TOWARDS THE DEVELOPMENT OF BENCH TESTING FOR LOWER-LIMB PROSTHETIC SOCKETS FOR SPORT APPLICATIONS

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Prosthetic sockets are the bespoken part of lower-limb prostheses. Knowledge about the mechanical properties of sockets is essential to ensure patient safety and comply with current medical device regulations. This includes sockets designed for sport activities. Unfortunately, the literature is extremely limited and contradictory as described in a recent systematic review. The aim of this study was to initiate a research activity aiming to design a mechanical bench system for socket testing and perform a comparative analysis of the ultimate strength of alternative socket layups. Results highlight substantial differences in the maximum loading at failure, stressing the importance of increasing the knowledge about socket mechanical properties to support prosthetists provide reliable and safe products to patients and athletes.

KEYWORDS: prosthetic sockets, sport, bench testing, mechanical failure.

INTRODUCTION: Prosthetic sockets are the custom element connecting the residual limb of a person with lower-limb amputation to their prosthetic foot and (possibly) prosthetic knee through distal attachment modules. The socket has to guarantee good fit and function while being lightweight and structurally sound during the activities of daily living relevant to the patient. Nowadays, this might also include sports; thanks to the advances in prosthetics, in the past years persons with amputation have become more and more active, taking part in competitive and non-competitive physical activities, such as gym training, jogging, cross-fit, weightlifting, athletics etc. (Matthews, Sukeik, and Haddad 2014) (Morriën, Taylor, and Hettinga 2017). During sport activities, the socket needs to sustain demanding loads, e.g. over 6 body weights (Willwacher et al. 2017).
However, given the absence of widely accepted guidelines or standards dedicated to socket construction and structural testing, its mechanical properties remain unknown. This might result either in over- or under-dimensioned sockets; while the first may have negative consequences in terms of weight and thus in terms of sport performance and residual limb health, the latter could cause socket failure, which can lead to patient's injury. Additionally, limited knowledge of socket mechanical properties hinders the development of alternative socket solutions especially in terms of layup compositions and socket-to-foot attachment. Finally, increasing knowledge is essential to fully comply with the new MDR regulation 2017/745 Appendix XIII (Gariboldi, Pasquarelli, and Cutti 2021).
The purpose of this study was to design a mechanical testing system for lower-limb prosthetic sockets and conduct preliminary mechanical tests on alternative socket layups. This will help understanding to which extent socket design can influence its ultimate strength.

METHODS: Given the absence of dedicated standards or guidelines, preliminary research of the literature was conducted. Unfortunately, as reported in the recent systematic review by Gariboldi et al. (2021) (Gariboldi, Pasquarelli, and Cutti 2021), the literature regarding structural testing of lower-limb prosthetic sockets is very limited (16 articles) and sparse, and results difficult to compare even for the activities of daily living such as gait. As described in the review, most of the authors that performed socket testing were guided by ISO 10328 (ISO 2016), the reference standard for off-the-shelf lower-limb prosthetic componentry. This standard does not apply to the socket as a whole, and the researches had to apply adaptations to deal with a series of knowledge gaps, such as socket alignment within the test machine, load transfer mechanism from test machine to the socket, etc. Nevertheless, despite these

limitations, ISO 10328 standardization level seemed a viable and helpful starting point for socket testing, as it describes testing factors that can easily be applied to the socket, such as critical test configurations, lever arms and load levels normalized to body weight.
In this study, the authors decided to assume the ISO 10328 adaptation proposed by Gerschutz et al. (Gerschutz et al. 2012) in toe-off condition. To implement this adaptation, a socket testing machine was built in the Laboratory of Machine Design of the University of Padua (Figure 1).

