis's biomechanics are thoroughly described [3], i.e. understanding how gait deviations and muscle actions interact to control forces and lower socket-stump contact stresses. The tissue at the stump end has been adapted for weight-bearing in the kneeling posture. Hip muscles have the potential to control forces via a lengthy lever arm and are mostly intact and physiological. Greater stump length implies lower socket-stump contact stresses, compared to the AK prosthesis. The higher stump length increases the coupling arm between the summated force effects, lowering their amplitude and pressure. The biomechanical evaluation of the lower limb residuum/socket interface may aid with socket fit by assessing lower limb prosthesis interface kinematics and kinetics. Walking speed had an impact on the vertical and horizontal shear forces. Compared to self-selected speed, the vertical and horizontal shear forces were decreased by 5% and 33%, respectively, at rapid speed. At a slow speed, the vertical and horizontal shear forces increased by 7% and 17%, respectively [10].

Lower limb prosthetic sockets have to provide sufficient circumferential forces for the patient to comfortably bear weight, stand, and walk. The easiest way to assess prosthetic socket comfort is to ask the patient how they feel about their prosthetic socket. However, physicians must be assured that the specified uniform socket pressures will be distributed as evenly as feasible after the patient leaves the clinic to provide long-term comfort.

Prosthetic socket materials have changed significantly throughout time, moving from wood, leather, aluminium, and plastic to plastic and other synthetic materials. A wide range of composite and reinforcing materials are used in thermosetting. Carbon fibre, nylon-glass, polyester, and glass fibre are among the composite materials that are rising in popularity globally [11]. Because they combine outstanding characteristics of each distinct material, composites perform better than their constituent parts and may be utilised to make prostheses for amputees and the handicapped [12]. Furthermore, it has been revealed that the kind and quantity of reinforcement layers affected the mechanical characteristics of the prosthetic socket [13].

There are many challenges related to the design and manufacturing of TK prostheses: including the prosthetic socket's material and subsequent fatigue and stress conditions. Despite the enormous range of biomaterials accessible, humans continue to experience prosthesis-related challenges [14, 15], i.e. a challenging issue requires adequate skills. Numerous strategies have been proposed in the literature to address the challenges of material selection and enhance the efficiency of the design process [16, 17]. The other problem is to endure the stresses and the corresponding pain during walking. Therefore, the aim of this study is to identify the best composite materials for TK prostheses to withstand fatigue loading in Iraqi rehabilitation centres for special-needs patients. In particular, the objective of this research is to find the optimum composite materials as well as to offer a critical evaluation of the functions of the TK prosthetic units, their levels of mobility, kinetics, and gait. Moreover, to verify sufficient socket pressure, F-socket was used to measure residual limb socket pressures during walking.

The present paper is structured in the following manner. The literature review is provided in section 2. The methodology, which involves the preparation of materials for testing and the measurement protocol, is explained in section 3. The findings presented in section 4 are accompanied by a comprehensive analysis and interpretation. The subsequent sections, namely section 5, provide a detailed discussion of the results and outline the study's limits, respectively. The conclusions of this investigation are summarised in section 6.

2.Literature review

Prosthetic socket materials have been traditionally authorised. Jweeg et al. [18] conducted theoretical and experimental research on composite reinforcement fibres. Unidirectional fibres have a higher modulus of elasticity (E) than woven varieties in the transverse direction. Takhakh et al. [19] developed composite tensile and fatigue testing. They utilised 12 layers of perlon, 2 carbon fibres, and 10 without. Experimental and finite element approach findings agreed well. For the first lamination, they proposed 3.032 and for the second, 1.7578. On the other hand, Chiad [20] introduced two kinds of laminations (4perlon + 2 carbon fibres + 4perlon) for lower limb prostheses. He stressed effect. Good impact qualities in the second lamination scheme compared to the first offer confidence in absorbing impact loads and may be utilised to make durable lower limb prostheses. In line with these results, the best laminated composite specimens, as tested by [21], were 3 layers of Jute and 4 of carbon fibre. Tensile strength and E exceeded 162 MPa and 3.60 GPa, respectively. Scanning electron microscopy (SEM) observations imply a brittle to semi-ductile transition as the broken surface becomes smoother. Muhammed [22] investigated the mechanical properties of hybrid composite materials comprised of fibreglass, carbon fibre, perlon, and epoxy resin. This lamination is examined for fatigue and tensile strength. The results indicate that when the number of perlon layers was increased to 11, E improved by 44%, but tensile strength decreased by 22%. A study has been conducted to determine the tensile strength of carbon-fibre laminates with varying numbers of laminations [23]. Due to the increase in carbon-fibre layers in subsequent samples, carbon-fibre laminate tensile strength improved. A 10-layer carbon fibre specimen showed 576.079 N/mm^2 tensile strength. Second, increasing the loading rate from 2 mm/min to 5 mm/min during tensile testing of constructed samples increases deformation.

