World Academy of Science, Engineering and Technology
International Journal of Materials and Metallurgical Engineering
Vol:9, No:9, 2015

Pressure Relief in Prosthetic Sockets through Hole Implementation Using Different Materials

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Abstract**—**Below-knee amputees commonly experience asymmetrical gait patterns. It is generally believed that ischemia is related to the formation of pressure sores due to uneven distribution of forces. Micro-vascular responses can reveal local malnutrition. Changes in local skin blood supply under various external loading conditions have been studied for a number of years. Radionuclide clearance, photo-plethysmography, trans-cutaneous oxygen tension along with other studies showed that the blood supply would be influenced by the epidermal forces, and the rate and the amount of blood supply would decrease with increased epidermal loads being shear forces or normal forces. Several cases of socket designs were investigated using Finite Element Model (FEM) and Design of Experiment (DOE) to increase flexibility and minimize the pressure at the limb/socket interface using ultra high molecular weight polyethylene (UHMWPE) and polyamide 6 (PA6) or Duraform. The pressure reliefs at designated areas where reducing thickness is involved are seen to be critical in determination of amputees' comfort and are very important to clinical applications. Implementing a hole between the Patellar Tendon (PT) and Distal Tibia (DT) would decrease stiffness and increase prosthesis range of motion where flexibility is needed. In addition, displacement and prosthetic energy storage increased without compromising mechanical efficiency and prosthetic design integrity.

Keywords**—**Patellar tendon, distal tibia, prosthetic socket, relief areas, hole implementation.

I. Introduction

THE prosthetic socket is the interface between the human and the mechanical support system. The design and fit are what ultimately determine the energy expenditure, comfort, support and patient acceptance of the socket. Therefore, the primary design constraint is to maintain the structural integrity of the socket and to provide a good fit while maintaining comfort for amputees. For lower extremity amputees, a well-fitting socket is an important element for a successful rehabilitation [1], [2]. The socket provides the interface between the prosthesis and residual limb, which is designed to provide comfort, appropriate load transmission, and efficient movement control. In order to improve the performance of below knee amputee's sockets, several factors were analyzed using Finite Element Model (FEM) to calculate stresses and displacements. Data presented in Tables I-III were collected and analyzed using Design of Experiment software (DOE).

It is well known that each amputee's residual limb is different and changes with time, it is essential to have flexible socket made from flexible and wear resistant materials to conform to different amputees [3]-[5]. Most of the wear in prosthetic socket occurs due to unreliable pressure relief areas where different loads can results in large interface pressure. When the socket material is not displaced to relief pressure, amputees will complain about poor socket fit where wear debris will result. Debris can penetrate the skins under high pressure and cause patient discomfort. High pressure problems will cause the accumulation of tissue fluid (edema) in the distal end, which lead to thicker and drier dead cells. Contact pressure has been studied extensively by Nehme and found several solutions to minimize wear and increase flexibilities. Studies involved engine tribology and biomechanics prosthesis [6]-[12]. Moreover, recent development work has demonstrated that the CANFIT System has the capability to manage a wide variety of anatomical shapes. The system has currently expanded to incorporate the design and manufacture of a full range of prosthetics and orthotics, including above-knee sockets, below-knee cosmeses, spinal orthoses, orthopaedic footwear and corsets such as the one shown in Fig. 1. As previously stated, the Trans-tibial sockets can be designed within a matter of minutes with the *Canfit*™ BK Design software. This CAD program, being extremely easy and economical to operate, currently incorporates two brim styles which are: PTB (Patellar Tendon Bearing) and PTS (Patellar Tendon *Supracondylar*).

