Static strength of lower-limb prosthetic sockets for the activities of daily living

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***Abstract*—Despite the central role that a prosthetic socket plays as the link between the patient and their prosthesis, yet no common guidelines or standardized methods exist to test their mechanical strength. Consequently, the socket structural properties remain largely unknown. The absence of a method to quantify socket structural strength has negative consequences, such as: the tendency to over-fabricate the socket, a general limitation in the introduction of innovative materials and techniques, and a challenge in complying with the current European regulatory requirements. To overcome these limitations, the authors defined a five-step plan intended to serve as a groundwork in the prosthetic field for the definition of a standardized testing method for prosthetic sockets. This plan includes the systematic analysis and organization of the available literature into key domains, the proposal of recommendations to address the current gaps in knowledge, the design, implementation and application of a test bench system based on the available evidence and on a worst-case approach and, finally, the definition of manufacturing guidelines based on quantitative data to be included in the production process of the INAIL Prosthetic Center. The activities described in this manuscript should guide other researchers of the prosthetic community to take coordinate action in the definition of a standardized method for socket testing.**

***Keywords*—Prosthetic sockets, structural testing, ISO 10328, lower-limb.**

I. Introduction

A PROSTHETIC socket is the custom element that serves as interface between the residual limb of a person with lower-limb amputation and the off-the-shelf mass-produced components of the prosthesis (e.g. prosthetic foot and possibly knee). The socket transfers load between the person and the rest of the prosthesis and allows control of the prosthetic limb. For this reason, it has to conform to the anatomy and clinical presentation of each unique limb, ensuring comfort and safeguarding its soft tissues.

Despite the central role of the socket in the prosthesis, no standards or common guidelines exist to test its structural strength, which therefore remains unknown. The current standard for structural testing of prosthetic components (ISO 10328 [1]) does not encompass custom-made devices, such as the socket, but only off-the-shelf mass-produced components (e.g. foot, knee). The traditional manufacturing techniques for sockets, such as lamination with composite materials and vacuum-bagging, are based on manual and highly operator-dependant processes that, to make up for the absence of quantitative data, tend to rely on over-fabrication to ensure safety. Despite having several downsides in terms of increased weight, rigidity and ultimately patient discomfort, this approach has higher risk of failure when experimenting with new materials and fabrication methods, for which training and clinical rules of thumb are not yet established. Finally, the absence of standardized test methods challenge the compliance with the current European Medical Device Regulation (MDR 745/2017) that requires documenting the expected performance of custom-made medical devices, such as sockets [2].

To overcome the current limitations associated to the absence of a standardized test method, meet the current regulatory requirements and improve the present manufacturing procedure of the INAIL Prosthetic Center, the authors have laid the foundation for the definition of a unified testing method based on the available evidence by drafting the following five-step plan:

A. Analyse and compare the current methods for socket testing available in literature;
B. Initiate a collaboration with other international scientists to take action in a coordinate manner;
C. Design and implement a test bench for socket testing based on literature findings;
D. Perform a socket testing campaign to analyse the mechanical strength of prosthetic sockets manufactured at the INAIL Prosthetic Center (Vigorso di Budrio, BO, Italy);
E. Draft internal guidelines for socket manufacturing based on quantitative data.

II. Methods

A. Review of the literature

A systematic review of the literature was conducted in 2021 to collect information about available socket mechanical testing methods. The review had the objective of analyzing the methods used for structural testing of lower-limb prosthetic sockets and among them identifying and analyzing the ones based on ISO 10328:2016 [3]. The review was conducted using the PRIMA process [4] and the findings were organized in key categories, such as socket information (amputation level, shape, fabrication technique and material), test characteristics (reference used, test setup, test sample, mock residual limb, alignment between sample components) and load characteristics (alignment of load line, type of loading, passing condition) [3].