Abbas and Kubba [24] investigated three laminated composite material groupings including perlon, glass fibre, and carbon fibre reinforced the 80:20 composite material matrix. These three groups were tested for mechanical characteristics. ANSYS utilised tensile and fatigue test data from the socket composite material. These mechanical property testing yielded: using only perlon reinforcement; the properties are yielding strength =33:6MPa, ultimate tensile strength =35:6MPa, and E = 1:03GPa; using (3perlon +2carbon fibre +3perlon) layers, the properties were 65:5MPa, ultimate tensile strength =92:5MPa, and E = 1:99GPa; and using (3perlon + 2 glass fibre + 3perlon) layers, the results were 40MPa, 46:6MPa, and 1:4 GPa. The computed safety factor for a prosthesis manufactured from a composite material with three layers (3 Perlon+2 carbon fiber+3 perlon) is 1.037, making it safe for design prosthetic applications. Socket failure may occur after TK amputation. Therefore a study [25] recommends composite materials to improve prosthetic socket comfort. Using the F-socket test, the stump-socket interface pressure (IP) was calculated. ANSYS used experimental and theoretical IP data and geometry to calculate von-mises stresses and safety factors. Von-Mies stress is 15.42 MPa for the suggested composite. The revo fit solution with the socket was studied to enhance suspension and reduce socket weight [26]. Through theoretical and experimental findings, it was discovered that utilising carbon fibres, with their arrangement within the structure, improved the ultimate tensile strength and E [27–29]. Due to its durability being greater than that of perlon fibre, the impact resistance was also increased.

Bombek proposed systematic lamination process improvements to improve composite material quality [30]. They aimed to enhance resin impregnation and eliminate gaps between and inside fibres. The existing material (B) was compared to three newly constructed materials that changed the lamination process: B1, with an infusion spiral tube; B2, with resin degassed; and B3, with mesh and peel ply. Lab tests determined specimen strength. After normalising for specimen thickness, the current material exhibited the maximum bending strength, on average. B1 and B2 have lower tensile strengths than

B ($p < 0.001$). Due to the increased average specimen thickness, Material B3 had the lowest average tensile strength but could not be statistically differentiated from the others. Only B1, B2, and B3 were evaluated for compressive strength. Their averages did not vary statistically ($p = 0.291$).

Faheed et al. [31] tested resin polymers and natural fibres to find an optimal combination. Stockinet-woven sockets were used for testing. Different fibre stacking sequences affected volumetric and mechanical properties. Mechanical tensile tests were utilised to evaluate laminated specimens' strength, E, and % of elongation. The best composite specimens contained three sisal layers and two carbon fibre layers, with tensile strength and E of (261–4760) MPa, respectively. The contours of safety factor, equivalent von-mises stress, equivalent von-mises strain, and total deformation were anatomised using the finite element technique. Ten socket models, which were three-dimensional (3D) structural composite materials, were used to complete this technique. Results show that the variation in the material of the socket has a significant impact on its tensile strength and modulus of elasticity. This can be observed through the (strength/density) ratio, E, and ultimate tensile strength of the stacking arrangement consisting of 4 perlon, 3 sisal, and 2 carbon fibre. In this arrangement, the tensile strength and E reach values of 261 MPa and 4.76 GPa, respectively. This research shows that bio-composites with improved performance may be made by combining natural and synthetic reinforcements.

The lightness of the prosthesis allows additional prosthesis improvement segments to be inserted without affecting function. In this area, Zaier and Resan [32] examined how the modified shank affected the patient's stride and its mechanical qualities. They used solid work to design and analyse the shank, which was 3D printed. Acrylonitrile butadiene styrene (ABS) and polylactic acid (PLA) are utilised for constructing shanks. Then a specific gadget was designed to test the new shank's life under alternating stress. After practical and numerical testing, the new shank's mechanical properties were satisfactory, matching prosthetic limb criteria.

Researchers have used 3D printing and computer-aided design (CAD)/computer-aided manufacturing (CAM); CAD/CAM to make prosthetic sockets for over 30 years. Additive manufacturing (AM) is chosen for CAD-designed prosthetic sockets because it can manage residual limbs' intricate morphologies [33]. Novel topologies may produce fully integrated monocoque prosthetic sockets using AM technology [34]. Despite its popularity, printing materials are too strong for therapeutic application [35]. Polymers strengthened AM prosthetic sockets. AM-printed items may be strengthened by fill compositing [8] and direct printing of sandwich structure composites [36]. These results propose using vacuum infiltrated fill compositing and printed sandwich structure combinations to improve AM printed prosthetic socket mechanical properties. Improving the mechanical performance of these AM materials may help prosthetic clinics adopt digital technology and its advantages faster. Several studies revealed International Orga nisation for Standardisation (ISO) load-compliant AM polymeric materials [37, 38]. Fused deposition modelling (FDM) prosthetic socket printing became possible. Static testing failed these sockets horribly. Most fractures were circumferential brittle. These scholars advocated for new material research to meet unmet needs. A study has shown that AM sockets break brittlely at this juncture before final fatigue strength [39]. On the other hand, vacuum-infiltrated sandwich structure composite AM prosthetic sockets seem promising. American society for testing and materials (ASTM D638), standard test method for tensile properties, tests 18 composite material combinations [40]. Vacuum infiltration was used to make these composites. Material-matrix-print composites outperformed full-infill control samples in ultimate tensile strength and anisotropy. Porosity makes these composites mechanically weak. Hoover infiltration constructed a proof-of-concept prosthetic socket.

By using finite element analysis, research has examined how liner and soft tissue material qualities affect stress distribution [41]. When peak normal and shear stresses were examined, liner-soft tissue interface alterations were prevalent. Urethane and thermoplastic elastomer (TPE) had lower peak values than silicone, even in standing and mid-stance. The stump's internal stress distribution yielded the most intriguing soft tissue material property changes. Stiffer residual limbs had higher stress values, even though material qualities did not alter soft tissue stress distribution.

