Review on the Interface Pressure Measurement for Below Knee Prosthetic Socket

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Abstract. The prosthesis consists of several essential parts such as socket, shank, ankle, and foot. A socket is an important part of prosthetic limbs; it is an interface between the residual limb and prosthetic parts. Biomechanics of socket-residual limb interface, particularly the effect of pressure and force distribution, has on the amputee regarding comfort and function. The most demanding process is designing and fitting of the socket. This is because each patient's residual limb is unique and complex. It is very significant to take into account the interface pressure of an amputee patient. The prosthetic socket dispenses the entire weight of the amputee's torso while in the walking cycle. This is why it is vital to measure the quantity of these interface stresses to measure the amount of damage the socket imposes on the residual limb tissues. Different types of methods have been utilized to identify the locations of extreme stresses that might cause skin breakdown. A comparison of stress distributed in a number of socket designs was made to assess interface cushioning and suspension systems, among others.

Keywords. Interface Pressure, Below Knee, Prosthetic Socket.

1. Introduction

The materials used for manufacturing prosthesis structures were composite materials. However, in the last year, these materials' mechanical properties are modified with various composite materials applications. Where, the composite materials being by mixing resin materials by reinforcement fiber, [1-3], then, additive powder materials to modify the mechanical properties, [4-6], and finally additive of the Nanomaterials to increase the mechanical properties for composite materials, [7-12], with different applications. So, the composite materials are used in vibration, [13-14], buckling, [15-17], fatigue, [18-20], and other applications, which is where the application is given agreement behavior for structure with composite materials. Then, after calculating the useful properties of composite materials, manufacture the prosthesis structure from composite. There, manufacturing different parts from composite materials and given good characterizations with different applied load, such as prosthesis socket, [21-24], prosthesis foot, [25], hip joint structure, [26], Partial Denture, [27-28], prosthesis knee, [29-31], and other application, [32-35]. Finally, artificial prosthesis was modified by manufacturing a robot structure with different movement directions [36-40]. There is an increase in amputations in developed countries due to diabetes motor vehicle accidents, the latter being the major causes. [41-43]. A prosthesis situated below the knee consists of numerous vital parts, i.e., socket, shank, ankle, and foot, as shown in Figure (1). The socket provides the link between the residual limb (stump) and the prosthetic device's remaining parts. Designing and mounting the socket is the hardest process because of each patient's residual limb's individuality and intricacy. An uncomfortable
prosthetic part results from misfit and poor design at the socket/limb interface leading to extreme stresses [44-48]. The main foremost reason for a prosthetic foot, shank, and socket are to substitute the means of replacing the missing structure and function of the skeleton and muscles of the foot, ankle, and shank. This comprises delivering support from a stable foundation, the flexibility that simulates the normal walking succession, and generation absorbing shock due to healing contact. Muscle spasm is also important because of the energy or absorption by the ankle [48-51]. Bearing loads have the primary role for a prosthetic socket for transtibial amputated patients; because of this, the amputee's patients socket's structure is very significant, and their (the patients) comfort as well as the function of the prosthesis are prominently influenced by the mechanical interaction between the skin of the amputated limb's skin and prosthetic socket [52]. How long it takes a prosthetic socket to become uncomfortable and needs replacement expressed by its life cycle. Thus, the numerical value for this is obtained by applying the part to cyclic loading and unloading, where a phenomenon known as hysteresis may occur during this phase [53-56].

This research aims to compare different interface pressure measurement methods and then know each method's advantages and disadvantages.

2. Prosthetic socket

The luxury and overall performance of a prosthesis's socket, which links the prosthetic to the patient below the knee, is significantly enriched by design. Fitting the socket at the lower part of the amputated limb specifies the prosthesis' value. Traditionally, the preparation of prosthetic sockets is dependent on the practice of prosthetists [57]. A socket's part of a trans-tibial prosthesis is considerable since the rest of the extremities do not encompass the similar weight-bearing capacities as the base. As a result, the designing and fitting of a socket are substantial factors for succeeding in the patient treatment process. The socket border design can be subdivided into three requisite categories due to weight-bearing character: Patellar Tendon Bearing (PTB), Total Surface Bearing (TSB), and Hydrostatic Loading. The socket manufacturing may be achieved by two methods [58-61], as shown in Figure (2).

Figure 1. Below-knee prosthetic components.

