

ADDITIVE MANUFACTURED LOWER LIMB PROSTHESIS

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Doi: https://doi.org/10.34107/YFMV730937

ABSTRACT

Approximately 150,000 patients per year undergo a lower extremity amputation in the United States. Lower leg prosthetics are readily available for adult patients. However, unique challenges exist for juvenile age groups, due to critical years of aggressive growth and physical changes demanding more adaptive methods in providing affordable prosthetics. Youth want and need to be active, however, prosthetics for running are ineligible for insurance reimbursement because insurers do not deem running a "life necessity." Privately financing the purchase of a running limb is confounded by the fact that children quickly outgrow the device, requiring frequent replacement and additional costs. To address this need, a novel combination of design process, material selection, and manufacturing is proposed, with the potential to reduce cost and increase availability of running prosthetics for youth. Within this investigative work are discussed the design, simulation, fabrication, and testing of a topology- optimized, lower-limb, C-style running blade fabricated using selective laser sintering (SLS). Preliminary prediction to test validation was conducted and aligned with CDC load testing guidelines relative to Juvenile age and percentile curves.

Keywords: additive, prosthesis, topology, gait, optimization, simulation

INTRODUCTION

When the loss of a limb occurs, it brings with it lifelong challenges. If an infant is missing a lower limb, they will ideally be fit for a prosthetic by the time they are in the "pulling-to-stand" stage (between 10-14 months) [1]. In a study done from 2009-2015 involving a database of 36.5 million children, 14,038 individuals had a major lower limb loss [2]. The Study found that nearly 50% of the overall annual out- of-pocket outlays of these children's medical care was for prosthetic services. If the mean annual prosthetic related costs for insured families can range from $50-$29,112,[2] and the costs found by [3] echo those costs with a range of $73,140-$116,040. [3] goes on to state that many third-party insurers only pay for one or two prosthetic devices over the entire lifetime of the patient and/or insurance policy. Since a child's skeletal structure is not fully mature, they will generally require a new prosthesis every 12-24 months until they are skeletally mature [1]. These amputees also report participation restrictions associated with mobility limitations. These restrictions can cause play barriers, such as limiting activity types or simply not being able to keep up with their peers when walking from place-to-place. This impediment takes away the physical and psychosocial benefits kids get from participation in active play within their community [4]. This lack of activity, which is a vital part of children's development relating directly to their quality of life and future life outcomes [5], has another underlying danger. Sedentary lifestyles can lead to the onset of diabetes—one of the leading causes of disabilities in the world [6] and other long-term disease progression [7]. A solution to this problem would not only need to be cost-effective and have fast delivery, but also needs to be customizable on a patient-by-patient basis. Advanced manufacturing technology, and specifically, additive manufacturing through 3D printing, was identified as a potential solution. The 3D fabrication method chosen for this work was selective laser sintering (SLS) based on the author's prior knowledge and experience with various additive manufacturing technologies. Specific advantages SLS include high material recovery, greater degree of isotropy, complex geometries, .1mm layer resolution and short process time with larger parts.

The material selected was a Nylon (PA-12). Since Nylon 12 Powder has been evaluated in accordance with ISO 10993-1:2018 and has passed the requirements for the following biocompatibility risks: ISO