Another point should be taken into consideration is "Normal gait". Many prosthetics and patients accept a "good enough gait" that balances comfort, patient preferences, and performance. A 3D-printed porous shank design and fabrication was investigated [42]. The new shank's influence on the patient's gait analysis and its mechanical qualities were evaluated. Researchers examined the foot anatomy to enhance fatigue and mechanical qualities of foot materials. As walking speed increases, the ground reaction force (GRF) triples, making it difficult to choose prosthetic limb components for active young people who run, push carts, and more. Therefore many researches utilised various reinforcing fibre to enhance foot strength and fatigue [43, 44]. This study examined how walking speed affects a novel BK prosthetic shank. Tang et al. [10] employed kinetics and kinematics to evaluate a socket interface biomechanics platform. The method uses an interface sensor to detect multi-directional stresses. A 3D motion capture system examined the interface coupling motion. The evaluation platform was similarly responsive to walking speed. A combined biomechanical evaluation platform for the residuum/socket interface based on socket movement and interface stresses may help with the socket fitting procedure and create patient-specific adjustable sockets and fully integrated limb systems.

Prosthetic gait training for lower limb amputation patients requires monitoring gait change to create and alter rehabilitation protocols. A research examined spatiotemporal characteristics and lower limb coordination in unilateral transfemoral amputees (TFAs) during prosthetic gait training [45]. TFAs underwent 12-week prosthetic gait training and 3D motion analysis every two weeks. Spatiotemporal characteristics and hip-knee joint phase were assessed. The continuous relative phase was most symmetric at week 8 and walking speed improved greatest at week 4. TFAs had a higher in-phase lower limb coordination pattern and reduced coordination variability than controls. TFAs' lower limb coordination changed slower than spatiotemporal characteristics and was statistically different from controls even after training. TFAs require therapy interventions to enhance lower limb coordination, which affects walking efficiency, balance, and fall risk.

Rasheed et al. [46] opened research questions surrounding the prosthetic knee unit, kinematics, gait assessments, and control frameworks for transfemoral prosthetic legs. As a means of filling in knowledge gaps and improving current prostheses, ambulation exercises, flat-ground walking, jogging, and walking uphill are all taken into account.

In general, prosthetics are still considered a cutting-edge scientific development. AK and BK prosthetic socket design and production are widely documented in the literature. However, research on TK prosthesis is still limited, and there is a general deficiency in this field. Accordingly, this study identifies the best composite materials for TK prostheses to withstand fatigue loading in Iraqi rehabilitation centres for special-needs patients.

3.Materials and methods

The experimental data was collected at Al-Nahrain University's Department of Prosthetics and Orthotics Engineering. The experimental procedure of this study included the following three stages in sequential order:

Stage 1: The tensile, bending and fatigue properties of three laminated composite material groups have been tested. Subsequently, based on the findings of these properties, the best option among the three tested groups was selected to manufacture the socket for TK prosthesis.

Stage 2: The IP between the wall of the socket and the stump at the four sides of the stump were tested using F- socket.

Stage 3: Gait analysis was evaluated on the prosthetic and sound legs. Moreover, spatiotemporal gait parameters were reported as well.

3.1Participant

A 30-year male individual who had a transtibial amputation of his right leg performed 5 years prior (due to an accident) participated in this study. Detailed characteristics of the prosthetic limb used by the amputee subject are presented in *Table 1.*

Other than limb amputation, the participant had no present or prior phantom limb discomfort or neurological or muscle health issues. He was recruited from (Baghdad artificial limbs centre), and before participating in the study, for which Al-Nahrain University's Internal Review Board granted approval, the participant provided written informed consent.

Table 1 Demographic features of the participant

Variable	**Amputee Subject's Data**
Age (year)	30
Height (m)	1.80
Body weight (kg)	95
Body mass index (kg/m^2)	29.3
Duration of amputation (year)	5 years
Prosthetic type	Through knee prosthesis
Amputated leg	Right leg
Cause of amputation	Car accident (severe traumatic injury)

3.2Materials

The materials that are used in the process of manufacturing prosthetics and orthotics, such as white perlon, carbon fibre II, acrylic resin, and hardening powder, with inner and outer elastic polyvinyl acetate (PVA).

3.3Equipment

- A mould made of gypsum that is used for the manufacture of samples, the manufacture of the prosthesis.
- The system for releasing pressure and trapped air, which consists of a motor and a holder to hold the gypsum mould.
- Mechanical workshops for manufacturing, cutting and assembling samples, as well as assembling the components of the prosthetic limb.
- Apparatus for testing tensile samples and fatigue samples.
- Analyse the patient’s gait cycle using a gait analyser (force plate).
- F-socket for calculating the overlapping or confined pressure prosthetics socket.

3.4Materials preparation for testing

The gypsum material is used as a mould to create composite material samples. To avoid the creation of bubbles within the samples, they are securely fixed and tied to pressure vacuum equipment, and the connection is created using pipes.

PVA material is placed to cover and release the resin to the gypsum mould. Pressure pipe wrench at a pressure of 40 kPa. The nine layers of carbon fibre II were added, then, an outer layer of PVA was placed.

This method used to manufacture samples uses the same for fibre of perlon and glass fibre layers. A 400 to 500ml of 80:20 resin was mixed with hardener and put on the layers of composite materials. Therefore, samples were prepared for the standardised mechanical tests, including tensile, flexural, and fatigue.