Figure 2. Socket manufacturing methods.
3. Interface pressure Measuring

The shape of the socket is not a replica of the residual limb. However, it contains modifications (corrections) such that a significant transfer of load between the prosthesis and the remaining limb has been achieved [62]. Even though force and/or pressure sensor is used as a direct investigation method to the interface pressure, the sensors and wiring are positioned between the amputated limb and socket unavoidably interrupt the mechanical order at the interface [63]. Pressure probes devoted to measuring the distribution of stresses within the sockets may be piezo-resistive, strain gauges, capacitive, or optical. All the methods implemented are for evaluating pressure, and socket residual limb tension was intended to increase precision and produce results with an approximation to the practical and medical situation [64]. The methods for interface pressure of a socket were.

3.1. Vacuum diaphragm and liquid sensor

In 1959, D. S. McKenzi researched improving the entire sockets' exterior plane. To make an exterior bearing with a self-suspending atop the socket knee where the load would be dispersed as homogenously as achievable to evade and the uneasiness accompanying excessive concentrated loads at with high loads concentrated in related zones, [65]. Chino N. et al. (1975) measured the sub-zero pressures of the small void between the distal stump and the prosthetic socket situated below the knee. This was accomplished during the swing stage for nine individuals. It was found that a sleeve of a molded rubber that connected the prosthetic enhanced this effect in which the suspension suction was carried out through the whole swing stage [66]. R. G. REDHEAD (1979) investigated Ferranti silicone etched diaphragm type ZPT50A (7/8" long x 1/4" diameter) was elected as the transducers for pressure 16 holders were fixed to the socket's wall to maintain the seal's suction pressure [67]. Nine transducers were attached (screwed) into the socket's wall. For each socket, 16 transducers were fixed to the socket wall [68].

Van Pijekeren et al. (1980) improved a sensing system, as illustrated in Figure (3); in which the used sensors were very thin and can be attached to the inner surface of the socket wall to as slightly as it is possible to disrupt the prevailing pressure shape [68]. Dynamic pressure for the whole socket was logged and determined by MARINUS NAEFF, M .D and TEUN van PIJKEREN (1980); instead of using water air ("aerostatic" casting procedure), an equivalent pressure was applied to the Paris plaster as a hardened to apply equal pressure to plaster of Paris wrapping around the residual limb while it hardens. They also used a container with a flexible plastic bag inside [69].

![Figure 3. Principle of interface pressure measurement system by Van Pijekeren [68].](image)

In this method, they measured only "normal" pressures, i.e., pressures observe at the local socket wall or seat. They did not consider shear forces parallel to the wall because the skin is very easily moved over subcutaneous tissue, and therefore the shear force will be small. The capability to recurrently
observe the pressure at the prosthetic's socket/the remaining amputated limb's interface can supply important data to the scientific and medical societies. Taking all of these into consideration, this research can be defined as an original type of sensor which contains a MEMS pressure sensor and patterned electronics packed inside a bubble filled with a fluid by Jason W. Wheeler (2011). The sensor is characterized and compared to two commercially-available technologies. The bubble sensor (as shown in Figure 4) has great drift and excellent detecting resolution [70].

![Figure 4. Fluid-filled bubble sensor.](image)

3.2. Displacement sensor
Francis A. Appoldt et al. (1968) conducted research to determine the amount of slip at numerous places inside the socket's suction, as shown in Figure (5-a and b). The range of overall slip values in four patients is set as a locating task inside the socket under the walking level settings [71]. The residual limb/prosthetic socket interface pressures and shear stresses were measured by Joan E. Sanders et al. (1997). The maximum stresses for 13 of the interface while in the stance stage were measured for two patients with amputation of type unilateral transtibial (TTA). A prosthetic of patellar-tendon-bearing with full contact was used. The stress interface transducers were attached to mounts that were fixed on the surface's exterior [72] (as shown in Figure (5-c)). Jumaa S. Chiad et al. (2014) suggested developing an interface pressure measurement system (Displacement Sensor) to obtain the interface's pressure amid the remaining amputated limb and the fabricated socket. This new method was used for patients that have amputation above the knee [73].

