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COMPUTERIZED DESIGN OF TRANSFEMORAL SOCKETS A LITERATURE REVIEW

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ABSTRACT

The Syrian crisis threw its weight on all aspects of social, economic and followed by a parallel rise in the census number of amputations in the upper and lower extremities, which imposed a great interest on the design and of the prostheses. On the other hand, the prostheses design and manufacturing should be achieved according to scientific and academic bases in order to ensure their effectiveness and suitability to the requirements of the patient. For this reason, this study was suggested to summarize previous works for all topics related to the design and manufacturing of lower prosthetics, starting from obtaining the digital model of the stump, passing through the most important principles used to suspend an artificial limb, and finally a summary of the methods used to test the designed parts before their fabrication.

KEYWORDS: Prosthetists Seek, Artificial Limb & CAD / CAM

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INTRODUCTION

Prosthetists seek to restore the ability of amputees, to perform all the activities of daily life which can be carried out by trying to achieve the best connection between the prosthesis and the body [1]. The patient's comfort and satisfaction are the most important factors involved in evaluating the efficiency of the artificial limb [2-3].

Rehabilitation process depends on the elements forming the prosthesis, which must be determined according to the real needs of the patient, and are affected by the suggestions of a team of experts as well as by the willing and the enthusiasm of the patient.

Initially, the design and implementation of the artificial limb was manually achieved, by taking some remarks for the installation, then implementing a negative model which is finally used to make the positive model necessary to produce the trial prosthesis which was adjusted several times, according to the patient's comfort. Despite widespread use, this method is subjected to personal opinion without any control or specific criteria. Furthermore, it takes a long time, and it did not seem possible to compare several design types for the same patient [4Since 1960, Foort proposed to design and implement the artificial limbs through the computer (CAD / CAM).

The socket of the artificial limb is the most important part, and is defined by the stability in the sagittal and frontal plans. It represents the securing support for the body weight, and it controls the knee according to the willing of the patient [5-6].

The two main types of sockets designs are Quadrilateral walls [7], and is chial containment [8].

Despite the availability of several suspension systems now, the selection of the appropriate system is still based on the personal experiences of the prosthesist, without the reference to the selection of academic standards [9].

Theoretically, prosthesis properties should be in line with the dynamic mechanical requirements of the amputee, in order to obtain the maximum benefit from this prosthesis. Within this framework, this reference study may contribute to the development of these principles and to highlight the most efficient systems in terms of performance, which is currently not available in any agreement or standard for the selection or evaluation of these systems.

This study aims to review all previous studies systematically in order to contribute to the development of standards for the suspension systems of transfemoral amputees.

NUMERICAL MODEL OF THE INSTALLATION AREA

The first step of the numerical design is to produce a numerical model of the patient installation area. That means building a prototype determining the shape and dimensions of the socket. Hereafter, we will review the main principles used for this purpose.

Optical Scanning

Imaging laser for the scanner are shedding the installation area in order to obtain the initial shape and the dimensions of the remaining region of the amputation (The stump).

Several studies, including (Nicolas E. Walsh, 2005) developed a number of techniques to get to the model of the stump. On the other hand, Bill Rogers et al. proposed the use of laser scanning selective (sls) for the manufacturing of the sockets, by the use of software architecture design and laser selective technique, resulting in sophisticated and more efficient sockets according to amputee's requirements [10-11].

Radiographic Tomography

Since the early nineties, and with the technical development of medical systems, medical imaging, the use of medical images was suggested to produce a computer model for the installation, especially that these systems are supported by embedded programs to show the three-dimensional figure, which may facilitate the design of the prosthesis, along with the fact that the resulting images with a spatial resolution is relatively high, and not related to the experience of the designer.

In 1989, Faulkner used computed tomography (CT) scans to produce a three-dimensional model for the installation of transtibial amputees, where the process of modifying computer model was performed through the screen. Similarly, Smith has produced computer models and comparing the size of the installation area without the wear and with two different types of artificial limbs in 7 amputees below the knee. They highlighted the size differences in the installation area in order to assess the quality of artificial limb [12]. Later, the same team suggested comparing numerical models obtained by CT machine with two models acquired by the use of magnetic sensor and optical sensor in 7 amputees below the knee. In both cases, radiology device showed relatively high spatial resolution of the order of 2 mm [13].

Parallel attempts proposed the use of ultrasound, and the results were promising, as the cost of the purchase and use of this device was relatively low, as it does not expose the patient to any ionizing radiation.

In this context, the use of two-dimensional B-scan mode and a three-dimensional pattern was used to produce a 3-D representation of the installation area.