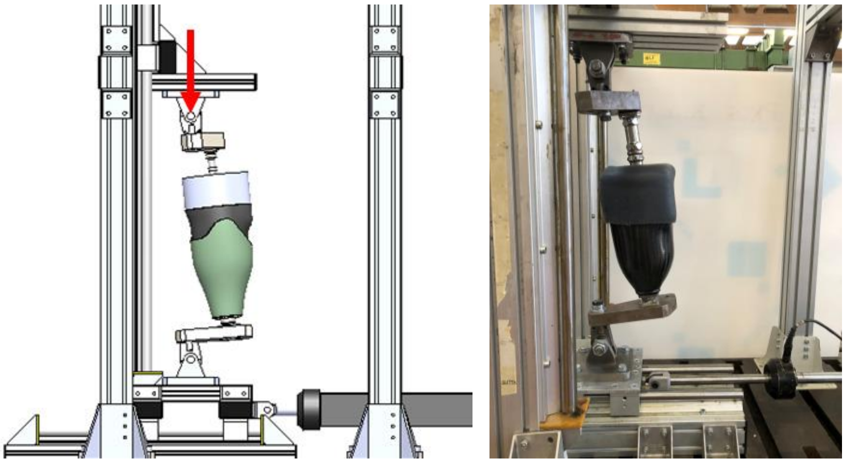

Figure 1: Test machine for structural testing of lower-limb prosthetic sockets.

Load was applied vertically on the upper lever arm by an actuated sliding cylinder, and it was transferred to the socket using a hard-resin custom-made mock residual limb. Top and bottom lever arm sizes were chosen to comply with ISO 10328 P5 configuration in test condition II (toe-off) to generate the highest bending moment. This configuration is not intended to be representative of a typical gait cycle, but rather of an extreme event, such as abruptly falling on the prosthesis during toe-off event. This is relevant in the context of motor activities, such as gym training.
The interface between the mock residual limb and the socket was provided by a styrene liner and a set of cotton socks to ensure proper press-fit.
Two carbon-fiber laminated transtibial sockets were manufactured (Figure 2). They were manufactured from the same residual limb shape, i.e. a template developed by Gerschutz et al., which represents the 98th percent American male model (circumference at the patellar tendon bar of 52.4 cm, length from the patellar tendon bar to the distal end of 19.2 cm).

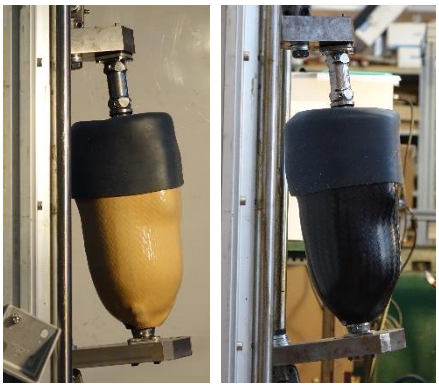

Figure 2: Sockets tested. Socket 1 (left) and Socket 2 (right).

The two sockets differed solely for the material layup and distal attachment module, which are described in Table 1.

Table 1: Layup, distal attachment module and resin of Socket 1 and 2.

Socket 1		Socket 2	
Layer material	Location	Layer material	Location
Nylon stockinette x2	Everywhere		
Carbon unidirectional	Lateral, medial, distal	**Ottobock 5R2**	
Carbon twill 3K	Lateral, medial, distal	Nylon stockinette	Everywhere
Carbon unidirectional	Proximal & distal ring	Carbon twill 3K	Distal (ML)
Nylon stockinette	Everywhere	Carbon twill 3K	Distal (AP)
Ottobock 4R41		Carbon unidirectional	Lateral & medial
Carbon twill 3K x2	Distal	Carbon unidirectional	Proximal & distal ring
Carbon braid 12K	Everywhere	Carbon braid 6K	Everywhere
Nylon stockinette x2	Everywhere	**Ottobock acrylic resin**	
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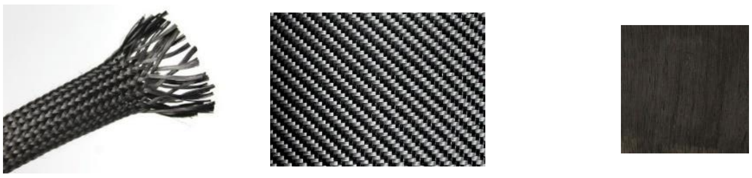

Carbon braid   Carbon 2x2 twill weave   Carbon unidirectional pattern

Figure 3: Possible patterns of carbon fibers used in the layups.