![Figure 5. Different types of sensor position.](image)

3.3. Force sensing resistors and strain gauge
The pressures that existed at the stump/socket were measured by Appoldt et al. (1968), two patients supplied over the knee prosthetic. The strain gauge is the popular primary sensor used in this type of installation method. They investigated the consequences when the legs' alignments changed with the
passaging of time are detailed in terms of local dynamic pressures felt while strolling [74]. J.E. Sanders and C.H. Daly (1993 ) improved transducers to determine stresses in three orthogonal trends to which directed at an amputated below the knee inside the prosthetic's socket while strolling [75]. In order to determine the dynamic pressures at the interface between remaining amputated limb and socket "Force Sensing resistors were employed while going through the gait of a trans-tibial amputated patient. Three hundred fifty (350) pressure-sensitive sensors were fixed to the inside of a hydro-cast socket. P.Convey and A.W.Buis (1997) presented a comparison of pressure dispersal between a hand-cast socket to that of a hydrocast socket. The study was performed on the same patient. The pressure's gradients for Patellar-Tendon-Bearing (PTB) hand-cast are higher than that of the hydro cast sockets. The proximal "ring" of elevated pressure in the hand-cast PTB socket is replaced with a further distal pressure in the hydrocast socket [76]. Interface pressures and shear stresses were determined on two adults, male, unilateral, transtibial volunteer amputee subjects wearing patellar-tendon-bearing (PTB) design sockets by S. G. ZACHARIAH and J. E. SANDERS (2001 ) determined compressive stress and two right-angled with respect to the shear stress of the transducer's face. They have been placed on 13 locations strain transducers on the prosthetic socket [77]. Interface pressures were determined during ambulation with a normal total-surface weight-bearing suction socket and a vacuum-aided socket by Tracy L. Beil et al. (2002). The vacuum-assisted socket has been shown to eliminate daily volume loss. Urethane liners were instrumented with five force-sensing resistors to measure positive pressures and one air pressure sensor at the liner's distal end to document negative pressures. Nine unilateral transtibial amputees participated in the study [78]. The pressure distribution depends on the ground reaction force's value at the gait cycle, as shown in Figure (6). Also, J. C. H. Goh et al. (2003), with the aid of pressure-sensitive transducers, determined dispersion of pressure and gait boundaries were determined concurrently while the patient stood and walked [79].

![Figure 6. Interface pressure distribution with the gait cycle.](image)

3.4. Tactile Pressure Sensor and piezoelectric sensor
Measurement of pressure and prosthetic sockets mapping has improved the understanding of prosthetic fit at the same fundamental level and has helped facilitate objectively-based designs of the socket. The sensor of the F-socket was used based on piezoelectric ink between two layers. The area of contact between the ink particles was increased as pressure increased due to the changing resistance to current flows through the ink [80-84]. Engsberg et al. and Houston et al. (1992) were pioneers studying the interface pressure underneath the knee socket using such a method. They presented optimistic results on the possible usage of F-socket pads in clinical sets. The F-socket sensing pads exhibited and were both sensitive and flexible; they were also easy to use [85]. Kazuko L. Shem et al. (1998) used a Rincoe socket fitting system (SFS) to measure interface pressure. With this system,
sensor strips are placed between the residual limb and the socket; in this study, the amount of interface pressure relieved was measured in transtibial amputees with thigh lacer side joint prostheses [86]. You-Li CHOU et al. (2003) investigated the dissimilarities at different strolling speeds, gait, maximum forces, and pressures at the interface between residual limb and socket. To study the system's kinematics and kinetic, an analysis of the system's motion implemented to study the kinematics and kinetics of the gait, and the Pedar system was used to measure the maximum forces and pressures between amputated limb and socket through different strolling speeds. Fifteen male transtibial amputates rounded up this study. The force-time integrals' discernment was the same when a comparison was made with maximum force, and the pain scale of subjects' subjective feeling [87]. The problem of a bio-mechanical answer for human mobility post amputation of a lower limb. Using a transtibial prostheses socket designed by Rajtukova, V.A (2004). An inapplicable action occurs in the socket/stump vicinity, steering to enhancing friction and succeeding surface impairment to the soft tissue. In exclusive personal types of transtibial prostheses, position sites can be loaded and those that cannot. Based on this research for the amputated limb's foreshore, two unloadable and three loadable locations were registered. With the aid of the "TACTILUS" tactile pressure sensor (Sensor Products Inc.) to observe the pressure dispersion for these locations, this was considered in assessing exerted pressure on the selected location technique [88]. Sadeeq Ali et al. (2013) measured the pressure at the interface with a transducer (9811E||) F-socket; this was accomplished while going up and down a staircase stump to have finer insight on the pressure between the stump and socket. Front, middle, and side sensor devices were fixed in the middle of the patella level [89]. Tim Dumbleton et al. (2009) performed a comparison between dynamic interface pressure dispersion of hands-off and hands-on transtibial prosthetic systems. They performed this by charting pressures determined 90% of the dynamic pressure utilizing pressure mapping. They measured the dynamic pressure contour of the area in the prosthetic socket with the aid of four Tekscan F-Scan socket transducer arrays. A comparison was made between socket concepts for interface pressure [90]. Muhsin J. Jweeg et al. (2012) investigated the effect of high temperatures in hot weather countries on a socket fabricated from a composite material while in gait. Interchanging pressure on the inside surface (obtained by Piezoelectric disk sensor) of the socket is created and guides to alternative stresses resulting in the composite material's fatigue failure. It is essential that as temperature increases, the mechanical properties decline through time due to creep, which is a source for socket failure due to the interaction of fatigue and creep [91]. Shireen H. Chalob et al. (2015) evaluated the effect of stress relaxation on the socket material by testing this material at 50 °C by creep test and evaluating creep data by using the Burger model to obtain the equation of the stress relaxation modulus with time; the interface pressure was measured by F-scan sensors[92]. Ikram R. Abd Al-Razaq et al. (2015, 2016) investigated the effect of temperature below the knee socket manufactured by Modular Socket System (MSS) and compared it with the traditional method. The interface pressure was measured by F-scan sensors [93-94]. Kadhim K. Resan (2016) subjected four polypropylene groups at different times of exposure to an ultraviolet ray. The lengths of times of subjection were: zero, 20 hours, and 40 hours. Stresses were determined for shear relaxation at 50 °C for the same group. This research was conducted to investigate the ultraviolet ray effect on tensile strength, hardness, and polypropylene morphology. The pressure for the interface was taken in the vicinity below the knee's socket and amputated lime, between the knee socket and prosthetic with F-socket sensors' aid, after which the socket is modeled using ANSYS workbench [95]. Gianna Morelli et al. (2019) also showed how the pressure mapping socket technology used in the F-Socket system is essential to developing stronger, more comfortable, and more efficient prosthetic technologies. The sensors used in this system are paper-thin and can be sized and readjusted to fit securely in the socket's curvature [96-97].