The laminated composite material were cut according to the standard of ASTM638– standard test method for tensile properties [47] to create samples for tensile strength. The flexural bending test was carried out based the standard, American society for testing and materials–standard test method for flexural bending (ASTM D790) [48]. Eight samples of composite materials were used for each group to perform the fatigue test. The composite material with the most favourable mechanical characteristics, as determined by the mechanical testing conducted in this study, was selected for the production of the prosthetic socket. The manufacturing process for the samples was replicated to ensure consistency. The pressure exerted between the socket and the stump was measured using the F-Socket sensor. The pressure was quantified by positioning the sensors on four distinct areas of the remaining limb, namely the anterior, lateral, posterior, and medial portions. The aforementioned forces are generated as a result of the patient's walking.

As a summary, three laminated composite material groups' tensile, bending, and fatigue characteristics were evaluated, as shown in *Figure 1*. Based on these features, the socket for TK prosthesis was made from the best of the three evaluated groups.

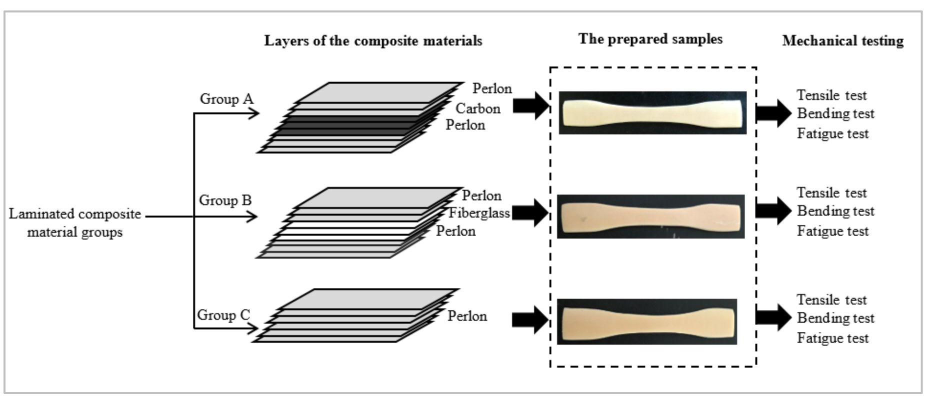

Figure 1 Three laminated composite material groups were examined for tensile, bending, and fatigue characteristics

3.5Measurement protocol

Following selecting the optimum composite materials for TK prostheses to withstand fatigue loading and successfully fitting of the prosthesis, the individual completed a 5-minute walking trial. An F-socket was attached to the residual limb of an amputee. Sensor data in kilopascals (kPa) were captured in real time. The participant was asked to walk on a force plate at his self-selected walking speed. Meanwhile, peak pressure was measured within a step. During walking on the force plate, the GRF for the prosthetic and the sound legs was recorded, and the corresponding spatiotemporal gait parameters were measured. Finally, the symmetry index (SI) was calculated to compare the dynamic performance between the prosthetic and the sound legs.

3.6Gait analysis

This step is aimed to evaluate the spatiotemporal gait parameters of the prosthetic and the sound legs. The participant had been instructed to walk over a 6-meter path at his walking pace. A force platform (Tekscan) was used to capture the GRF. From heel strike until toe-off, the GRF was measured by a force plate and characterised the stance phase. The GRF's was normalised to each gait cycle stance phase, i.e. it was converted to a percentage of the subject's weight.

3.7Symmetry index(SI)

As demonstrated in Equation 1, the asymmetries in gait characteristics were measured using a SI expression, which was developed by Robinson et al. [49].

$$SI = \frac{(X_P - X_S)}{0.5\ (X_P + X_S)} \times 100\% \qquad (1)$$

Where,

X_P is the prosthetic leg's gait variable.

X_S is the sound leg's gait variable.

A zero value for SI means that the variables X_P and X_S have no difference. In actuality, this means that the individual variable has ideal gait symmetry. A positive SI finding indicates that $X_P > X_S$, whereas a negative number shows the opposite.

3.8Statistical analysis

The statistical packages for social science (SPSS, Version 26, IBM) were used for the statistical analysis. Statistical tests of normality, namely Kolmogorov-Smirnov and Shapiro-Wilk, were used. These showed that the data were normally distributed, and therefore, a parametric test, analysis of variance (ANOVA), was performed to compare between groups and t-test was performed to compare between the prosthetic and sound legs, using a significance level of 5%.

4.Results

4.1Tensile test

Table 2 displays the tensile test findings for the three group. Significant differences between groups were observed. The stress strain pattern for each group was illustrated in *Figure 2*. On the basis of these findings, the mechanical properties of each group involved in prosthesis's manufacturing were determined. *Table 2* shows the effect of increasing or decreasing the materials layer or increasing the amount of acrylic for each of the carbon fibres and glass fibres on the mechanical properties.

Table 2 Tensile test characteristics for each group

Laminations	No. of layers	Thickness (mm)	σ_y (MPa)	σ_{ult} (Mpa)	E (GPa)
Group A	9	2.8	123 [a,b]	155 [a,b]	1.99 [a,b]
Group B	9	2.6	90 [a,c]	128 [a,c]	1.4 [a,c]
Group C	6	2.3	33	37	1.03

Group A (3 layers of perlon fibre, 3 layers of carbon, 3 layers of perlon fibre); Group B (3 layers of perlon fibre, 3 layers of fiberglass, 3 layers of perlon fibre); Group C of six-layers of perlon only. [a] significant between A and B groups (P<0.05). [b] significant between A and C groups (P<0.05). [c] significant between B and C groups (P<0.05).

