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Comparing Maximum Lifespan of a New Flexible Keel versus Non-Articulated Prosthetic Feet

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Abstract

The number of amputees worldwide is increasing for different reasons, such as diseases, accidents, and acts of violence. In developing countries, conventional prosthetic feet like the Solid Ankle Cushion Heel (SACH) foot are commonly used because of their affordability, ease of maintenance, and use. To improve the features of the SACH foot, a new prosthetic foot was developed that resembles it but has a flexible keel. The new foot consists of a wooden keel, carbon fiber reinforced polymer support, and a flexible filler material, silicone rubber, that provides flexibility to the foot's movement. The process of pouring liquid silicone rubber and rice husk ash into a metal mold. The new foot was tested for fatigue foot life and dorsiflexion angle using devices such as the Fatigue Foot Tester and dorsiflexion tester to estimate its expected life. The outcomes were relative to those of the SACH feet, and it was found that the new foot has a better fatigue life of 510,382 steps compared to 473,241 steps for the SACH foot. Additionally, the new foot has a higher dorsiflexion angle of 5.7° compared to 2.3° for the SACH foot.

Keywords: Dorsiflexion; Fatigue; Flexible keel; Prosthetic foot; SACH

1. 1. Introduction

The World Health Organization (WHO) has estimated that around 1.3 billion people, which accounts for about 16% of the world's population, have some form of disability. Most of them, around t 80%, inhabit economies in transition. The number of people with disabilities is increasing for various reasons, such as war, landmines, inadequate healthcare, natural disasters, poverty, and other forms of violence. Lower limb amputation is the most common disability, with below-knee amputation (BKA) being the most frequent type. Many young and older individuals in Iraq have had BKA due to landmines or limb illness. A prosthetic replacement is the only option to resume everyday life, at least temporarily [1],[2].

Over the years, numerous studies have been conducted on pathological and non-pathological human gait to develop prosthetic devices that can improve patients' control, comfort, and appearance by mimicking the characteristics of a natural limb [3] [4].

Jweeg et al. [5] developed a polyethylene (PE) prosthetic foot and compared it with the commonly used SACH foot to determine differences in walk patterns that would cause any patient issues. Clinical and scientific studies have identified factors such as energy return, dorsiflexion, eversion, fatigue foot test, impact test, effective length ratio, and others essential for a natural gait. Compared to the SACH foot, the polyethylene prosthetic foot exhibited favorable characteristics such as good dorsiflexion, stored and returned energy, and a longer lifespan. Carpenter et al. [6] designed a low-cost prosthetic foot made of polypropylene (PP) and polyethylene (PE) for transtibial amputees. The foot was tested with two existing designs, the SACH feet and North Western's energy and shape-efficient prosthetic foot, and found to have acceptable static loading conditions based on testing. Emad [7] compared another prosthetic foot made of PTFE polymer to the SACH foot in terms of stress distribution, dorsiflexion, return of energy, fatigue feet, impact, price, and weight. The modified foot was found to be significantly cheaper and lighter while also closely resembling the characteristics of the SACH foot.

Other studies were conducted on prosthetic feet to improve their design and functionality. Ali [8] examined a prosthetic foot made from (PE) which was non-articulated and designed to simulate natural walking. Hamzah et al. [9] designed a carbon fiber (CF) ankle-foot prosthesis tested for dorsiflexion and plantar-flexion. Mohammed and Mohammed [10] created a more human-like prosthetic foot using random E-glass-polyester composites and FEM techniques. The study found that the prosthetic foot had better dorsiflexion than the SACH foot.

The main objectives of the current study are to enhance foot stiffness while preserving forefoot flexibility (indeed, it is more flexible than the SACH Foot after shortening the wooden keel and replacing it with a CFRP one, but still stiffer than rubber silicone) and to Enhance and refine the features of the suggested prosthetic foot to overcome the shortcomings of the SACH foot.

2. Types of Fixed movement Joint prosthetic Feet

Artificial feet can be classified structurally into two categories: without joint movement feet, which have a fixed joint to the prosthetic shank, and movement joint prosthetic feet, which have a movable ankle tool [11].

The most common types of non-articulated feet are the SACH foot and low-cost prosthetic feet such as the Niagara Foot, Jaipur Foot**,** Al-kinani Foot, S-Foot, and Shape and Roll Foot [12]-[15].

