

3D-Printed CPX-KyronMAX® Definitive Sockets Meet ISO 10328 Loading Levels in Static and Cyclic Testing

Background

Prosthetic sockets are an intimate component of prosthetic limbs serving as the interface between the soft residual limb skin to the hard manufactured components. Socket fit has been shown to impact both effective force transfer and skin health, with a poor fit resulting in skin deterioration, infection, or asymmetrical and harmful compensation mechanisms during gait^{1,2}. Despite the importance of sockets, most people with lower limb amputation still report discomfort and dissatisfaction³. Furthermore, failure of a socket could be catastrophic for a user but overengineering or overbuilding sockets has other negative impacts on wearers like increased weight^{4,5,6}. Manufacturers must create comfortable, stable, durable sockets to encourage wear and reduce compensation mechanisms and skin damage.

All sockets are custom-designed and built for each user and limb. Test sockets are first created to evaluate and refine socket fit for a person's limb and worn for a limited time, while definitive sockets are created once both a prosthetist and patient are satisfied with the fit and are intended to be more durable for longer-term use. Traditionally, sockets are made by creating a modified form of the person's residual limb using a casting and molding process with refinements made to the form by the prosthetist^{3,6,7}. However, with the increasing capabilities of additive manufacturing and digital scanning, 3D-printed sockets are now a more viable alternative to molded and hand-shaped sockets⁸.

While there are standards and guidelines on the structural reliability of prosthetic limb components (ISO 10328), there are currently no standards for the manufacture of or guidance on the use of additive manufacturing to produce custom sockets. Recently, efforts have been made to advance standardized test methods for sockets by industry and standards groups, including the ISO Prosthetic Testing Technical Committee (ISO/TC 168 WG3) and the AOPA Socket Guidance Workgroup. Manufacturers intending to provide 3D-printed sockets must then determine how to use existing guidance for novel manufacturing methods.

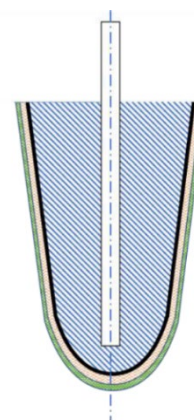
PROTEOR has created a new manufacturing capability to quickly and accurately develop 3D-printed sockets. This report summarizes testing and performance of custom 3D-printed definitive sockets. It was hypothesized that custom 3D-printed definitive sockets would meet loading levels outlined in ISO 10328.

Methods

A multi-layer mock residual limb was constructed to closely mimic a biological limb based on known mock limb fabrication techniques and in a geometry designed to simulate the highest stress concentration. ISO 10328 static testing procedures were adapted for the P6 level (body mass of 125kg) in the second loading condition (P6-II). CPX-KyronMAX (a proprietary material made by PROTEOR and Mitsubishi Chemical Group) sockets designed for the mock limb geometry shown below were loaded at a rate of 50-200 N/sec until failure. Sockets were also tested cyclically at 2 and 3Hz and until failure. According to ISO 10328, the P6-II condition acceptance criteria are at least 4425 N in ultimate static test force and 3 million cycles. Ultimate force (force recorded at failure) and number of cycles to failure were recorded for each test.

MOCK LIMB CONSTRUCTION [Starting with inner layer]

1. Polyurethane foam positive
2. Fiberglass fabric/acrylic resin laminate
3. EVA Keasy Liner
4. Silicone Liner



¹ Saey et al. 2019. IEEE Explore

² Sanders & Fatone. 2011. J Rehabil Res Dev

³ Paterno et al. 2018. IEEE Trans Biomed Eng

⁴ Gariboldi et al. 2022. Med Eng & Phys

⁵ Gariboldi et al. 2023. Prosth & Orth Int

⁶ Van der Stelt et al. 2021. J Eng in Med

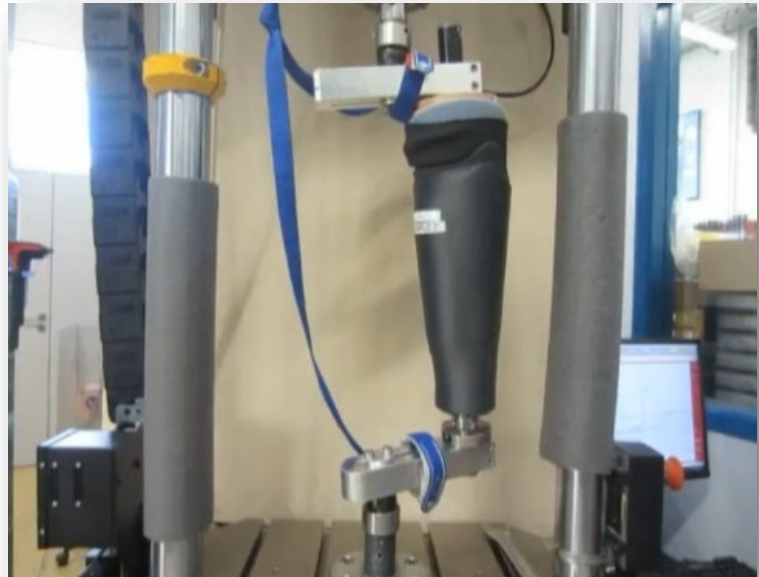
⁷ Rajashekar et al. 2024. J Eng in Med

⁸ Kim et al. 2023. PLOS One

Results

Twenty-seven (27) definitive sockets of CPX-KyronMAX were 3D-printed to a 6mm thickness and tested for their ultimate strength and two (2) were tested cyclically to failure or until they reached the target 3 million cycles. Socket configurations differed slightly and weighed an average of 518g.

On average, the (4) CPX-KyronMAX sockets in the final socket configuration had an ultimate strength of 5598 N, with the highest result at 6556 N. Both sockets tested cyclically completed 3 million cycles without failure.



Discussion

Despite the criticality of sockets, no manufacturing standards or guidelines exist for prosthetic sockets like they do for other prosthetic components. Thought leader groups have recommended following test procedures outlined in ISO 10328⁹. Manufacturers and designers have published a variety of test procedures adapted from ISO 10328 or ASTM standards including static and dynamic (cyclic) testing protocols at various loads.

The advent of 3D printing and digital scanning has allowed for quicker manufacturing of sockets, but only recently have these been tested against international standards. Most published studies chose the late stance phase loading conditions outlined in ISO 10328 (test condition II) and set the acceptance criteria at the P5 level (body mass of 100kg). Some studies included fatigue testing data but most referenced static strength testing. Cyclic loading ranged from 1-3 million cycles⁹. A recent white paper¹⁰ tested 3D-printed carbon fiber and PA12 sockets and found cyclic failure before 1 million cycles and an ultimate strength of 3335 to 4207 N. PROTEOR's CPX-KyronMAX material in our definitive socket configuration outperformed these to an average ultimate strength of 5598 N, with the highest result at 6556N, and achieved 3 million cycles.

Summary

PROTEOR's proprietary CPX-KyronMAX material outperformed the upper limit for the adapted ISO 10328 P6-II standard and other 3D-printed sockets, indicating it is possible to consistently 3D-print strong, durable, definitive sockets.

⁹ Literature review on file with PROTEOR.

¹⁰ HP. Internal White Paper. 2023