TABLE I
DOE Factors Used in Analyzing Prosthetic Sockets for Below Knee Amputees Using FEM Model

Test No	Factor A: Materials Type	Factor B: OverallWall Thickness (mm)	Factor C: Relief Areas Inside Wall (2 mm) or (1 mm)	Factor D: Hole between PT and DT (Diameter: 10mm or 0)
11	UHMWPE	4	1	10
3	UHMWPE	4	1	0
16	PA6	4	2	10
12	PA6	4	1	10
10	PA6	3	1	10
1	UHMWPE	3	1	0
7	UHMWPE	4	2	0
5	UHMWPE	3	2	0
15	UHMWPE	4	2	10
13	UHMWPE	3	2	10
9	UHMWPE	3	1	10
8	PA6	4	2	0
4	PA6	4	1	0
6	PA6	3	2	0
14	PA6	3	2	10
2	PA6	3	1	0

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TABLE II
DOE STRESS RESPONSES USED IN ANALYZING PROSTHETIC SOCKETS FOR BELOW KNEE AMPUTEES USING FEM MODEL

Test No	Response 1: Maximum Stress at Bottom (Mpa)	Response 2: Maximum Stress at PT (Mpa)	Response 3: Maximum Stress at FH (Mpa)
11	12.51	5.93	5.23
3	11.22	6.75	6.21
16	10.97	4.77	4.92
12	11.41	4.83	6.13
10	27.83	10.41	6.67
1	28.05	11.33	6.72
7	12.28	5.32	5.11
5	22.13	2.97	4.41
15	10.23	4.73	4.12
13	20.12	2.77	3.92
9	26.17	8.93	5.66
8	12.43	5.77	5.04
4	10.22	6.84	7.11
6	21.98	4.72	5.02
14	20.13	4.11	4.07
2	29.63	12.12	7.58

TABLE III
DOE DISPLACEMENT RESPONSES USED IN ANALYZING PROSTHETIC SOCKETS FOR BELOW KNEE AMPUTEES USING FEM MODEL

Test No	Response 4: Maximum Displacement at Top (mm)	Response 5: Maximum Displacement at PT(mm)	Response 6: Maximum Displacement at FH (mm)
11	3.32	2.64	1.37
3	3.12	2.43	1.22
16	2.96	2.84	1.32
12	4.87	2.91	1.42
10	3.98	2.79	1.67
1	3.22	2.61	1.51
7	2.77	2.34	1.08
5	3.01	2.10	1.13
15	2.88	2.48	1.17
13	3.08	2.27	1.28
9	3.47	2.69	1.77
8	2.88	2.54	1.13
4	4.47	2.72	1.32
6	2.93	2.51	1.21
14	3.08	2.67	1.37
2	3.88	2.71	1.62

II. MATERIALS AND METHODS USED IN THE ANALYSES

Duraform PA6 provides strength and durability required for prosthetic practice. Duraform PA6 has broad range of chemical and thermal resistances with a deflection temperature of (180ºC) and resistance to alkaline, hydrocarbons, fuels and solvents. The young modulus, yield strength and poison ratio of Duraform PA6 are 1600 MPa, 44 MPa and 0.31 respectively. Ultra High Molecular Weight Polyethylene (UHMWPE) is a very tough material. Because of its remarkable toughness, wear and excellent chemical resistance (Melting point ranges between 138ºC and 142ºC), UHMWPE is used in a diverse range of applications. The young modulus, yield strength and Poisson ratio of UHMWPE are 690 MPa, 22 MPa and 0.44 respectively.

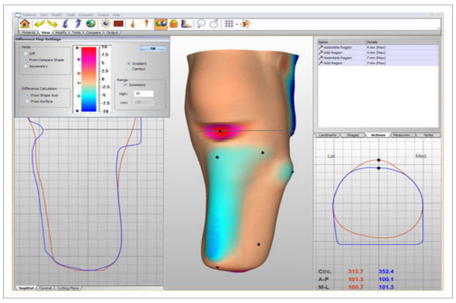

Fig. 1 CANFIT digital modeling

The design is based on the weight of an 80 kg human male and the loading is limited to slowly moving physical activity where the majority of the load is distributed on the upper face of the socket. Its value is 63% of the total body weight which comes to 494.424 N.