2.1. The SACH Foot

This type of foot is a simple and inexpensive option suitable for individuals with restricted walking needs and no variation in speed or terrain. It is made of a soft outer shell molded over a stiffer inner component (keel), designed to resemble a human foot. While the SACH foot's cushioned heel provides adequate shock absorption for low-impact activities, its inflexibility and inability to handle uneven terrain make it less suitable for moderate to high-activity prosthesis users who require more versatility [11]. The prosthetic replacement should enable the wearer to stand, move, sit down, and stand up. Although SACH feet offer energy absorption and cushioning, they do not store or return energy as effectively as dynamic-response feet [16].

The benefit of fillers in artificial feet is that they add aesthetics and enhance durability, in addition to binding other components of the prosthetic foot. The SACH foot consists of the following elements:

- **The keel** is an important part of artificial feet. Its function is to transfer stored energy from the heel area to the toe area. It facilitates the dorsal flexion movement during the gait cycle and also helps with the twisting and eversion movement, which depends on the surrounding foam material [17].
- **The heel:** The artificial heel has two functions: the first is to absorb the shock generated during the walking cycle, and the second function is to provide a stable and smooth transition to the front of the toes [16].
- **The cushioning materials**: The density of the filling material and its physical properties are important factors in the characteristics of artificial feet, as they significantly affect the process of ankle twisting and other movements, such as upward bending. Fig. 1 shows the components of a traditional artificial foot [17].

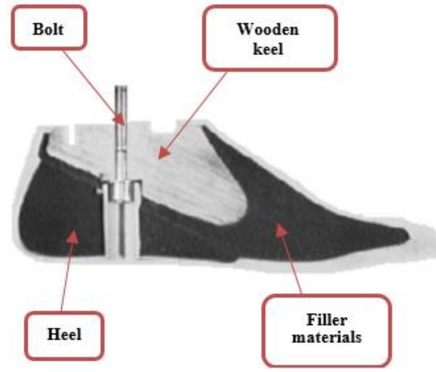

Figure 1. Components of SACH Foot [16]

2.2. The New Suggested Foot

The SACH foot is a commonly used prosthetic foot in developing countries like Iraq. However, it lacks dorsiflexion in the ankle region and can be uncomfortable due to how the forefoot bends. The keel of the SACH foot is also prone to failure in the middle region between the phalanges and metatarsals, where it receives an alternative load [7], as shown in Fig. 2.

To overcome the drawbacks of the SACH foot, a new foot was designed and manufactured with improved dorsiflexion and mechanical properties that prevent fatigue failure. The new foot consists of a wooden keel with a supporting part made of carbon fiber-reinforced polymer (CFRP), surrounded by a silicone rubber shell as a filler material. Fig. 3 depicts the newly designed foot.

Figure 2. Regions of failure in the SACH foot [7]

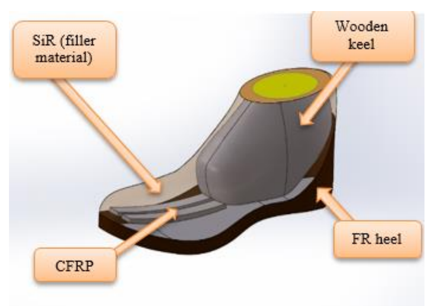

Figure 3. The suggested design of the new foot by SOLIDWORKS**.**

3. The Experimental Work

3.1. Prosthetic Foot Materials

The newly designed prosthetic foot utilized several materials, including Room-Temperature Volcanonized Silicone Rubber (RTV-2 SiR) as a filler material and fiber of Carbon Reinforced

Polymer (CFRP) as a supportive component of the wooden keel, as shown in Table 1, for increased durability and shock absorption in the heel region and insole. The design process involved using the SOLIDWORKS program to create a prototype, which was then used to manufacture a negative mold for creating a prototype of the new foot.

Table 1. Mechanical properties of a new foot

Materials	Tensile strength (MPa)	Yield strength (MPa)	Young Modulus (MPa)
Composite materials: carbon fiber - Orthocryl 80:20	179	143.5	3219
Silicon rubber	8.33	5.85	3.2

3.2 Manufacturing of The New Prosthetic Foot

The proposed foot sample process of manufacturing includes the following steps:

- Manufacturing the metal mold, as shown in Fig. 4.
- Assemble the important parts of the proposed foot (wood piece, two CFRP parts of 150 mm x 15 mm x 4 mm, filler, and heel) and fix them using Sikaflex-11 FC Purform polymer adhesive, then fasten them with screws to ensure good adhesion between the parts, as in Fig. 5.
- The important components are then placed inside the metal negative mold, and the different filler materials are mixed and poured into the negative mold.
- 4. After one day, the mixture is inside the mold, which is then opened to obtain the proposed foot with its different components, as shown in Fig.6.