3.5. Fiber Bragg grating (FBG) sensors method
Fiber Bragg grating (FBG) sensors used by Ebrahim A.AL et al. (2013), these sensors were implemented to determine the pressure between the amputated limb and the prosthetic socket; interface; of a trans-tibial amputated patient. FBG element(s) were repainted with entrenched in an alight film of epoxy substance to form a sensing cushion, which was, in turn, entrenched in a silicone
polymer substance to make a pressure sensor. The sensor was experimented with in real-time by slotting in a heavy-duty balloon into the socket. Ebrahim A.AL et al. (2016) researched an efficient fiber Bragg grating (FBG)-based sensory cushion that can measure the interface pressure inside prosthetic sockets and shows four required sensitivity, greater robustness, and the lowest possible five hysteresis error. Three essential manufacturing boundaries were studied to assess their effects on the performance of different sensory pad model blueprints [98-99]. Also, Ebrahim A.AL et al. (2017 ) introduced an innovative, customized FBG instrumented silicone liner that eliminates the previous limitations and provides a practical and straightforward means of sensing. It is designed to cushion the typical loads applied by the socket to the residual limb and functions as a real-time interface pressure sensing tool [100-104].

4. The Disadvantage of different methods to measure the interface pressure
I. Vacuum diaphragm and liquid sensor, the disadvantages of these type of sensor are,
   a. It is measured the normal pressure only, which means the shear stress is neglected.
   b. The low impact resistance (Limited life when subject to shock and vibration)
   c. Hysteresis on cycling.
   d. It measures pressure at a point, meaning that it cannot measure the pressure distribution for all areas inside the socket.
   e. Lower measurement pressure.
II. Displacement sensor disadvantages
   a. It measures pressure at a point, meaning that it cannot measure the pressure distribution for all areas inside the socket.
   b. It is measured the normal pressure only.
   c. It is not accurate, as it depends on the deformation in the socket, and if the socket is of high stiffness, the piston of the sensor not move sufficiently, Although high pressure was applied
III. Force sensing resistors and strain gauge disadvantages
   a. It measures pressure at a point.
   b. Strain gauge measured lateral deformation; therefore, it is not accurate to measure the normal pressure.
   c. Temperature-sensitive
   d. The thermoelastic strain causes hysteresis
IV. Tactile Pressure Sensor and piezoelectric sensor disadvantages
   a. Mats may wrinkle and malfunction during experiments.
   b. 2- Dynamic sensing only
V. Fiber Bragg grating (FBG) sensors method disadvantage
   a. It is thermally sensitive.
   b. The mats sensors are not fully flexible
   c. It is expensive to build and maintain.
   d. It is challenging to discriminate wavelength shift due to temperature and strain separately.

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