B. Collaboration with the AOPA Socket Guidance Workgroup

In 2020 an international and multidisciplinary group of experts hosted by the American Orthotic & Prosthetic

Association (AOPA Socket Guidance Workgroup) was formed to provide the prosthetic community with evidence-based recommendations regarding socket structural testing methods to meet the emerging regulatory requirements. Using a systematic approach similar to the Delphi process, the first activity of the workgroup was the drafting of a discussion paper meant to highlight the problem of socket testing and call the stakeholders to action.

Starting from the findings of the systematic review [3], the aim of the paper was to describe the current state of knowledge available in literature regarding structural testing of transtibial prosthetic sockets, identify the knowledge gaps in this field and provide recommendations for how to address them. The possible recommendations were chosen from a pool of three options: 1) application of the exiting evidence from the literature, 2) group consensus, motivated by evidence in literature and/or knowledge of experts, 3) formation of a study group to assess the problem and find a way to address it. The paper was submitted and accepted for publication in *Prosthetics & Orthotics International* and is currently in the process of publication.

C. Design and implementation of a test bench for sockets

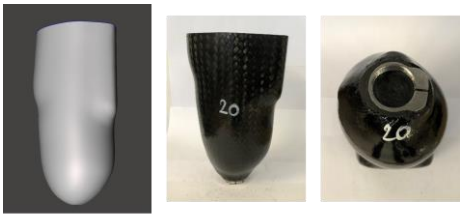
Based on the evidence collected from the Systematic Review and on the discussions in the workgroup technical meetings, a test bench system for lower-limb prosthetic sockets was designed and implemented at the Laboratory of Machine Design of the University of Padua (Padua, Italy) [5]. The test bench was designed to adapt the testing methods of ISO 10328:2016 to socket testing. Decisions about the modes of adaptations were made using a worst-case approach.

D. Socket testing

Thanks to the design and implementation of a test bench, an exploratory study was conducted at the University of Padua, aimed to analyse the effect of fiber layup, matrix and distal adapter on socket strength [6]. Twenty-three sockets were manufactured at the INAIL Prosthetic Center (Vigorso di Budrio, BO, Italy) from the same identical plaster model, using the traditional lamination technique with composite materials and resin infusion under vacuum-bagging. Each socket had a different combination of stratigraphy, distal adapter and resin. The shape of the limb represented the 98th percentile American male model of transtibial amputees, with a circumference at the patellar tendon bar of 52.4 cm and a length from the patellar tendon bar to distal end of 19.2 cm [7]. The different combinations of fiber layup, lamination resin and distal adapter were taken from the current production line of the INAIL Prosthetic Center.

The sockets were tested using the test bench designed and implemented at the University of Padua.

This study was described more extensively in a manuscript that was submitted and accepted with minor revision to *Medical Engineering & Physics*, and that is currently under review.



(a) (b) (c)

Fig. 1: Limb shape (a), example of test socket (b, c).

E. Guidelines for socket manufacturing

The test results allowed drafting lamination guidelines to be used in production at the INAIL Prosthetic Center (Vigorso di Budrio, BO, Italy). For each family of distal adapter, the guidelines were defined based on the sockets that reached the highest ultimate load at failure with lowest weight and with the simpler layup.

III. Results

A. Review of the literature

According to the results of the systematic review [3], only 16 peer-reviewed articles exist in literature that describe socket testing. The same result was also confirmed by recent a scoping review [8]. Given the absence of a standardized test method, most of the articles (13) are based on ISO 10328, each presenting different adaptation modes that were systematically summarized and organized in the review [3].

In particular, the socket was either tested alone or in combination with off-the-shelf components (e.g. prosthetic pylon, foot). Only transtibial sockets were tested, with the shape of the limb varying across studies (subject-specific vs. generalized). Three alignment modes were identified: a neutral and two worst-case alignments (with and without a prosthetic pylon). Among the two possible test conditions described in ISO 10328 (condition I, heel loading and condition II, forefoot loading), forefoot test condition was the most used across studies. Most of the articles performed static testing using the ISO 10328 passing conditions, which depend on test condition (I or II) and on loading level (P3 to P8), associated to different ranges of body weight.