3.3. Prosthetic Foot Tester

3.3.1. Foot Fatigue Testing Machine

A foot fatigue testing machine was developed based on the ISO 10328 standard [18] to simulate a person's gait cycle. The tester uses a couple of electrical valves, two linear actuators, a register, an air moisture removal filter, an electrical circuit, a compressor unit, and a monitor to apply alternating loads to the heel and toe-off regions of the foot [19]. A structure with a pressure regulator holds the electrical and mechanical components in place. The applied load on the amputee is 70 Kg according to ISO 10328, which produces a ground response force of approximately 870 N.

Fig. 7 shows the design of the fatigue foot tester. The life of fatigue of the newly designed prosthetic foot was determined by subjecting it to cyclic loading using the fatigue tester. The cyclic load was achieved by alternating the load on the foot through the first piston hitting the heel, followed by the second piston striking the forefoot, and this was repeated multiple times [20]. A monitor registers the piston number, while the speed control switch controls the piston speed based on ISO standards. Similar experiments were also conducted on the SACH foot to compare the results.

3.3.2. Dorsiflexion test

This test is carried out according to ASTM F2665-21 [21] using a compression test device. The machine was rectified to include a wooden piece under the crosshead and supported by a vertical ruler grade. The newly prosthetic foot was then placed on top of the wooden piece, and by applying a force similar to the force generated when a person walks on the ground, and the test on the traditional foot to find out the difference in the results with the standards the wooden triangle, and a force was applied to mimic the ground reaction force (GRF). The same test was also conducted on the SACH foot to compare the results with those of a regular human foot. The amount of Dorsiflexion was calculated using a ruler that measured the descent of the heel during load application and the length of the foot**.** The dorsiflexion angle can be calculated using Equation (1) [22].

$$Dorsiflexion\ angle\ =\ tan\text{-}-1\ \frac{y\ distance}{x\ distance} \quad (1)$$

Fig. 8 illustrates the dorsiflexion tester.

4. Results and Discussion

4.1. Fatigue Foot Test Results

A comparison of fatigue life was conducted between the new prosthetic foot and the SACH foot to assess the validity of the new foot, as shown in Fig. 9. Both feet failed at cycles 473241 and 510382, respectively. The conventional SACH foot (manufactured by Otto Bock in Germany in 2019) failed due to deformation in the forefoot area, resulting in cracks at the bottom of this area, as it is the end of the wooden keel and the foam rubber has weaker mechanical properties than the keel.

In contrast, the new foot exhibited good fatigue life due to the presence of two pieces of carbon fiber that provided good support for the keel in the forefoot area, which has a high resistance to bending. However, the layers of rubber foam in the heel area were slightly separated due to a weakness in the adhesive between the layers.

The new foot did not fail suddenly, allowing the amputee to replace it appropriately without causing a sudden accident.

