Extremiti 3D

3D Printed Trans Tibial Sockets Testing

A Report on ISO 10328 Ultimate Strength Requirements and the Test Results on Extremiti3D Prosthetic Sockets

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3D Printed Trans-Tibial Sockets – Testing

Extremiti3D empowers amputees using additive manufacturing. We produce 3D printed sockets and protective covers which have multiple advantages over traditionally fabricated devices. 3D Printing, or additive manufacturing (AM), is a method of fabrication used to create objects by adding material in individual layers, one at a time, until ultimately that object is complete. The printer follows code that is derived from the scan of a patient's limb or of a mold of a limb. There are a number of technologies used to perform AM, such as FDM (Fused Deposition Modeling), SLS (Selective Laser Sintering), or FF (Fused Filament Fabrication). Each of these methods has its strengths, and some can create more robust parts than others. This is as true for prosthetics and orthotics as it is for any other industry. There are a handful of companies printing sockets and protective covers, but unfortunately, few have tested their products. With proper testing to international industry standards, companies can assure their customers that they will receive a quality product.

At Extremiti3D, we designed our 3D Printed Trans-Tibial sockets to meet the ISO standard for testing of lower limb prostheses, ISO 10328. This test defines what conditions the components of the device must withstand for optimal performance*. In a Department of Defense funded study, we reviewed scanning methods, modeling software, printer technology, material specifications, and printing techniques. After exhaustive development, we created a system that incorporates a specific printing method with dozens of variables using proprietary materials. This system produces sockets that are strong enough to pass the rigors of the ISO 10328 static proof and ultimate strength test standards.

Figure 1. 3D Printed Socket Being tested to ISO 10328 Ultimate Strength Requirements

The testing consisted of several steps. The sockets were connected to a prosthetic foot and load tested to the ISO 10328 test standards for 100 kg and 125 kg users (P5 and P6 load levels). The hardware used to align and position the foot was rated to at least 125 kg. Specimens were set up in the test machine as shown in Figure 1 and loaded to over 940 lbs (for the P6 ultimate strength test).

The test sequence was:

1) Heel static proof (P5 load level)
2) Toe static proof (P5 load level)
3) Heel static proof (P6 load level)
4) Toe static proof (P6 load level)
5) Heel Ultimate Strength (P5 load level)
6) Toe Ultimate Strength (P5 load level)
7) Heel Ultimate Strength (P6 load level)
8) Toe Ultimate Strength (P6 load level)

After each test the socket was checked for damage. To meet the ISO 10328 standard, damage is allowed to occur during ultimate strength testing, as long as there is no catastrophic failure. In our final design, no damage was found after the entire series of tests were performed. Our sockets do not require additional lamination, as other companies recommend for their products.

*Note: The ISO 10328 test standard contains test methods and load parameters for testing components of lower limb prostheses, such as connectors, knees and ankle-foot systems, but not necessarily sockets. The ISO 10328 test methods for static proof and ultimate strength were modified to permit testing of sockets. Even though all efforts were made to adhere to the ISO 10328 test methods and loading parameters, due to the absence of an ISO approved method for testing prosthetic sockets, the results of this testing cannot be claimed to be in compliance with the ISO 10328 standard.