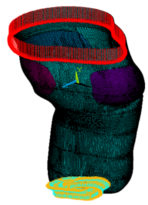

Fig. 2 Meshed boundary conditions and distributed load

This load will be represented on ANSYS by a distributed pressure on the upper surface of the socket and having a downward direction as shown in Fig. 2. The specific areas of interest are selected on an anatomical basis and are presented in Fig. 3. These areas are specified with the respective Elastic Foundation Stiffness (EFS) for each of the areas of interest

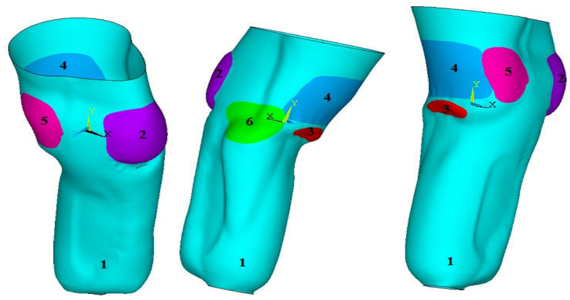

Fig. 3 Socket Views: Regular Material (EFS=0 kPa); Violet: Popliteal Depression (EFS=20 kPa); Red: Distal Tibia (EFS=249 kPa); Light Blue: Patellar Tendon (EFS=30.23 kPa); Fuchsia: Fibular Head (EFS=115.71 kPa); Light Green: Medial Tibia (EFS=7.57 kPa)

The elasticity of tissues is modeled in ANSYS by assigning an Elastic Foundation Stiffness (EFS) value to the defined pressure relief areas (5 designated areas) of the socket in contact with the residual limb. Elastic foundation stiffness (EFS) is defined as the pressure required producing a unit normal deflection of the foundation. The meshing using the SHELL63 element was done for all cases and it covers the entire socket. For each case, after choosing the proper material, overall socket thickness, relief areas, with and without through hole implementation, the same setting will be applied for all studies: linear, static analyses. The bottom surface of the socket is fixed in all degrees of freedom, the upper surface of the socket is free and a compressive uniform load of 494.424 N is distributed on it. Figs. 2-4 summarize the described setting for all cases, with the distributed compressive load in red, the mesh in blue, the constraints in yellow and cyan and finally the areas of interest in their appropriate colors as mentioned before.

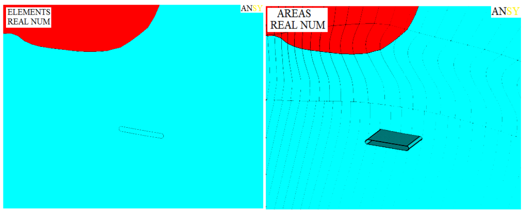

Fig. 4 Trough hole implementation between the Patellar Tendon (PT) and the Distal Tibia (DT)

III. Results

The Finite Element Analysis of displacement and Von-Mises stresses is displayed for all cases of socket designs. These stresses and displacements are considered as responses of the Duraform PA6 and Ultra High Molecular Weight Poly Ethylene to the compressive distributed load. The results for stresses and displacements are displayed in Tables II and III. The impact of materials and overall thickness of the socket played an important role when implementing a hole. Figs. 5-8 clearly showed that different diameter holes should be chosen for different materials and socket designs to increase the desirability of the model. For example: to increase flexibility and minimize stresses for polyamide 6 and UHMWPE sockets with 4 and 3 mm overall thickness, relief areas at the locations selected in Fig. 2 should be 2, 1.9, 1.6 and 1.56 mm respectively; where hole diameters between the PT and DT should be 4.2, 2.6, 3.0 and 2.53 mm respectively. These DOE calculated values will increase the desirability of the desired socket and help the below knee amputees feel comfortable due to reduced stresses and increased flexibilities. It is very important to note that the integrity of the design was not compromised during this analysis and the safety factor is very large since the stresses on the sockets are lower than the yield stresses of the materials.

Tests for all factors and designated socket areas responses are presented in Tables II and III where the values of finite element stresses and displacements are shown. The FEM presented the events that occur during extreme pressure cycles and the responses data collected were analyzed by the Design of Experiment (DOE) software. The goal of the DOE model was to point out the interactions among the different factors involved in the Finite Element Model (FEM) and to identify their mutual influence together with their relative influence with DOE techniques as reflected in the tables and figures. Desirability in DOE analysis is used when multi objective optimization is sought according to [13]. According to this approach, all responses used in the analyses should be converted into corresponding desirability functions. The desirability is high when all responses approach their target values simultaneously. Common goal types were optimum stresses and displacements at the PT and FH when an optimized relief area and hole diameter are considered without compromising the socket structural integrity. Each of these goals is linked to its own desirability function. The maximum value obtained for the desirability function was acceptable and shown in Figs. 5-8 of the Duraform PA6 and UHMWPE materials.