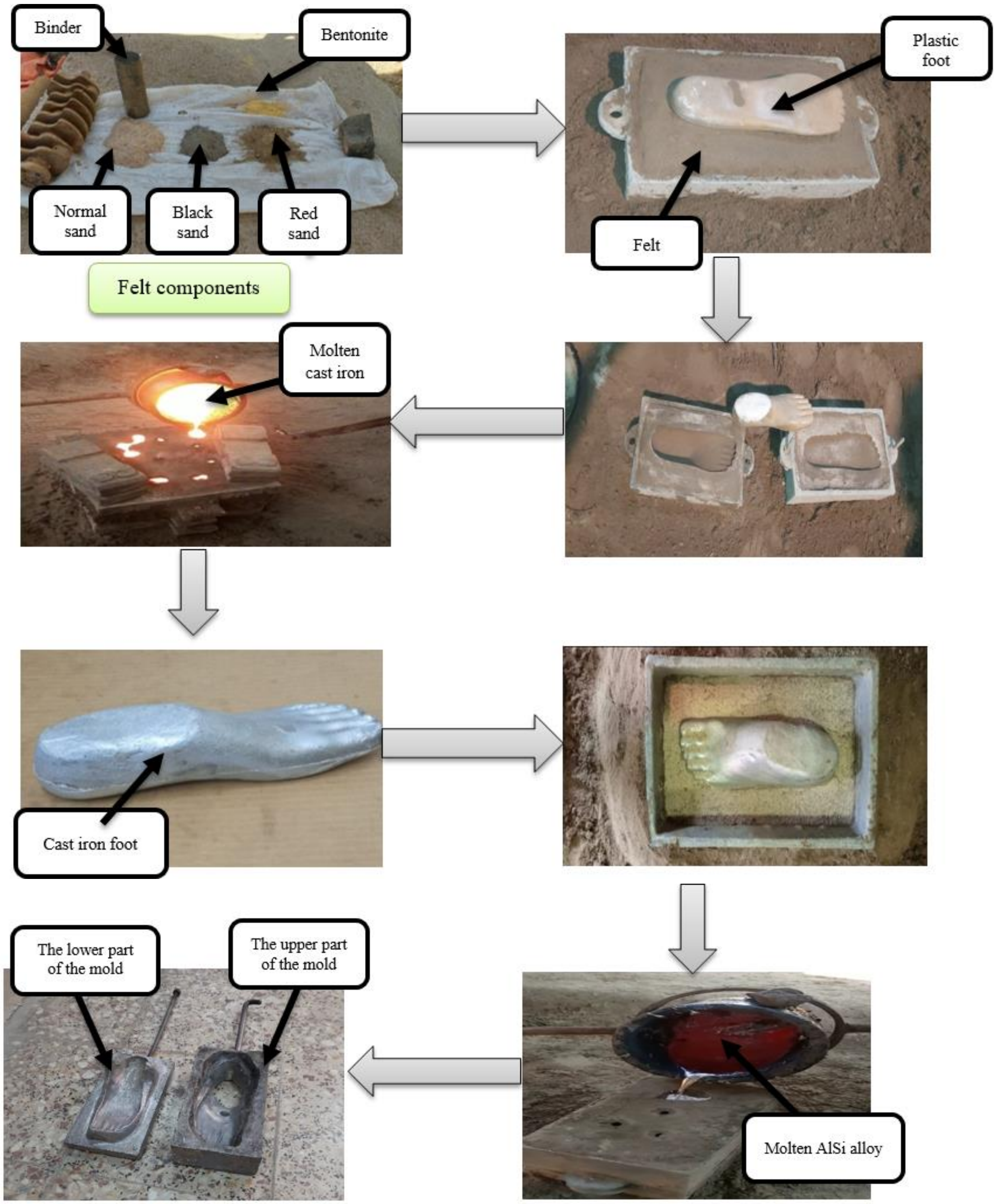

Figure 4. Manufacturing stages of the negative mold for the new foot

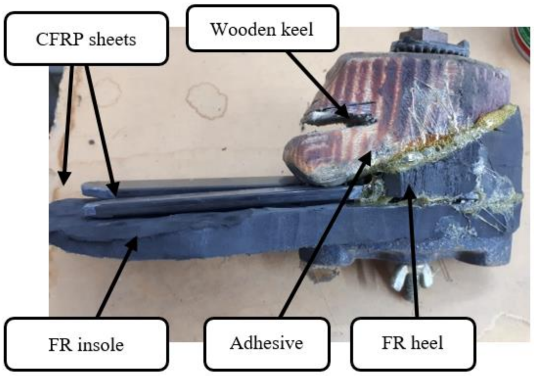

Figure 5. Basic components of the proposed foot

Figure 6. The new foot´s Sample

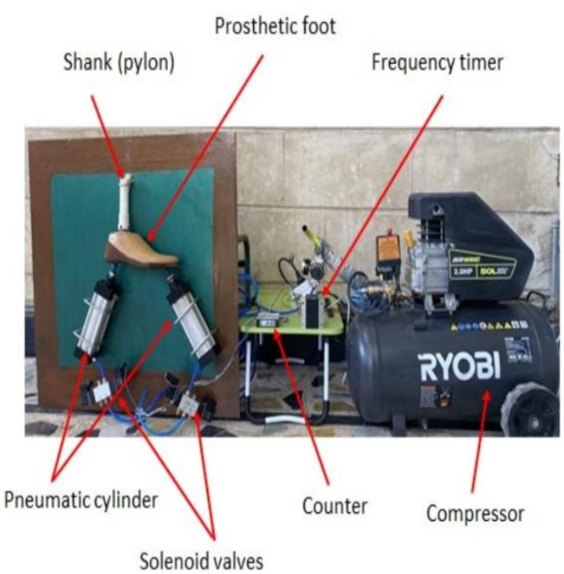

Figure 7. Fatigue foot tester device

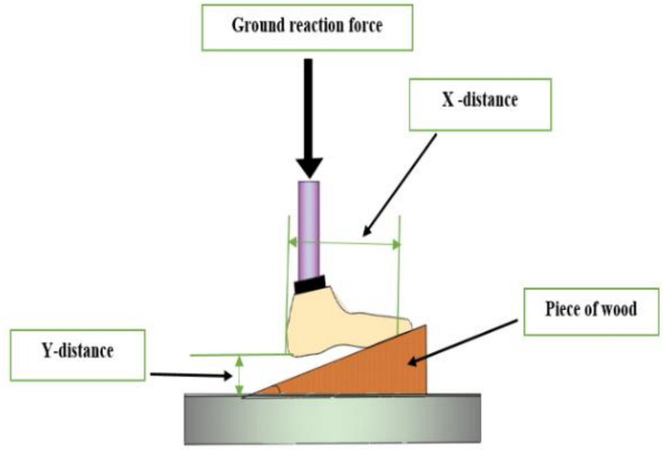

Figure 8. A sketch of dorsiflexion foot tester

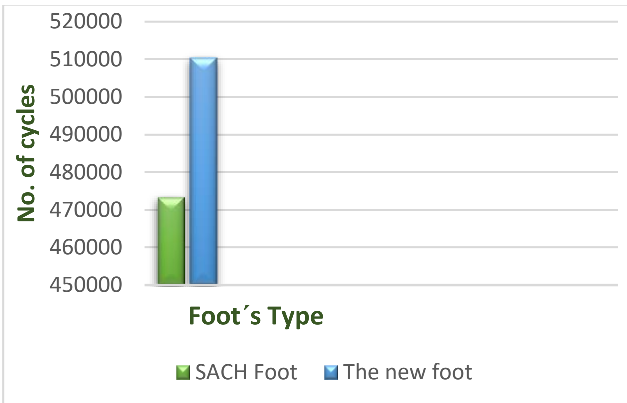

Figure 9 Fatigue foot test results

4.2. Test Results of Dorsiflexion

As stated earlier, the compression test was improved experimentally to measure the dorsiflexion angle. As shown in Fig. 10, the maximum dorsiflexion angles of the SACH and new prosthetic foot were found to be 2.3°and 5.7°, respectively, at toe-off**.**

These values indicate satisfactory characteristics for both types of feet since they fall within the standard range of 2˚-10˚ [16].

However, the new foot showed a better result than the SACH Foot.

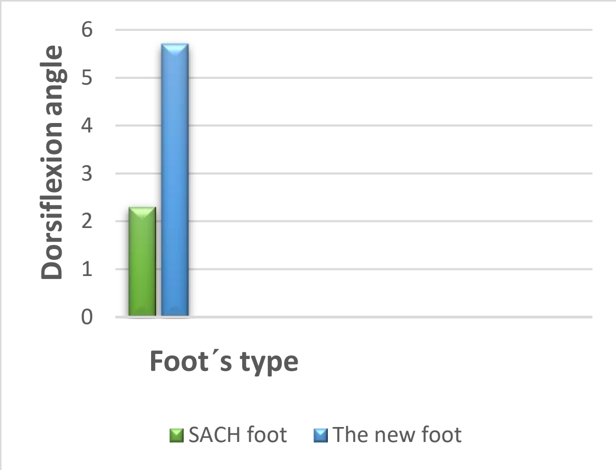

Figure 10. Dorsiflexion test results

4. Conclusions

Based on the experimental findings, it is evident that the flexible keel of the new prosthetic foot, by using two sheets of carbon keel, provides superior fatigue tester and dorsiflexion when compared to the traditional prosthetic foot where:

The newly designed foot significantly surpasses the SACH foot in fatigue life, extending expected use by 8%. This enhanced durability reduces the risk of sudden failure and allows for planned replacements, minimizing inconvenience and potential safety hazards.

Conflict of interest

The authors confirm the absence of any conflicts of interest about the submission and publication of this manuscript.

Author Contribution Statement

Hiba A. Abdalwahhab was responsible for the material preparation, examination, and fabrication of the new prosthetic foot. Kadhim K. Resan contributed by examining the prosthetic feet and leading the analysis, which he further refined. Ehsan Omaraa also played a key role in performing and refining the analysis of the results.

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