Mechanical testing summary

3D Printed Transtibial Socket

Invent Medical

Augo is a revolutionary 3D printed socket which represents a fully digital solution. Augo socket seamlessly combines 2 materials for a truly comfortable innovative design - a soft brim from TPU and a rigid body made of PA11. Due to 3D printing and design freedom, it is possible to integrate a large variety of suspensions (valve, lock, hybrid) into the socket itself and further optimize the geometry, such as the distal end to ensure minimal weight. Augo socket has also included metal nuts for quick attachment of a standard 4-hole adapter.

Augo socket has 3 versions:

- **Standard** (A rigid socket with a soft brim)
- **Comfort** (Includes paddings for sensitive areas)
- **Control** (Enables to easily change socket volume)

Invent Medical takes mechanical testing of products very seriously, as it is a crucial part of product development. Mechanical testing helps to verify product durability, mechanical properties and overall safety. In order to test Augo – 3D printed transtibial socket, Invent Medical has introduced an in-house testing methodology for prosthetic sockets. This methodology represents modified ISO standard 10328 – Structural testing of lower-limb prostheses.

Test Apparatus

The testing is performed on an in-house test apparatus, which was made to follow basic requirements of ISO standard 10328. The rig allows free settings of where the force is applied. This is enabled due to offsets on rigid steel fixture levers. These fixture levers allow consistent test setup between multiple test samples. Fixture levers are connected to the test apparatus using two metal 25 mm hitch balls. Setting of a test is shown in figure 1.

The test apparatus has a limit of maximum applied force of 5 kN. This test apparatus is used both for static and cyclic testing.

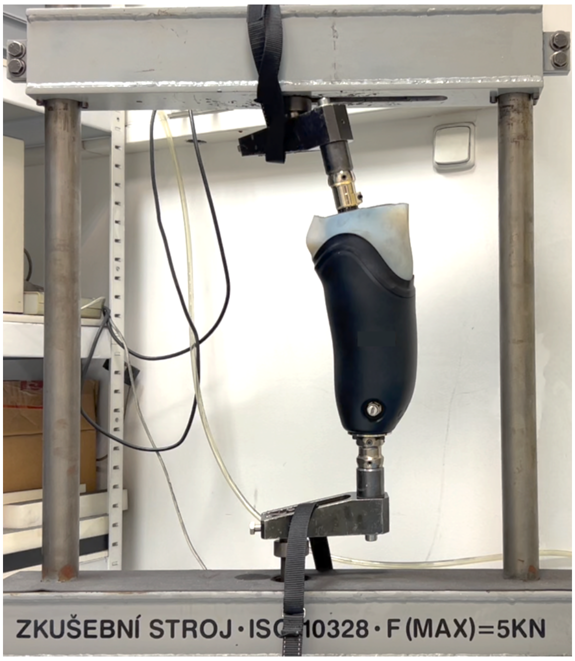


Figure 1 Test apparatus setting – Modified ISO 10328

Test samples

Test samples of Augo sockets (version Comfort) were manufactured based on a 90 kg male with a unilateral transtibial amputation. Manufacturing of the samples followed the standard procedures as regular production Augo sockets. Sockets were 3D printed on HP MJF 5200 series from materials PA11 and TPU. Two sockets were manufactured in-house, one socket was manufactured by a 3D printed service bureau. Altogether 3 sockets were manufactured for the tests. In figure 2 there is a back and side view of the test samples. Overview of the sample properties can be found in table 1. The socket alignment corresponds to realistic conditions based on the patient's needs. All sockets are manufactured to be ready for attachment of a standard 4-hole adapter. One sample has the 4-hole adapter attached in the figure.

Figure 2 Test sockets samples: back view (left) and side view (right)

Table 1 Sample sockets overview

Number of samples	3
Technology (3D printer)	HP MJF 5200 series
Materials	PA11, TPU
Weight (including suspension)	531 g
Model patient's weight	90 kg
Alignment	Realistic

In order to simulate realistic conditions, a limb model was manufactured. The limb model's shape corresponds precisely to the patient's limb and therefore to the inner surface of the sockets. The model was manufactured from a high-density resin with a thin layer of RTV silicone on the surface to simulate soft tissues. Duralumin tube was molded into the resin in order to properly apply force. This way realistic conditions of even load distribution were achieved. The limb model is shown in figure 3.

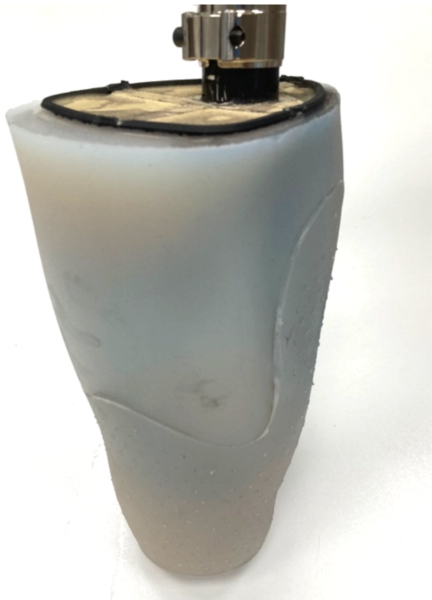


Figure 3 Limb model

Static test procedure

Static test was performed for both loading conditions defined by ISO 10328 – Condition I (heel loading) and Condition II (toe loading). Direction of the applied force was set to exactly match the ISO standard. Magnitudes of loading forces were slightly modified in comparison to the standard. The maximum force of the static test was set to verify ability of a socket to withstand the safety factor 4X. Safety factor 4X represents four times the load that occurs when a 100 kg patient walks. For this test 2 samples from 2 different manufacturing centers were used.