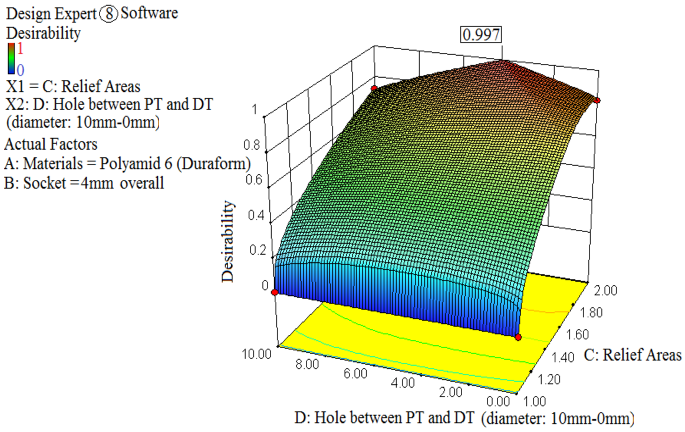

Fig. 5 DOE Desirabily (@97%) for Polyamide 6 socket with 4mm overall thickness and 4.2mm hole diameter

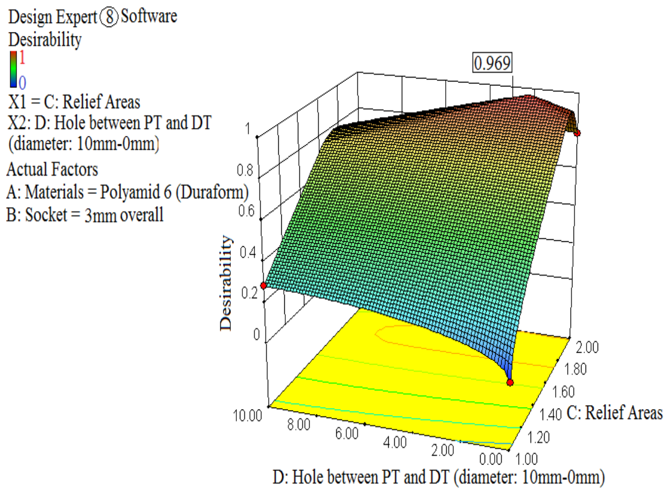

Fig. 6 DOE Desirabily (@97%) for Polyamide 6 socket with 3mm overall thickness and 2.6mm hole diameter

An adequate FEM-DOE framework ensured the validation of DOE results and case studies were performed using the DOE calculated relief areas and hole diameters. The sockets were tested using FEM model and two examples of displacements and Von Mises stresses are shown in Figs. 9 and 10. The DOE analyses made it highly probable that the dominant factors (relief area thickness at selected socket points and whole implementations) contributed positively to the comfort and safety of amputees.

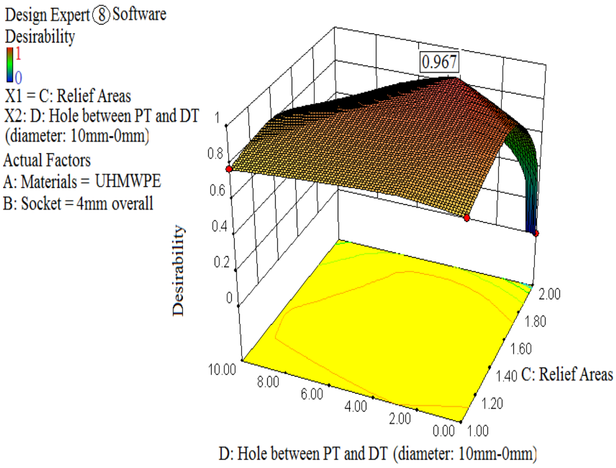

Fig. 7 DOE Desirabily (@97%) for UHMWPE socket with 4mm overall thickness and 3.0mm hole diameter

