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Towards standardized methods for prosthetic socket mechanical testing

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*A list of the AOPA Socket Guidance Workgroup is included in a note at the end of the article.

List of acronyms

MDR = Medical Device Regulation

FDA = Food and Drug Administration

AOPA = American Orthotic & Prosthetic Association

WG = Workgroup

TC = Technical Committee

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ISPO = International Society for Prosthetics and Orthotics

ISO = International Organization for Standards

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Prosthetic sockets serve as the link between the patient and their prosthesis, yet no common guidelines exist to test their mechanical strength. Without standardized test methods, the socket structural properties remain largely unknown[1]. Therefore, practice has evolved towards a reliance on the addition of reinforcement until safety is assured, essentially over-fabricating the socket.

Over-fabrication has several downsides. These may include economic and environmental costs due to greater material usage, and discomfort and functional impairment due to increased weight, rigidity and heat retention. Finally, reliance on prior experience may escalate the risk of failure when experimenting with new materials and fabrication methods, such as volume-adjustable sockets and 3D printing, for which our existing knowledge base for safe fabrication may not apply.

International regulatory frameworks are moving towards a requirement for socket testing. The current European Medical Device Regulation (MDR 2017/745) requires documenting the expected performance of custom-made medical devices such as sockets, in terms of strength and fatigue durability[2]. In the United States, because of the rise of 3D printing in orthotics and prosthetics, the Food and Drug Administration (FDA) is also considering closer alignment between the regulatory oversight for prosthetic devices and other similar medical devices, as well as with the European MDR[3].

In an effort to meet the emerging regulatory requirements and support innovators, the "AOPA Socket Guidance Workgroup" was formed in 2020, to provide the prosthetic community with evidence-based clinical best-practices and methods in the field of prosthetic socket structural analysis. The workgroup includes expert representatives of the clinical community, the ISO/TC 168 (Prosthetics & Orthotics) WG 3 (Testing), major manufacturers of engineered components, commercial providers of prosthetic sockets and/or socket materials, and both academic and government researchers from the United States, United Kingdom and Europe.

As a first activity, we set out to study the knowledge gaps regarding the requirements for such structural tests, beginning with transtibial devices. The results of this study are published in a discussion paper entitled, "Mechanical testing of transtibial prosthetic sockets: a discussion paper from the American Orthotic & Prosthetic Association Socket Guidance Workgroup". In brief, we identified knowledge gaps in four domains:

1. the shape and composition of a mock residual limb, required to support and generate *in vivo* representative loading within the socket,
2. prosthetic socket coordinate systems and alignment,
3. the components and requirements of test specimens, and
4. test conditions, loading parameters, and acceptance criteria.

The discussion paper describes these knowledge gaps in detail, and recommends potential solution approaches based on literature review, group consensus around existing knowledge, or the formation of new study groups.

Our intent is for the recommendations arising from the discussion paper to spur the community (researchers in the clinic, academia, industry and funders) to fill these knowledge gaps. Arising matters of expert consensus should be coordinated through the community's organizations

such as American Orthotic & Prosthetic Association (AOPA), the International Society for Prosthetics and Orthotics (ISPO) and the International Organization for Standards (ISO); this paper will provide guidance for any researcher that wishes to propose studies to address these gaps.

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AUTHOR CONTRIBUTION
All authors and Workgroup members were responsible for conceptualization.
Alex Dickinson was responsible for writing-original draft.
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