Clinical Considerations for 3D Printing Lower Limb Sockets

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Clinical Question: What should prosthetists consider prior to implementing 3D printing for definitive lower limb prosthetic sockets?

Background: Current methodology for fabricating lower limb prosthetic sockets is laborious and time intensive. Rapidly manufactured prosthetic sockets have been of interest in the prosthetic field as early as 1985[1]. As the amputee population increases, the desire to rapidly manufacture these devices becomes more appealing. The aim to reduce labor, cost, and time devoted to socket fabrication is foundational to the goal of definitively producing 3D printed sockets. While 3D printing is available, skepticism may remain for many clinicians desiring to introduce this fabrication technique into daily practice. The present O&P field lacks a defined method for assessing prosthetic sockets based on their strength, comfort, and overall safety. Within literature from 1985 to present, studies have researched 3D printed sockets and their overall strength, cost, patient acceptance, and feasibility. A commonly used outcome for assessing the structural integrity of the socket is ISO 10328, which is a standard developed to ensure the safety of componentry intended for the fabrication of lower-limb prosthetic devices[2]. The document lays out specific guidelines for mechanically testing lower limb prosthetic componentry. The purpose of the ISO 10328 test is to understand the structure of ankle-foot componentry, lower limb socket componentry, and the distal shin-to-socket or knee-to-socket connection[2]. ISO 10328 is necessary to ensure strength requirements of prosthetic componentry. However, its intentions are not for ensuring lower limb socket integrity. The inclusion of a socket within the ISO 10328 testing procedure defines the use of a socket or a socket "dummy" to assess its connection to componentry[2], and rather than the socket itself. While the ISO 10328 test is not designed to test the structural integrity of the socket, it has been used as a means for testing the integrity of 3D printed sockets[3-6].
It is irrefutable that socket strength is challenging to quantify as they are complex shapes and vary depending on the patient and prosthetist. As a result, rather than focusing on socket strength through mechanical testing (such as ISO 10328), it may be beneficial to focus on relevant clinical considerations surrounding 3D printing in prosthetic sockets. 5 research articles containing clinically appropriate information were gathered through a search for 3D printed lower limb prosthetic socket literature. Manuscripts were systematically excluded if they did not contain clinically pertinent topics, and the top 5 clinically relevant articles were included in this research.

Search Strategy:
Databases Searched: Google scholar, PubMed, oandp.org, AcESO, OVID
Search Terms: ('below knee prosthesis' OR 'prostheses' OR 'lower limb' OR 'prosthetics' OR 'prosthetic socket' OR 'transtibial' OR 'transtibial socket') AND ('rapid prototyping' OR '3D printing' OR 'three-dimensional' OR 'RP' 'printing accuracy' OR 'Fused Deposition Modeling' OR 'FDM' OR 'SLS' OR 'SLA' OR 'Additive Manufacturing' OR '3D printing materials')
Exclusion Criteria: Upper Extremity**,** Orthotics

Synthesis of Results: Five studies were identified (see Evidence Table). Each article is centered on additively manufactured sockets for lower limb amputees. The most common clinical consideration within the literature is noted as the requirement for patient comfort[7-10]. The benefit of 3D printed sockets in regards to comfort is the option to integrate multiple materials and provide different infill configurations for optimal support at load zones and compliance at off-load zones[9]. Thus, the produced socket ideally will provide comfort to the user while maintaining structural integrity. Additional clinical considerations are described within the literature as interfacial pressure distribution between the socket and residuum[8, 10], biomechanical analyses while loading the socket during static and dynamic conditions[8, 10], 3D printing fabrication time and cost requirements[4, 7], and material choices[4, 8-10]. The overall goal of 3D printing sockets is to directly manufacture sockets to save time and money while maintaining product quality[7].

Clinical Message: Currently there is no single measure for assessing lower limb socket integrity, composition, or comfort level for conventional fabrication or 3D printing. Previous measures (such as ISO 10328) may not be appropriate for understanding socket strength since the measures are not designed to assess the socket. Therefore, any prosthetists that aims to implement 3D printing into their practice for definitive lower limb sockets may find it beneficial to consider the clinically relevant topics mentioned above and determine their role in producing definitive sockets. Patient comfort, compliant designs, gait analysis, internal socket pressures, materials choices, and financial realities are all considerations to examine when 3D printing. A combination of clinically relevant topics should be considered to achieve the goal of producing a socket that saves both time and money while maintaining socket strength and patient comfort.