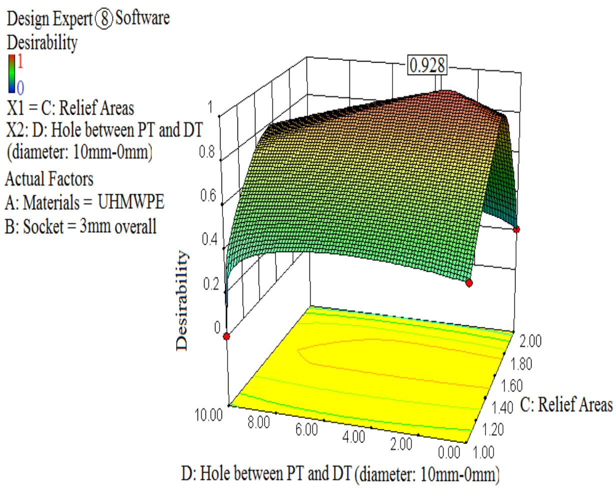

Fig. 8 DOE Desirabily (@97%) for UHMWPE socket with 3mm overall thickness and 2.53mm hole diameter

IV. Conclusion

In this study, the below knee amputation prosthetic socket is controlled using the Finite Element Method. The design was divided into several cases as mentioned earlier in the analysis. The socket plays a very important role in load and energy transmission. The results for stresses and displacements for an 80 kg human male do not show any dangerous values, all stresses are found to be below the yield strength of both materials. The implementation of a hole between the DT and PT areas had two main impacts: a stress relief in the entire DT area and a stress concentration on the curvatures of the hole. FEM gave an approximation to this complicated engineering problem and identified the best design to be chosen for this kind of patient. It must be taken into consideration that minimal errors might have resulted from the use of FEM and ANSYS. Also, the setting of the problem was simplified in terms of constraints and boundary conditions due to the limited time and resources available.

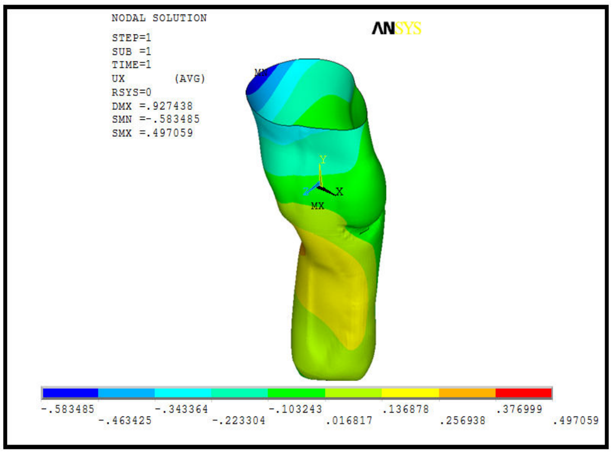

Fig. 9 Frontal displacements (UX) [mm]

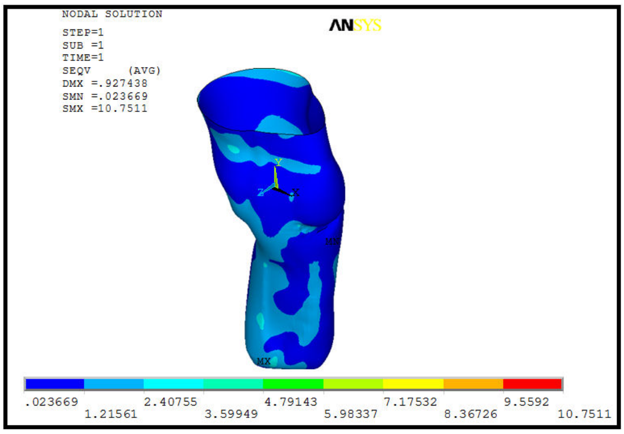

Fig. 10 Von Mises Equivalent Stress (SEQV) [MPa]

Acknowledgment

Support provided by the State of Texas as part of a Technology Development and Transfer Grant and Platinum Research Organization LLC is gratefully acknowledged. The authors would like to thank The University of Texas at Arlington and University of Balamand for their contribution.

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