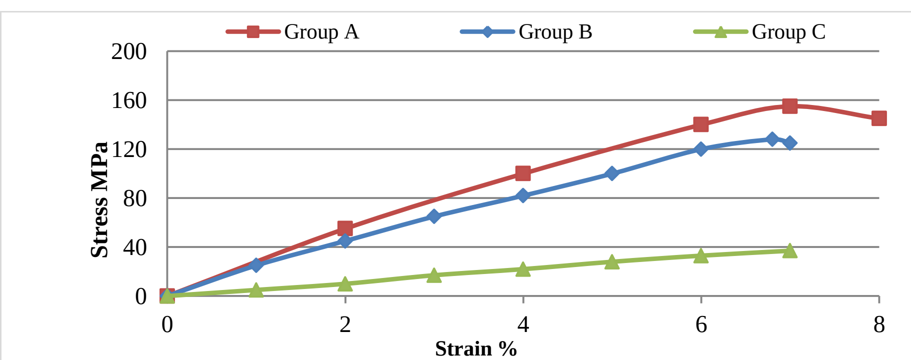

Figure 2 Stress-strain curves

4.2Point load bending properties

The results of the bending test represented the bending stress and modulus. The stress test results were obtained from the stress deformation curves shown in *Figure 3*.

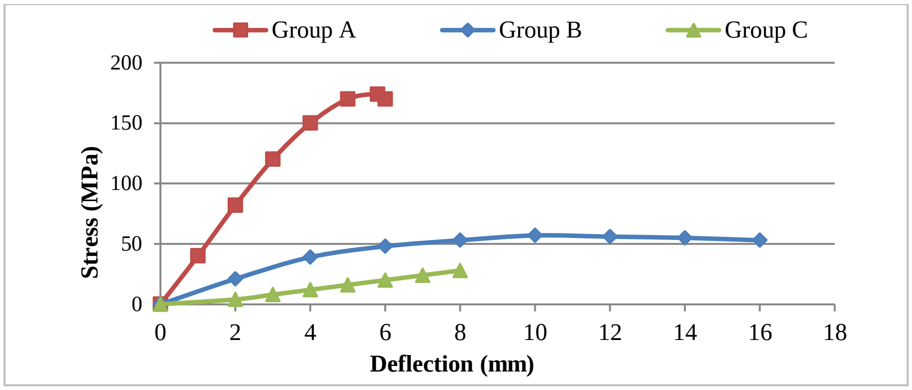

Figure 3 A plot of stress versus deflection

4.3Fatigue test

The fatigue results are shown in the following *Figure 4*, where the stress and strain diagram for each of the samples shows for all the groups used in this work. When the temperature is held constant, it was discovered that increasing the number of cycles used to achieve the failure stress of the samples led to a drop in the failure stress rate of the samples.

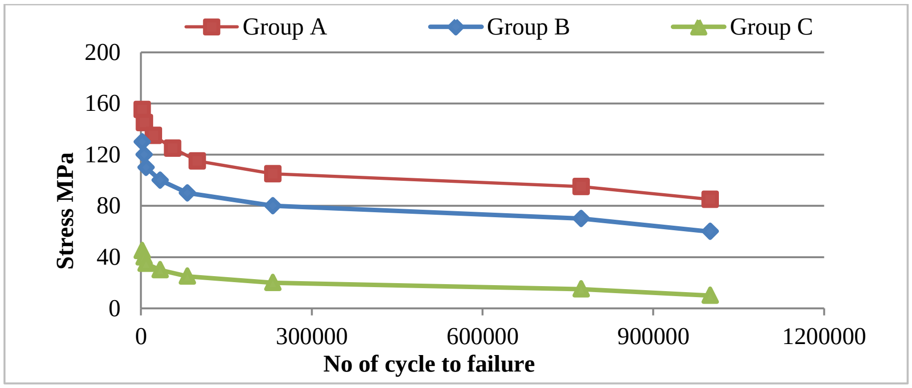

Figure 4 A plot of stress versus no of cycle to failure

4.4Gait cycle

Tables 3 and *4* include information on the patient's gait cycle analysis. Asymmetric gait after unilateral TK prosthesis is shown by shorter stance and longer swing phases for the prosthetic limb than sound leg and reduced prosthetic leg propulsion power. The prosthetic leg has a shorter step length than the sound leg. The prosthetic limb has shorter stride length and velocity. The sound leg had a longer stance phase than the prosthetic leg. No significant differences, between the prosthetic and sound legs were observed in gait-time, time of initial double support, time of passive propulsion, step-time, stride- time, step-width, and foot-angle suggested that these outcome measures were not the most sensitive methods to differentiate between the prosthetic and sound legs.

Table 3 Temporal parameters of the gait cycle (s)

SI	Prosthetic leg	Sound leg	Variable
0	1.24	1.24	Gait-time
-6	0.79 †	0.84	Stance-time
12	0.45 †	0.40	Swing-time
-5	0.40	0.42	Single support-time
0	0.20	0.20	Time of initial double support

SI	Prosthetic leg	Sound leg	Variable
5	0.21	0.20	Time of terminal double support
0	0.45	0.45	Time of total double support
67	0.24 †	0.12	Time of mid stance
-23	0. 38 †	0.48	Time of propulsion
-46	0.15 †	0.24	Time of active propulsion
-5	0.20	0.21	Time of passive propulsion

† Significant differences between prosthetic and sound legs (*P*<0.05).