The developments of the device, to get the 3-D representation remained complex, far from the reality of practical application. Therefore, the number of implemented stages appeared to be long, and thus included relatively large overall design errors [14-19].

Radiographic Tomography

In contrast to radiographic and ultrasound methods, Magnetic resonance imaging (MRI) showed many advantages that are worth sacrificing and paying more than in order to get a prosthetic comfortably and effectively, especially it will be designed once in a person's life.

In fact, the MRI device does not use any ionizing rays, and does not depend on the experience or the performance of the doctor, although it works on the production of the installation when the computer models do it without contacting the patient. In additions, the MRI devices have a very High contrast quality between bones and soft tissues, and also have the ability to show blood vessels within the area of the installation. Since 1994, prosthetics' aim of modeling forces and moments generated with amputees across the knee, where the study confirmed the efficacy of these images in the production of computer models with high spatial accuracy of the order of 0.5 mm.

Since then the studies followed using MRI images in the production of computer models for the amputees where the installation done either for the hip or the knee [20-22].

In 2006, Buis has completed a study to examine the usefulness of MRI device in the field of computerized design comparing with the waves of ultrasonic devices and CT scan [23].

The study showed that there are no effects on the MRI Photo with wrapped and lining material of the installation such as silicon or the cover of Paris Plaster of Paris (POP), and the study discussed the clarity and ease of acquisition of images which is compared with the methods of the probe or ultrasound waves.

SUSPENSION SYSTEMS

The vertical movement within the socket is considered as an indication of the quality of the suspension in artificial limbs for transfemoral amputees, since the suspension systems are supposed to reduce the movement of the stump within the socket, and that leads to reduce the pain of the patient and the effects of skin in the installation area.

Several studies showed how some types of suspension systems cause less pain, caused by the presence of lining material. Firstly, the vacuum system was proposed to alleviate the problem of stretch in the installation area during the swing phase and some skin edema, especially in cases of elderly patients or people with vascular disease [24-27]. However, this system was not advisable for patients having some meanders in the installation area on the other hand, the pin-lock and magnetic lock systems showed good performance in case of relative expansion in the installation area, and the value of the vertical movement of these systems was close to the values that are produced based on vacuum systems.

In general, prosthetists preferred the use of the magnetic lock systems with the lining, compared with the pin-lock system, especially for socket divesting and donning.

A review of previous studies showed that thick linings are more comfortable, therefore it can distribute the pressure evenly on the installation area, but excessive sweating was the most negative disadvantage of total surface bearing (TSB) sockets, especially when silicon or polyurethane lining were used.

NUMERICAL ANALYSIS OF THE DESIGNED PROSTHETIC

Finite element method is an effective tool for the analysis of structures and behavior, especially when the sample is complicated for modulation in traditional analytical ways. In this context, the main purpose of this type of studies is to establish a digital non-linear model which is used to estimate the pressure at the surface interval between the installation area above the knee and the socket artificial limb.

Some of the previous studies tried assessing the mechanical loads that are generated on the borderline between the installation area and the socket of the artificial limb, either by making some clinical measurements using different types of sensors or techniques using digital simulation.

Knowing the vital mechanical changes allows loads that are located on the interface interval assessment of the functional effectiveness, considering the distribution of the load on the stump surface is a very important clinical factor. And contrast sensors, which in the process of measuring the loads directly to the process of walking are affected and the results are controlled by the places of these sensors which are integral to direct measurements.

Zachariah & sanders study methods based on mechanism that detects automated point petitions and overlaps between numerical models to prevent interference with each other, that it simulate the process of wearing the artificial limb [28]. Lacroix used finite elements digital model, by applying the shift beam with the medial part of the socket before the simulation process and this is what gave greater reliability compared with previous studies, which has got the highest value of the average pressure of 4Kpa and a standard deviation of 1.7. Median values ranged of shear between the value of 0.6 Kpa-1.4Kpa in both directions longitudinal and peripheral respectively to maintain the stress case that has been generated in the first phase, in the second phase that was applied loads on the stump which is obtained from analysis of walking in inner surface of the socket to get even distribution pressures and stresses on the interface [29].

At this stage, method of detecting motions between the socket and the installation is done. Where also adding friction coefficient at this interface interval, as is allowed a certain amount of withdrawal from touched parts in case exceeded the limit shear stresses friction allowed.

