The Provision of 3D Printed Orthoses and Prostheses Should be administered by a Certified/Licensed Orthotist/Prosthetist

The American Academy of Orthotists and Prosthetists (The Academy) is the premier organization representing professionals in the field of orthotics and prosthetics. The Academy is dedicated to promoting professionalism and advancing the standards of care through education, literature, research, advocacy, and collaboration.

In keeping with our mission, the Academy supports additive manufacturing (3D printing) and other innovative manufacturing techniques as tools to advance orthotic and prosthetic patient care. These techniques have the potential to improve strength-to-weight ratio, increase fabrication speed and efficiency, and improve access to care. 3D printing and related technologies are continually advancing; as new materials and techniques emerge, the opportunities for utilization will also continue to increase.

As the profession adopts new innovations and technologies, we must ensure the orthoses and prostheses provided continue to be appropriate, safe, and meet or exceed current standard of care. Stringent safeguards are required for the long-term use of these technologies by individuals with disabilities outside of a clinical or research setting. These safeguards are especially critical when making claims to the public regarding the utility of these orthoses, prostheses, and associated components.

All custom orthoses/prostheses, including those fabricated via additive manufacturing/3D printing, should be provided by or in partnership with a certified/licensed orthotist/prosthetist and under the prescription and supervision of a treating medical provider. Orthotist/Prosthetists are healthcare providers who undergo rigorous education in anatomy, biomechanics, materials science, and clinical assessment/reassessment directly related to the provision of orthoses and prostheses as regulated by the National Commission on Orthotic and Prosthetic Education (NCOPE) and the Commission on Accreditation of Allied Health Education Programs (CAAHEP). These professionals must pass certification examinations and maintain certification via continuing education, and they are ethically bound to their credentialing body's Code of Professional Responsibility.[1] See the Academy's Position Statement on Minimum Education Standards and Credentialing[2] for more details.

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1 American Board for Certification in Orthotics, Prosthetics and Pedorthics (ABC). The Code of Profession Responsibility. January 2020. https://www.abcop.org/docs/default-source/publications/code-of-professional-responsibility.pdf?sfvrsn=d38e7a1a_3

2 American Academy of Orthotists and Prosthetists Position Statement on Minimum Education Essentials & Credentialing for Providers of Custom-Fabricated and Custom-Fitted Orthoses and Prostheses. September 2013. https://cdn.ymaws.com/www.oandp.org/resource/resmgr/Files/Policy_Statements/Min_Education.pdf

It is incumbent upon providers of orthoses and prostheses to adhere to ABC/BOC[3] and state licensure guidelines, as well as the recommendations provided herein by the Academy to protect the patients receiving orthoses and prostheses:

1. First and foremost, the safety of the patient receiving any orthosis, prosthesis, or associated components must be the priority. Safety consists of structural safety, integrity of the materials and fabrication process, durability, and appropriate fit to prevent skin irritation and/or breakdown of the orthosis or prosthesis for long-term use during various activities, including normal activities of daily living as well as high level activities such as recreation and sport.
2. Functional outcomes must be demonstrated to be consistent with or improved over current standards of practice and consistent with applicable or relevant regulations and guidelines provided by ISO, FDA and other organizations.
3. Provision of custom orthoses and prostheses must be provided only by prescription and with appropriate physician oversight.
4. The standards in place for provision of care must be duly carried out by only certified/licensed orthotist/prosthetists to ensure optimal outcomes, safety, consistency, and liability protection in these cases.
5. Consistency of material fabrication and design must be demonstrated. This is critical to ensure the long-term safety and security of the patient as well as provide the functional outcomes expected.
6. All orthoses, prostheses, and associated components should be assessed to ensure appropriate strength and durability, as well as fitting standards associated with the current provision of orthotic and prosthetic care.
7. The Academy encourages efforts to develop standards associated with provision of orthoses and prostheses.

3 American Board for Certification in Orthotics, Prosthetics, and Pedorthics (ABC) or Board of Certification/Accreditation (BOC)