The settling force was 800 N and it was held at this value for one minute. No changes in shape during this time were seen after 60 seconds. Then the force was gradually increased to 5000 N (approximately with speed of 10 N/s), which is the maximal achievable force on the in-house test apparatus. Ultimate force of 5000 N is above the ultimate force for test loading level P6 (patients over 100 kg) defined by the ISO standard, meaning in-house conditions were more critical. After reaching the maximum force with no sign of failure, the force was lowered to the minimum (approximately with speed of 50 N/s). The whole loading cycle is shown in figure 4. The initial settling stage was cut off and is not shown in the graph.

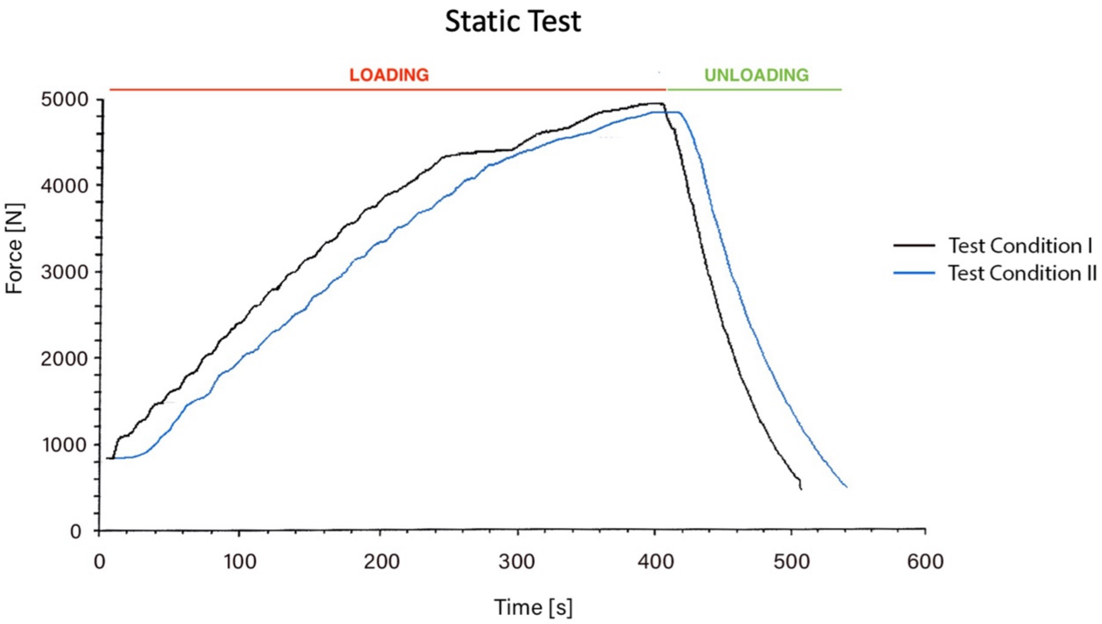
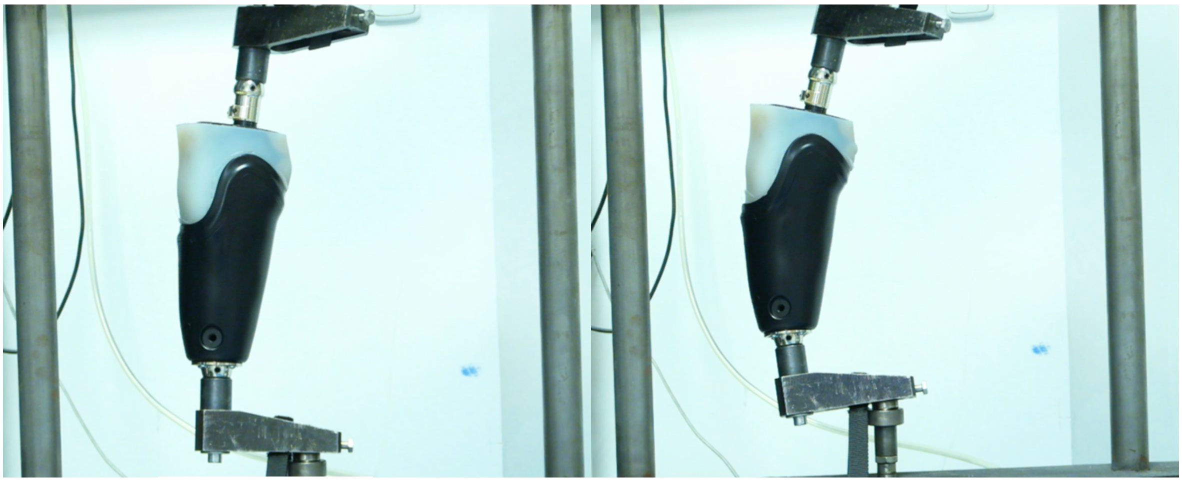


Figure 4 Static Test: Force loading over time

Comparison of unloaded and maximally loaded socket is shown in figure 5.