Studied Engineering Structures:

The obtaining of engineering structures for surface mounting area and the interior surfaces of bone for the amputee patient, where they are obtaining a digital model for the installation through one of the aforementioned imaging modes, and here attention should be paid to spatial accuracy of the scanning device, and which reflects the accuracy termination of the details on the digital model which is obtained. It is often recognized as the bony areas and fragmented by using image processing software such as Mimics, 3d doctor, Invesialus.

It obtained the results within Hypermesh version 8 program, which has been generating soft tissue to conduct digital subtraction between the original model and the surfaces of the bone then networking was produced for models which were generated using a three-dimensional elements of the hierarchy, so that the final model contained a sum of 1808 hierarchical elements of bone, 16288 and 1496 soft tissues and socket, respectively.

Material Properties

It has been assumed that the mechanical properties of bone and socket as a flexible and linear, united and homogeneous properties, where it was given the properties of materials by a factor of elasticity and Poisson factor 15Gpa and 0.3 for bone and socket values. Studies after making measurements on the muscles of amputees above the knee in the case of relaxing have shown elasticity modulus values ranging from 53.2 to 141.4kpa to the soft tissue, depending on the measurement site.

When the patient wears the socket, the muscles would be in a state of tension and this increase the value of Young's modulus. That's why the assumption that the value of Young's modulus and Poisson is (200Kpa) and (0.45) for the soft tissues

Boundary Conditions

There has been a modeling for the bones and the soft tissues as one structural body. Whereas, the socket and the installation area were considered as separated designed elements. And there was an assumption that there was a fraction factor within (0.5) between those two elements [28-29].

The analysis has been performed within two-steps, in the first step; there was a production of an initial state of tension to stimulate the process of wearing the artificial limb. And that works when it's applied on carrying a value of (50N) on the upper surface of the soft tissue. In the second step, the values of stresses and the primer deformation that came from the first level was sustained. Meanwhile, the external load on the lower surface of the socket was applied, with the installation of the soft tissues.

And three scenarios of the loads has been applied separately, in order to stimulate a different condition loads for the walk circle. And shows the distributions of stress between the socket and the stump, however, the concentration was on the outer surface, in order to know the mechanism of the mutual effects between the socket and the stump.

One of the most important steps in finite elements modeling is to make sure that the mesh density is sufficient to achieve the convergence of the solution, as the corner mesh segments would produce inaccurate values and will come along the presence of a small analysis of the elements at the edges and the narrow areas [28-29].

Mesh convergence is an iterative process, which includes a uniform applied load and boundary conditions and therefore it verifies that the change of the size of the mesh element would produce the same values of results produced with different values for the size of elements. When changing the size of the elements of analysis does not cause any change in the results or when the variation in results is less than pre-defined threshold, the analytical solution is said to be converged.

DISCUSSIONS

In this study, we searched within the scientific databases (PubMed, science direct) to obtain all the articles related to getting digital model systems for the installation area, the lower suspension prosthetic, as well as the designed numerical analysis.

In fact, there are commonly several systems in the lower limbs for amputees across the thigh. Prosthetic designers need to determine the suitability of suspension system for different conditions for the installation area such as dimensions? Muscle strength, soft tissue, bony protrusion and amputee level of physical activity and its budget.

Conversely, it has not yet been any clear agreement about the most effective suspension system.

The vertical motion is considered within the socket prosthetic for amputees above the knee. The suspension systems can be depended on negative pressure or vacuum to achieve a motion for the stump within the socket and so oppositely for systems adopted on the lock and key system.

Depending on that, they are increasing the durability petition between stump and socket, and this leads to ease the pain of the patient, and effects skin on the installation area and especially on the body tissues.

Studies shows that these systems cause less pain, due to some liner materials that it consists of, compared with the pin-lock system. Moreover, the use of that system leads to the reduction of the problem of skin extension at the installation area during the swing phase, where the skin extension could lead to massive pain, especially at the amputee area.

CONCLUSIONS

This study contributes to the assessment of principles used in prosthetic computerized design. We also presented a systemic review based on the practice and experience to choose the right kind of prosthetic socket for transfemoral amputees.

Depending on the previous studies, the vertical motion was a good index of the quality of prosthetic suspension systems. Studies showed that the vacuum systems were able to relive the stump within the socket and reduce asymmetry and pain in the installation area. However, this system was not a good choice for amputees with meandering in the installation area.

This study showed that the thick liners were more comfortable, as they are able to distribute pressure uniformly on the stump.

The problem of transpirations was the most important barrier in the case of silicon liners and polyurethane, except there was not any supportive clinical census to determine the type of the standard suspension system suitable for all the transfemoral amputees. On the other hand, TSB socket seemed to be the most favorable for the majority of patients.

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