B. Collaboration with the AOPA Socket Guidance Workgroup

The discussion paper of the AOPA Socket Guidance Workgroup identified knowledge gaps and solution approaches for four key domains: 1) mock residual limb shape and composition; 2) prosthetic socket coordinate system and alignment; 3) components and requirements of test samples; 4) test conditions, loading parameters and passing conditions.

All four knowledge gaps were deemed to lack sufficient high-quality literature for resolving via literature review alone. The group concluded that six of the gaps within these domains may be resolved adequately by expert consensus combined with existing literature, but three knowledge gaps will require new research studies to adequately address.

C. Design and implementation of a test bench for sockets

The test bench was designed starting from one of the adaptations of ISO 10328 described in the reviewed literature [7]. The test bench allowed to reproduce heel loading and

forefoot loading, i.e. the two most critical events during the stance phase according to ISO 10328 [1].

In the bench, the load was applied vertically through a uniaxial hydraulic cylinder used in force control. Load was then applied to the socket through a mock residual limb made of hard PU resin with the interposition of a soft styrene liner (Shore A 30) and cotton socks to ensure proper press fit. The load was transferred from the machine to the mock limb-socket system using rigid mounting elements (loading plates) that allowed applying the lever arms prescribed by ISO 10328 in forefoot loading for a patient weighing more than 100 kg (P5 to P8 condition). The bench could be used to perform both static and cyclic testing, according to the test procedures specified in ISO 10328.

(a) (b)

Fig. 2: Test bench for testing of lower-limb prosthetic sockets for the activity of daily living, CAD model (a) and implementation (b).

D. Socket testing

Among the twenty-three sockets tested, 50% weighted more than 600g and were therefore deemed too heavy for the size of the limb. 30% of all sockets did not reach the required strength (4500 N). Altogether, only 26% met the required strength (>4500 N) with acceptable weight (<600g) [6].

E. Guidelines for socket manufacturing

Among the sockets with required strength (>4500 N) and acceptable weight (<600g), five sockets were identified, one per type of distal adapter, and were used to define the lamination guidelines for the INAIL Prosthetic Center (Vigorso di Budrio, BO, Italy).

It was quantified that these new lamination guidelines allowed reducing material waste of manufacturing by 50%.

IV. Discussion

The aim of this study was to define a well-structured plan that should serve as a groundwork in the prosthetic field for the definition of a unified testing method for prosthetic sockets and thus help overcome the current limitations derived from the absence of a dedicated standard.

The systematic review of the literature [3] was the first element in this plan and highlighted that the literature regarding socket testing is very limited. ISO 10328 was commonly used as a guide for socket testing, but details of its adaptation to sockets varied considerably among articles. The main reason for this heterogeneity is that ISO 10328 was not designed for socket testing and consequently it is missing specific definitions and recommendations that would allow unambiguous implementation of such a testing.

Nevertheless, the findings of the systematic review were very valuable in the drafting of the discussion paper by the AOPA Socket Guidance Workgroup. The available evidence was organized in key domains, and for each of them the authors highlighted the knowledge gaps and proposed recommendations to address them. The discussion paper confirms that establishing a unified testing method for sockets is not an easy task. In fact, none of the knowledge gaps can be solved by simple application of the available evidence, and most of them will require the formation of study groups to carefully assess the problem. Nevertheless, it is the hope of the authors that the discussion paper will help spur the prosthetic field and serve as a roadmap for stakeholders to take coordinate action in their respective field of interest.