Table 4 Spatiotemporal gait parameters

SI	Prosthetic leg	Sound leg	Variable
0	0.66	0.66	Step-time (s)
-21	0.447 †	0.554	Step-length (m)
-21	0.677 †	0.84	Step-velocity (m/s)
0	0.12	0.12	Step-width (m)
-1	1.26	1.27	Stride- time (s)
-6	0.956 †	1.015	Stride-length (m)
-5	0.758 †	0.800	Stride-velocity (m/s)
9	627.44 †	576.17	RMS Force (N)
19	375.39 †	310.89	Impulse (N*s)
29	267 †	200	RMS pressure (kPa)
0	2	2	Foot-angle (degree)

† Significant differences between prosthetic and sound legs (*P*<0.05)

4.5Interference pressure (IP)

The pressure generated as a result of the muscles of the amputee patient and applied to the inner surface of the wall of the prosthesis is calculated and measured using a special type of sensor, which is in the form of a sensory strip that extends along the length of the stump. This sensor is placed in specific areas of the stump, the outer front and the inner back, and their results are shown in *Figure 5* to *Figure 8*. *Table 5* shows the results of the pressure distribution for each region sockets. The pressure was determined in four locations of the residuum, i.e., the anterior socket-region, posterior socket-region, medial socket-region, lateral socket-region. The anterior and lateral socket-regions creating a significantly higher IP compared to the posterior and medial socket-regions.

Table 5 Prosthetic socket IP values

Socket regions	Anterior-region	Lateral-region	Posterior-region	Medial-region
IP (KPa)	495 †	427 †	384	351