The two sockets were subjected to static loading using the above-mentioned machine. The load was applied at a constant rate according to ISO 10328 requirements up to failure. The ultimate load at failure was compared with the thresholds reported in the ISO 10328 standard. The output force-displacement curve was also found.

RESULTS: Figure 1 provides a visual comparison of the virtual and physical model of the test machine. The time necessary to set up and perform a single static test is around 10 minutes. Figure 4 displays the loading curve and the load-displacement curve (stiffness) for each socket. As showed by the first two graphs, the maximum load reached by Socket 1 is 5097 N, whereas for Socket 2 is 2895 N.

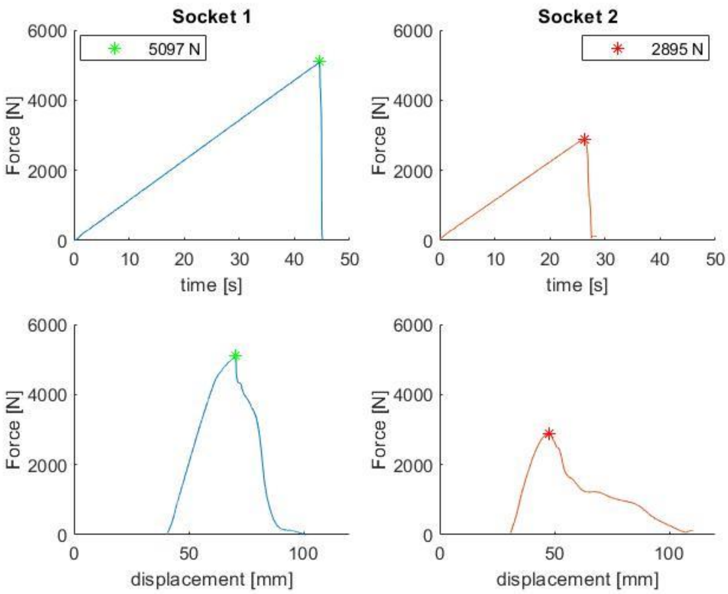

Figure 4: Loading curves (above) and load-displacement curves (below) for Socket 1 (left) and Socket 2 (right).

DISCUSSION: We decided to follow the Gerschutz et al. adaptation of ISO 10328 since it provides a worst-case scenario in terms of bending moment, by positioning the socket as low as possible inside the test machine. The two sockets reached very different load values. Socket 1 overcame ISO 10328 P7 upper threshold (4840N), whereas Socket 2 reached just above ISO 10328 P3 upper threshold (2790N). Even though the final assessment must consider the specific patient and activity, we can speculate that this latter result is hardly acceptable for most sport activities, because the socket does not even comply with the simpler condition of an extreme event in the ordinary activities (i.e. abrupt fall in toe-off during gait). The factors that influence test results and socket mechanical properties are various, and include both socket-specific variables, such as material layup, distal attachment module and resin, as well as setup variables, such as socket alignment within the test machine. In this study the two sockets were tested with the same setup conditions, therefore it can be intended as a comparison of the layup, distal attachment and resin composition. It is clear that socket-related factors can have a substantial effect on mechanical failure level. This remarks the importance of designing mechanical test experiments and optimize sockets, which can be achieved by first building a complete benchmark for socket mechanical testing and then move on to dedicated testing systems for specific sport activities, focusing on a subset of valid (i.e. benchmark) confirmations.

CONCLUSION: In this article, the authors performed a mechanical test on two different sockets, to evaluate the structural testing methodology proposed by Gerschutz et al. From the experimental tests, it turned out that different layups can lead to very different results in terms of mechanical properties, and it highlights the importance and need to perform socket testing, especially in the context of demanding physical activities. Future developments should focus on identifying loading profile that are specific for a chosen sport activity.

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