Evidence Table

	Freeman, 1998[7]	Rogers, 2007[10]	Sengeh, 2013[8]	Comotti, 2016[9]	Sabeti, 2018[4]
Population	1 unilateral TT amputee	Stage 1: 1 unilateral TT amputee Stage 2: 4 unilateral TT amputees Stage 3: 10 unilateral TT amputees Stage 4: 1 unilateral TT amputee	1 bilateral TT amputee	1 unilateral TF amputee	1 unilateral TT amputee
Study Design	Cost/benefit analysis Comparative outcomes	6-year Solid Freeform Fabrication (SFF) study with 4 different stages • Feasibility study • Evaluate clinical acceptability • Long-term durability test • Novel socket design	Finite element analysis paired with physical and clinical socket evaluation	Single socket of various infill ratios, pattern and orientation feasibility study	Experimental study of 3 different 3D printing materials with 2 different printing methods
Intervention	Stereolithography manufactured prosthetic socket for a 170-pound transtibial male	Stage 1: Dual wall socket (flexible inner, hard outer) through SLS printing Stage 2: Single wall socket with various wall thicknesses through SLS Stage 3: Users used SLS sockets for 1+ years Stage 4: Incorporated a more sophisticated design for increased flexibility control	• FastSCAN digitization, computational modifications, and Polyjet Matrix socket fabrication • Variable materials integrated into socket based on bone density (VIPr socket)	Single material at various infills, patterns and orientations with Leonardo Cube Meccatronicore Printer	Nylon 12, recycled Nylon 12, and PLA used to fabricate 3 sockets FDM and SLS printing methods
Comparison	Socket printing time and user comfort was compared while altering: • Resin • Wall thickness • Socket circumferences Capital cost of 3 SLA printers were also compared	• SLS sockets compared to conventionally manufactured sockets • Long term goal is to observe if the sockets fail or not	• Gait deviations • Internal socket pressures • Patient comfort • Finite Element Analysis • Structural strength	Infill ratios for each region of the socket	Socket strength of the 3 materials and 2 printers tested with ISO 10328 loading condition 1 at P4 level to failure
Methodology	Plaster impression with TSB casting method	Laser imaging helped produce definitive	FastSCAN STL file for internal socket	Contact pressure correlated to	• Each socket was 3D printed and

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	Model was digitized with Mind Seattle Provel digitizer File converted to ASCII file for RP SLA-250/40 printer was used to facture 2 test sockets	socket through SLS socket fabrication Prosthetic CAD files were converted to STL file format for SFF Nylon 11 or Duraform was used to fabricate all sockets Each stage progressively improved fabrication techniques	MRI imaging to realize residual limb stiffness/compliance Inverse linear equation correlated bone tissue to socket material Polyjet Matrix 3D printer integrated variable durometer materials for socket fabrication FEA assumed single material for analysis	elasticity in each socket region Young-Poisson graph determined different infill configurations	attached to a block with orthocryl resin • ISO 10328 statically evaluated the strength of the printed sockets with proof test and ultimate strength test then loaded to failure
Outcomes	Socket 1 – increased height, circumferences, and wall thickness with SLA-250/40 • 58 hours • Included 0.0625" exterior grooves • $3,480 Socket 2 – decreased height, circumferences, and wall thickness with SLA-250/40 • 26 hours • Removed exterior grooves in the socket wall • $1,560 Capital Costs SLA-250/40: $145,000 SLA-350/10: $380,000 SLA-500/40: $490,000	Stage 1: Dual wall socket fabrication too complicated Stage 2: Highest density socket failed, lower density sockets with higher laser had no issues Stage 3: Still ongoing when published, but no failures noted after several months Stage 4: Higher pressure found where the compliant sockets were stiffer	Peak forces during gait • 30% (heel strike) • 75% (just before toe-off) Percent reduction at heel strike with VIPr socket • 17% at fibula • 8% at tibia Percent reduction before toe-off with VIPr socket • 15% at fibula • 7% at tibia	Socket successfully fabricated with FlexiFil by FormFutura at 100% infill density for soft zones and PLA at 10% infill for pressure sensitive areas	• All unrecycled and recycled Nylon 12 met the minimum ISO standard for ultimate strength • Recycled Nylon 12 performed with lower ultimate strength than unrecycled Nylon 12 • The 2 PLA sockets resulted in failure before meeting required standards
Key Findings	• Capital cost > current fabrication costs • Resins used do not offer the same level of strength as conventional materials • Increasing laser power increases build speed • Build time needs to reduce significantly for SLA printing	• SLS produces durable prosthetic sockets • Must further understand patient comfort, socket pressures, and long-term durability	• Possible benefits of spatially varying socket material stiffness based on soft tissue characteristics of underlying residuum anatomy • 16% increase in self-selected walking speed for compliant sockets	• Infill ratio, pattern and orientation can provide socket flexibility in pressure sensitive regions • Varying material composition in socket regions provides another option for socket softness • In other sections of the paper, infill, topology	• PLA socket do not meet minimum ISO 10328 strength requirements • Failure observed at attachment block for unrecycled and recycled Nylon 12 • Nylon 12 provides promising strength requirements for sockets

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				optimization, multimaterials, and design functionality was discussed in detail	
Clinical Considerations	Patient comfort 3D printing fabrication time Cost requirements Overall goals of 3D printing sockets	Patient comfort Internal socket pressures Static and dynamic biomechanical analysis Material choices	Patient comfort Internal socket pressures Static and dynamic biomechanical analysis Material choices	Patient comfort Infill configurations for optimal support at load zones and compliance at off-load zones Material choices	3D printing fabrication time Cost requirements Material choices
Study Limitations	Published in 1997 Technological advancements have been made since	Lack of appropriate software at time of study	3D printed socket was 3x heavier than the conventional socket Compliant 3D printed sockets had much lower Factors of Safety than carbon fiber sockets	• Single subject study • Limited to FDM printing, while SLS is promising for fabrication • Multimaterial objects are difficult to fabricate	• Single subject study • Failure occurred at attachment block before the socket for unrecycled Nylon 12 • Additional strength tests required for recycled Nylon 12

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