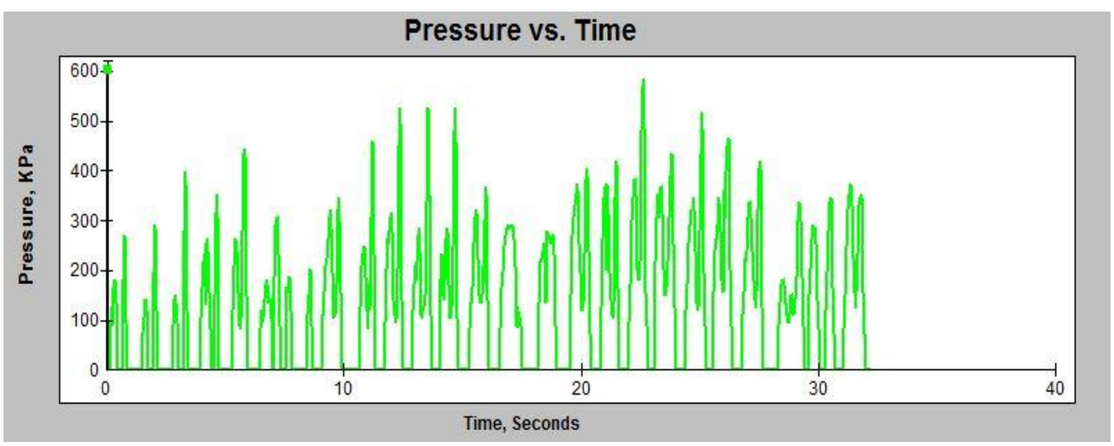

Figure 5 IP at the anterior socket-region

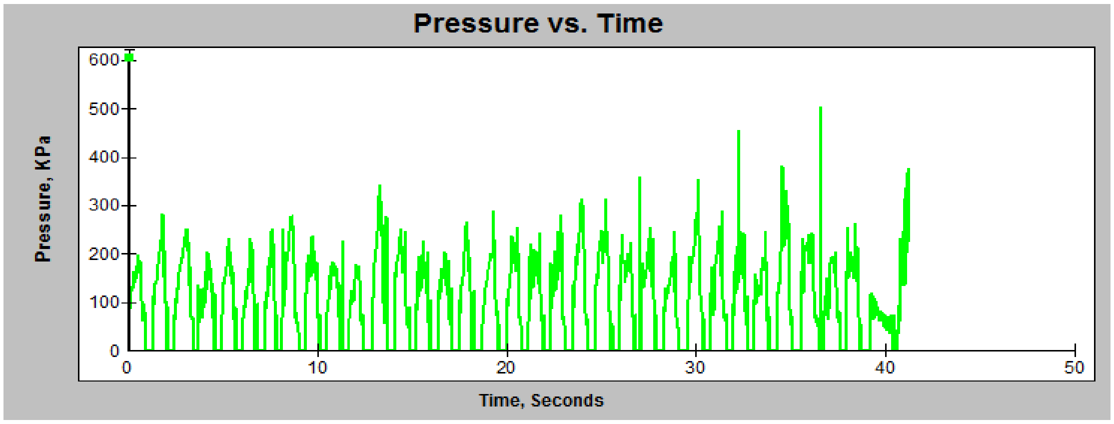

Figure 6 IP at the posterior socket-region

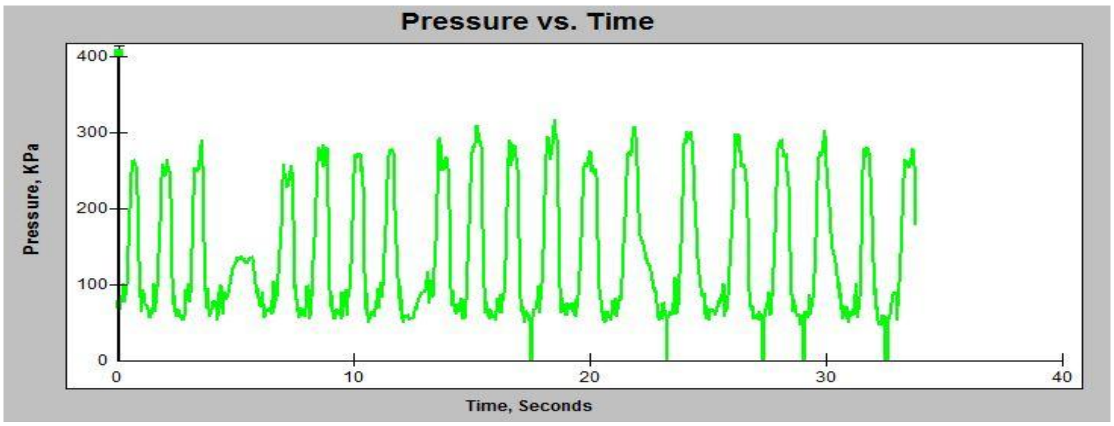

Figure 7 IP at the lateral socket-region

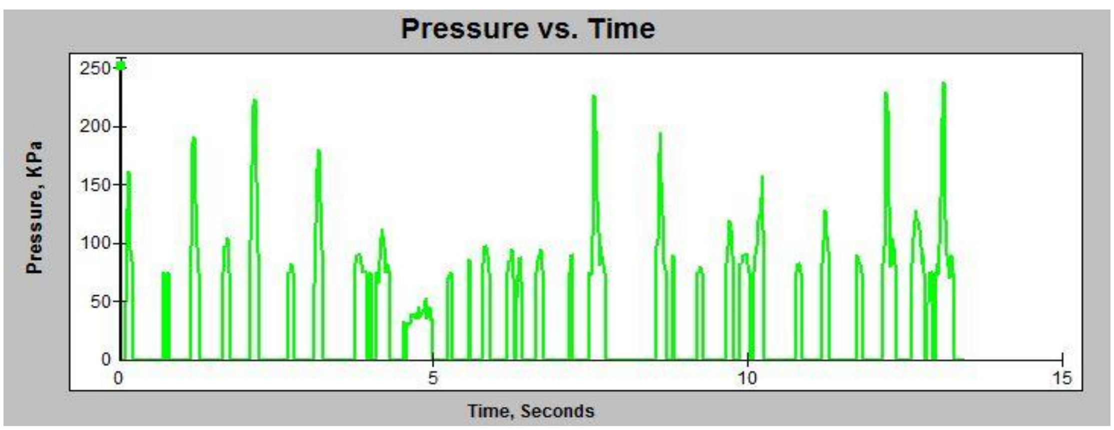

Figure 8 IP at the medial socket-region

5.Discussion

The key finding of this study is that the optimal evaluated composite material's outperformed performance is primarily due to the three-carbon layers and their matrix configuration. How do the layers' increase, leading to increases in Ϭy, and Ϭult. Results obtained from the tensile test of these materials used in the manufacture of the prosthesis in this research showed 123, 90, and 33 MPa for group A, group B, and group C, respectively. This means that it has good mechanical strength compared to the mechanical properties of polypropylene (43 MPa max), where it is usually used in a socket prosthesis or orthosis. Compared to previous studies, the suggested composite material (group A) has a greater mechanical performance. The ultimate stress in this study is 123 MPa, compared to 36-55 MPa [19] and 47-54.7 MPa [20]. This rise is mostly due to 3 layers of carbon and the matrix's carbon layer structure. Furthermore, it was found that the failure stress rate of the samples decreases by increasing the cycle's number to reach the failure stress of the samples when the temperature is fixed. Fatigue tests show the recommended composite material (group A) improves stress endurance by about 750%. This was owing to carbon fiber's mechanical characteristics being better than polypropylene's.

Between the prosthetic and sound legs, there are bilateral disparities in time duration and metrics of distance including stance and swing timings and length's step. These modifications might be a consequence of a significant mechanical difference between the prosthesis and unaffected sides, most notably the inability to actively create ankle power. Consequently, gait analysis reveals both GRF and spatiotemporal gait characteristics asymmetries.

Gait following unilateral TK prosthesis is asymmetric, as demonstrated by significant shorter stance and longer swing phases for the prosthetic than sound leg followed by a decreased prosthetic leg propulsion force. Step length was significantly reduced on the prosthetic leg compared to the sound leg (0.447 m vs. 0.554 m), where the sound step length is the distance between the sound and subsequent prosthetic foot implantation locations. Stride length and velocity were significantly lower for the prosthetic leg (0.956 m; 0.758 m/s) than for the sound leg (1.015 m; 0.800 m/s), respectively. Stance phase duration on the sound leg (68% of the gait cycle) was longer than on the prosthetic leg (64% of the gait cycle). Early toe-off has been examined as a consequence of asymmetric stride lengths, hypothesising that the absence of prosthetic plantarflexion causes the toe to depart the ground quicker than a normal leg [50].

In agreement with [51], TK prosthesis is related to slower walking speeds and less independence in transfers, walking, and stair climbing. The prosthetic leg walked slower than the sound leg (1.26 m/s vs 1.43 m/s). The limb shifts from shock absorption to stability during the mid-stance valley stage of GRF. In comparison to the sound side, the decrease in mid-stance time on the prosthetic side is most likely due to reduced offloading, i.e. the prosthetic limb contributed less to single-leg support body weight.