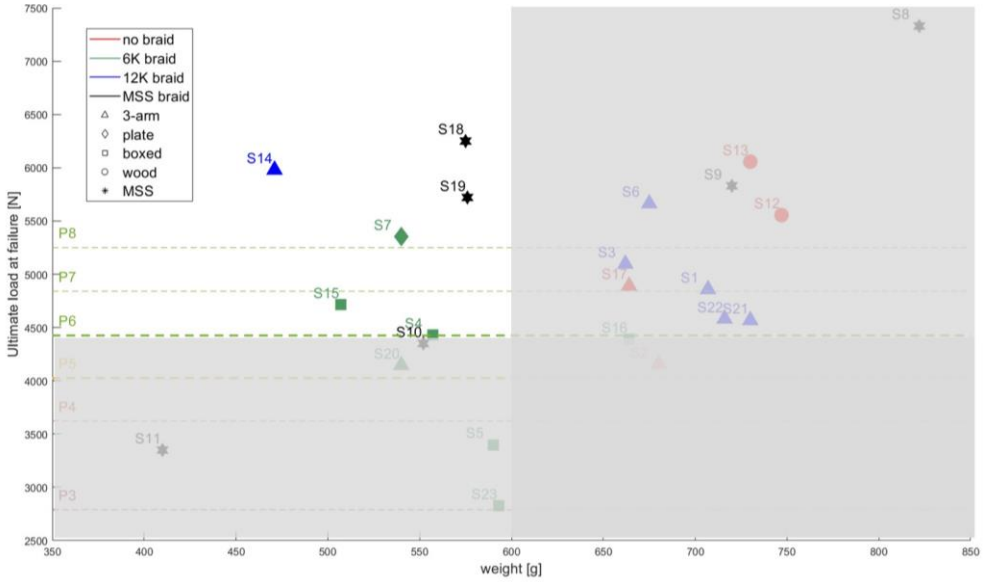


Fig. 3: Distribution of tested sockets according to ultimate load at failure and weight.

The systematic review and the discussion paper allowed to identify the topic areas that should be considered when defining a testing method for sockets. For each topic area the authors had to make decisions when evidence did not provide sufficient guidance. In the design of the test bench, the authors chose to adopt a worst-case approach that tended to maximize the bending moment at the socket distal end. We did so by implementing the adaptation of ISO 10328 proposed by Gerschutz et al. [7], which described testing the socket in isolation, in forefoot loading condition and P6 loading level. In addition, the limb increased dimensions represented a worst-case condition for pulled sockets and contributed to making the test more conservative. Even though it was the intent of the authors to establish a conservative testing system, the actual effect of different adaptations is unknown, and the decisions made on certain knowledge gaps will need to be confirmed once study groups are formed and/or consensus in the prosthetic community is reached.

Even with the limitations described above, the implementation of a test bench allowed to carry out a first test campaign with the objective of exploring existing combinations of layup-adapter-resin and establishing a benchmark based on the current practice of the INAIL Prosthetic Center (Vigorso di Budrio, BO, Italy). The study showed that the absence of an established method to quantify socket strength leads to a tendency of over-dimensioning. Half of the sockets were in fact deemed too heavy for the size of the limb. Overall, only 26% displayed sufficient strength (> 4500N) and acceptable weight (<600g).

Despite its limitations, this exploratory study allowed to identify correlations between certain combinations of layup resin and distal adapter and socket strength and/or weight. In addition, based on the sockets that produced the best output, it was possible to draft manufacturing guidelines for the INAIL Prosthetic Center, aimed at reducing material waste, unnecessary weight and maximize strength. The introduction of these guidelines in the production line of the Center has in fact allowed reducing the material waste by 50%, creating sockets that are lighter and stronger.

Overall, the path to the definition of a standardized method for socket testing is still long. Nevertheless, thanks to the activities described in this manuscript, the foundations have been laid and hopefully will guide other researchers of the prosthetic community to take coordinate in the definition of a unified method for socket testing.

V. Conclusion

The current manuscript outlines a possible approach to lay the foundation in the definition of a standardized method to test prosthetic sockets. This approach was intended to guide other researchers of the prosthetic community to take coordinate action in pursuing this objective.

Acknowledgement

Authors kindly acknowledge INAIL for funding the study through the OLYMPIA Project.

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