UNLOADED MAXIMUM LOAD

Figure 5 Static Test: Toe Loading – Test Condition II (Modified ISO 10328)

Static test evaluation

The static test was performed for 2 sockets. Both samples withstood the maximum force of 5 kN and fulfilled the requirement of safety factor 4X for Test Condition I and Test Condition II. Samples did not break during the ultimate force. When compared the initial and maximally loaded shape of socket, it is evident the socket still offers a proper support for the patient. Samples did not show any signs of plastic deformation after the test.

Cyclic test procedure

The cyclic test was performed for Test Condition II (toe loading) on the same test apparatus. The maximum force was set to 1200 N, minimum force was set to be no more than 100 N. Allowed deviation of force magnitude was ± 10 %. Frequency of the test was 1 Hz. Record from the cyclic test is shown in figure 6.

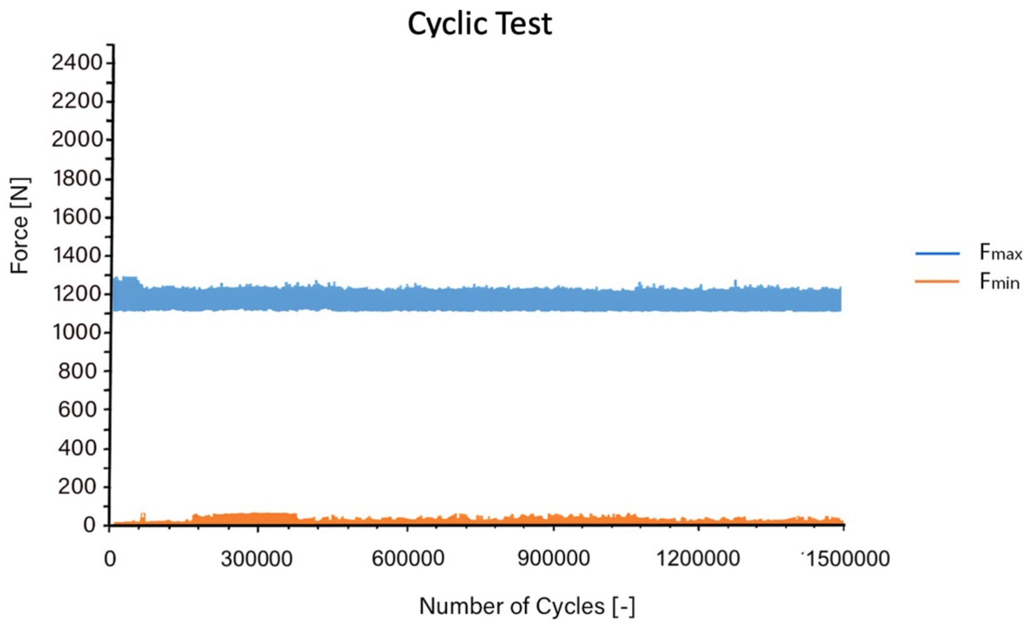


Figure 6 Cyclic Test Record

Cyclic test evaluation

The sample did not break after 1 500 000 cycles and did not show any signs of fatigue behavior. No change in shape or volume and no cracks appeared on the surface. The average maximum force was 1202 N, the maximum force during the cycle was within the interval 1120-1285 N with 95% probability, which is satisfactory given the specified tolerance of ±10 %. The average minimum force was 19 N, the minimum force was within the interval 0 to 39 N with 95% probability.

Conclusion

Static and cyclic tests were performed to evaluate durability of 3D printed transtibial sockets. For the static test, 2 sockets manufactured at two different locations were used. For the cyclic test, only one socket was used. Test methodologies were based on the ISO standard 10328 and modified for the in-house conditions.

Static test was consisted of two loading conditions – heel loading and toe loading. The ultimate force exerted by the test apparatus was 5000 N, which is more than the load defined by ISO standard 10328 for such patient's weight. None of the samples broke or showed a sign of damage and permanent deformation. Based on the results from the static test it is concluded that 3D printed Augo sockets are safe to use and do not pose higher risk of failure for patients than laminated sockets.

Cyclic test consisted of 1.5 million cycles. After this test the sample did not show any signs of fatigue damage.

Based on these achieved results it was concluded that Augo - 3D printed socket is safe to use. Durability of Augo sockets is good for both extreme static and long-term cyclic loading. During our continuous and thorough testing, we have learned that safety is not a result of a manufacturing method but mostly influenced by product geometry and design. Systematic approach to design and testing is the key to bringing safe and functional products.