Tang et al. [10] demonstrated that increasing walking pace has been linked with a reduction in vertical force at the mid-stance period (about 30% of the gait cycle). This might be explained by higher vertical displacement of the body's centre of mass, which is related to increased walking speed [52]. Indeed, increasing the vertical mobility of the centre of mass is a way of conserving metabolic energy [53].

The symmetrical indices in this research revealed that the gait variables exhibited asymmetrical values, such as more than 67 % and 46 % of the SI for the time of mid-stance and time of active propulsion, respectively. Both pressure and impulse exhibited high asymmetries among the other parameters. The word "impulse" refers to the amount of GRF absorbed by the body during stance, and injury risks increase as the body absorbs more energy in a shorter period of time.

It was discovered that the evaluation platform was sensitive to variations in spatiotemporal gait parameters. An integrated biomechanical evaluation platform for the residuum/socket interface that takes into account both socket movement and interface stresses may help with socket fitting as well as the creation of fully integrated limb systems and patient-specific adjustable sockets.

F-socket was used to validate the homogeneity of prosthetic socket fit for prosthetic construction procedures. In *Table 5*, through this test, it was noticed that the highest value of the pressure applied to the inner surface of the socket was on the front side, which is agreed with [20, 25], and amounted to 495 MPa, and also on the side of the socket and was at the amount of 427 MPa. The amount of pressure applied to the artificial stump was the result of muscle activity in these areas of the stump and was clearly visible when the patient walked. Residual limb pressure was successfully measured using F-socket, with the anterior and lateral regions having considerably higher peak pressure.

5.1Limitations

This research does come with certain limitations. Notably, marker-based kinematics were not taken into consideration. The principal aim of the study was to juxtapose the spatiotemporal and kinetic walking characteristics of the prosthetic and intact legs. However, it's worth noting that the placement of markers on the prosthetic knee and ankle locations, mirroring those on the intact side, could potentially influence joint centers. Consequently, the kinematic analysis might not have fully accounted for performance discrepancies in the prosthetic limb.

Furthermore, the pressure measurements were solely conducted during laboratory walking sessions, which could lead to variable socket pressures. It's worth considering that these sensors might eventually offer comprehensive prosthetic socket pressure measurements during real-world, unconstrained activities. Another aspect to acknowledge is the absence of recorded comments from the prosthetics' users regarding their experiences with the system. This unavailability of user feedback might limit the broader understanding of the prosthetic system's performance and user satisfaction.

A complete list of abbreviations is shown in *Appendix I.*

6.Conclusion

The tensile test results for the materials employed in the construction of the prosthesis in this study demonstrated values of 123 MPa, 90 MPa, and 33 MPa for group A, group B, and group C, respectively. This signifies a commendable mechanical strength in comparison to the typical mechanical properties of polypropylene (which maxes out at 43 MPa), a material commonly used for socket prostheses and orthoses. The endurance of the carbon fiber composite exhibited a remarkable increase of 750%, boasting superior mechanical attributes when juxtaposed with polypropylene. Successful measurement of residual limb pressure was carried out, revealing that the anterior and lateral regions both displayed significantly higher combined mean peak pressures in contrast to the posterior and medial regions, respectively. Notably, the highest-pressure value, reaching 495 kPa, was recorded on the frontal side of the amputation during both heel strike and toe-off phases. Secondary adjustments were made to the prosthetic legs in order to alleviate discomfort. These adjustments translated into shorter stance phases and longer swing phases in comparison to the sound legs, as well as reduced propulsive power and overall shorter, slower strides. Such a comprehensive evaluation of the TK prosthesis holds the potential to facilitate improved socket fitting procedures and the creation of patient-specific customizable sockets, driven by insights gleaned from gait analysis and IP assessments.

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None.

Conflicts of interest

The authors have no conflicts of interest to declare.

Author's contribution statement

Muhammed Abdul Sattar: Contributed to the conceptualization and writing of the original draft. **Aseel Ghazwan:** Contributed to the verification and visualization, analysis of experimental results, writing reviews and editing. **Saif M. Abbas:** Contributed to conducting experiments and investigation.

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Appendix I

S. No.	Abbreviation	Description
1	ABS	Acrylonitrile Butadiene Styrene
2	AK	Above-Knee
3	ANOVA	Analysis of Variance
4	AM	Additive Manufacturing
5	ASTM	American Society for Testing and Materials
6	ASTM D790	American Society for Testing and Materials– Standard Test Method for Flexural Bending
7	ASTM638	American Society for Testing and Materials– Standard Test Method for Tensile Properties

8	BK	Below-Knee
9	CAD/CAM	The integration of Computer-aided design (CAD) and Computer-Aided Manufacturing (CAM)
10	3D	Three-Dimensional
11	E	Modulus of Elasticity
12	FDM	Fused Deposition Modelling
13	GRF	Ground Reaction Force
14	IP	Interface Pressure
15	ISO	International Organisation for Standardisation
16	PLA	Polylactic Acid
17	PVA	Polyvinyl Acetate
18	SEM	Scanning Electron Microscopy
19	SI	Symmetry Index
20	SPSS	Statistical Packages for Social Science
21	TFAs	Transfemoral Amputees
22	TK	Through-Knee
23	TKA	Through-Knee Amputation
24	TPE	Thermoplastic Elastomer
25	Ϭult	Ultimate Tensile Stress
26	Ϭy	Yield Tensile Stress
27	X_p	The Prosthetic Leg's Gait Variable
28	X_s	The Sound Leg's Gait Variable